

October 30, 2018

Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
Mail code: 1101A
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: Public Comment and Peer Review Process for Initial 10 Risk Evaluations under TSCA

Dear Acting Administrator Wheeler:

Our organizations are committed to assuring the safety of chemicals used in our homes, workplaces and in the many products to which our families and children are exposed each day. During the legislative process to amend the Toxic Substances Control Act (TSCA), we worked hard to maximize public health protection and to assure that EPA has the necessary authority to evaluate and eliminate the risks of unsafe chemicals. We strongly support a proactive approach to implementing the new law that uses the improved tools that Congress gave EPA to deliver significant health and environmental benefits to the American public.

An early test of TSCA implementation is the initial group of 10 risk evaluations that EPA is conducting under section 6(b)(2)(A). The chemicals subject to these evaluations raise significant health and environmental concerns and have widespread exposure. The available hazard and exposure data on these chemicals are extensive and present numerous important scientific issues. The risk evaluations will fall short under TSCA and seriously damage EPA's credibility if they are not based on the best available science.

We understand that EPA is planning to release draft evaluations in late 2018 and early 2019 and then will seek public comment and peer review with the goal of finalizing the evaluations by the end of 2019. If EPA cuts corners on public comment and peer review, the quality of the evaluations will be fatally compromised. Thus, TSCA requires EPA to design a process which assures that the final evaluations fully reflect the input of stakeholders and leading independent experts, are based on the weight of the scientific evidence and the best available science, and draw on all reasonably available data and information.

Extensive guidance on the minimum elements of peer review for important and influential scientific work products is provided in OMB's Peer Review Bulletin and EPA's Peer Review Handbook. The application of this guidance is reflected in the public comment and peer review processes used for EPA's Work Plan risk assessments under the old law and recent IRIS assessments. Based on this roadmap, we recommend that EPA incorporate the following minimum steps in its public comment and peer review process for the 10 risk evaluations:

- EPA should allow 120 days for comments on the draft evaluations
- Some evaluations (e.g. for solvents) should be grouped together for review by a single panel while substances that raise unique issues (e.g. asbestos) should be reviewed separately
- Separate review panels should also be established to address EPA's systematic review methodology and other cross-cutting science issues
- Scientists under consideration as peer reviewers – including all members of the Scientific Advisory Committee on Chemicals (SACC) -- should undergo a rigorous review for conflicts of interest and bias regarding the 10 chemicals, including full disclosure to EPA of all sources of funding and business and

financial relationships, and the public should have an opportunity to comment on all candidate reviewers

- EPA should seek public comment on the draft charges for the peer reviews of the 10 evaluations
- The public should have the opportunity to provide written and oral statements to peer review panels
- The panels should prepare reports which summarize the recommendations of panel members and common themes in their reviews, fully document areas of agreement and disagreement and capture the views of panel members with common areas of expertise
- EPA should seek the advice of its children's health protection advisory committee on the 10 evaluations
- EPA's final risk evaluations should respond to all public comments and peer review recommendations

Section 6(b)(4)(G) of TSCA gives EPA up to three years to complete a risk evaluation but allows this deadline to be extended for an additional 6 months. While EPA should in general try to meet the three year deadline, an extension of six months for the initial 10 risk evaluations would provide critical breathing space for the public comment and peer review process. An additional 6 months would increase the likelihood that EPA receives high-quality comments, allow the reviewers the time necessary for an in-depth examination of each draft evaluation and preparation of a detailed report, and enable EPA staff to fully digest this feedback and incorporate it in the final evaluations. It would be a serious mistake for EPA to cut corners on these steps and to rush final evaluations out the door without the thoughtful comments and expert advice necessary to assure that EPA uses the best available science and all reasonably available information in assessing chemical risks.

1. EPA Should Allow 120 Days for Comments on the Draft Evaluations

For each of the 10 chemicals, the draft evaluations will address multiple health and ecological end-points, combine hazard information with exposure analysis, and determine the risks presented by numerous conditions of use. Thus, they will be more comprehensive and complex than the Work Plan risk assessments conducted under the old law, which focused on a limited set of end-points and uses. The evaluations will also have far-reaching regulatory consequences because they will be used to determine whether the 10 chemicals present an unreasonable risk of injury and should be restricted under section 6(a) of TSCA.

The breadth, novelty and complexity of the 10 risk evaluations will place heavy demands on commenters. As a result, preparing meaningful and thorough comments will require a significant investment of time and resources by our organizations and leading experts in the scientific community. These challenges will be greatly magnified by the likelihood that the comment periods for the 10 evaluations will overlap, requiring stakeholders and experts to review and prepare comments on numerous evaluations simultaneously.

Comment periods for Work Plan risk assessments and recent IRIS assessments have varied from chemical to chemical. Some were 60 days, others were 90 days, and one (for methylene chloride and N-methylpyrrolidone) was nearly five months. We believe EPA should allow at least 120 days for comments on the TSCA risk evaluations based on their scope and complexity, the large amount of data and analysis they will contain, their regulatory and policy implications, and the uniquely heavy resource demands of addressing multiple chemicals simultaneously.¹

¹ EPA's final risk evaluation rule (40 CFR 702.49(a)) provides that EPA will provide "no less than a 60-day comment period" for draft evaluations. Obviously, the rule contemplates longer comment periods in appropriate cases.

2. Under the SACC Umbrella, Chemicals Raising Common Issues Should be Reviewed by a Single Panel While Chemicals with Unique Issues Should be Reviewed Separately

Under OMB's 2005 Final Information Quality Bulletin for Peer Review, the TSCA risk evaluations qualify as Highly Influential Scientific Assessments (HISAs) because they not only will have "a clear and substantial impact on important public policies" but will be "novel, controversial, or precedent-setting or ha[ve] significant interagency interest."² OMB requires a robust independent peer review process for such assessments, noting that that the "intensity of peer review should be commensurate with the significance of the information being disseminated and the likely implications for policy decisions" and that "the need for rigorous peer review is greater when the information contains precedent-setting methods or models, presents conclusions that are likely to change prevailing practices, or is likely to affect policy decisions that have a significant impact."³

EPA's Peer Review Handbook uses the same definition of HISAs, emphasizing that "[t]he more far-reaching or significant the impacts of a scientific assessment, the more appropriate it is to categorize the product as an HISA." The Handbook advises that HISAs "are expected to undergo rigorous external peer review with opportunities for public participation."⁴

The Science Advisory Committee on Chemicals (SACC), created by the new law to provide expert advice to the TSCA program, is an appropriate umbrella body to oversee peer review of the 10 risk evaluations. We recommend that EPA utilize the scientific expertise of SACC efficiently while assuring that unique chemical-specific issues receive the special consideration they deserve. Thus, risk evaluations on solvents with similar uses and chemical compositions (trichloroethylene, methylene chloride, perchloroethylene and carbon tetrachloride) should be grouped together and reviewed by a single panel. However, other risk evaluations (for example, on asbestos and the HBCD cluster) will require separate panels because they raise unique issues that call for specific types of expertise.⁵

Even where risk evaluations are grouped together, it will be essential to develop chemical-specific charge questions, augment the review panel with experts knowledgeable about particular chemicals and their datasets, and issue separate reports on each risk evaluation. Meetings of the panel should also be structured to assure adequate opportunity for public comment on each risk evaluation. This would assure that each evaluation receives the full attention of the review panel and can be examined in sufficient depth to provide thoughtful and considered feedback to EPA.

3. Separate Review Panels Should be Established for Systematic Review and other Cross-Cutting Science Issues

Separate review panels should be established to address cross-cutting science issues presented by all 10 evaluations. The most important of these issues is the "systematic review" criteria EPA is using to determine

² 70 Federal Register 2664, 2671 (January 14, 2005).

³ Id at 2668.

⁴ U.S. Environmental Protection Science and Technology Council. Agency Peer Review Handbook 4th Edition; October 2015, at 43, 55, available at <https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015>

⁵ While EPA's September 13, 2018 Federal Register notice seeks nominations of experts to assist in reviewing the 10 evaluations, it makes no effort to identify the specific areas of expertise relevant to individual chemicals. 83 FR 46487. This makes it difficult for the public to choose which experts to nominate and runs the risk that EPA will lack the ability to select panel members qualified to address the unique issues raised by individual evaluations.

the quality of individual studies and determine how much weight they should receive in the evaluations.⁶ These criteria are out of step with other systematic review approaches used within EPA and across the government and were not peer reviewed before they were applied to the 10 chemicals. We have urged EPA to replace its criteria with another systematic review methodology that has been peer reviewed and reflects mainstream scientific thinking. If EPA continues to reject this course, it must at a minimum assure that its systematic review criteria receive careful, independent scrutiny by a group of experts knowledgeable about the design and application of systematic review methods. Given the novelty and importance of EPA's approach to systematic review, finalizing the 10 risk evaluations without such scrutiny would violate EPA's Peer Review Handbook and TSCA's requirement to use the best available science.

Other cross-cutting methodologies used to determine the weight of the evidence or for data integration and interpretation should likewise receive independent expert review. Examples include the use of mechanistic data and thresholds for cancer and non-cancer effects.

4. Candidates for Each Panel Should Undergo a Rigorous Conflict of Interest Review Which Includes Input from the Public

The SACC must comply with the mandate of the Federal Advisory Committee Act (FACA) that it be "fairly balanced in terms of the points of view represented and the functions to be performed" and protected from "inappropriate[] influence[] by the appointing authority or by any special interest." 5 U.S.C. app. 2 § 5(b)(2)-(3).

Consistent with FACA, the OMB Handbook underscores the importance of assuring that external peer reviewers lack conflicts of interest and are impartial:

The National Academy of Sciences defines "conflict of interest" as any financial or other interest that conflicts with the service of an individual on the review panel because it could impair the individual's objectivity or could create an unfair competitive advantage for a person or organization. This standard provides a useful benchmark for agencies to consider in selecting peer reviewers. Agencies shall make a special effort to examine prospective reviewers' potential financial conflicts, including significant investments, consulting arrangements, employer affiliations and grants/contracts. Financial ties of potential reviewers to regulated entities (e.g., businesses), other stakeholders, and regulatory agencies shall be scrutinized when the information being reviewed is likely to be relevant to regulatory policy. The inquiry into potential conflicts goes beyond financial investments and business relationships and includes work as an expert witness, consulting arrangements, honoraria and sources of grants and contracts

70 Fed. Reg. 2670.

While SACC members may have been screened for conflicts of interest (COIs) when they were initially selected, this review likely did not focus directly on the 10 chemicals undergoing risk evaluations or on broader scientific issues raised by these evaluations. Under applicable guidelines, financial ties to manufacturers of one of the 10 chemicals or consulting work or research for industry on these chemicals or the broader scientific issues they raise would present COI and impartiality concerns that may be disqualifying. To assure that these issues are fully addressed, a further examination of potential conflicts must be

⁶ 83 Fed. Reg. 26998 (June 11, 2018); Application of Systematic Review in TSCA Risk Evaluations, available at https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf

conducted before SACC members are cleared to serve as peer reviewers of the 10 evaluations. Any new experts added to SACC or selected for individual panels must likewise be screened for conflicts of interest.

Standard EPA practice for major peer reviews is to seek public comment on the qualifications of candidate reviewers, including whether they should be barred from serving because of conflicts of interest or bias. EPA accomplishes this by publishing a notice identifying candidate reviewers and soliciting public input. For example, EPA recently [issued](#) a call for public comment on candidates for its Science Advisory Board (SAB). EPA should follow this process for the 10 risk evaluations and include both current SACC members and additional experts under consideration for SACC membership or ad hoc participation in specific panels.

5. EPA Should Seek Public Comment on the Draft Peer Review Charge for Each Risk Evaluation

According to EPA's Peer Review Handbook, a "charge is a set of focused questions that identifies the scientific and technical issues on which the Agency would like feedback and invites suggestions for improving the document as a whole. . . . Preparing a good charge is time well-spent, as the charge is crucial for an effective peer review." Handbook, at 82.

Public input is often invaluable in shaping the charge and the EPA SAB and individual EPA offices normally seek comments on draft charge questions before finalizing them. Because the TSCA risk evaluations are unprecedented, framing the right set of charge questions will be particularly important to assure meaningful peer review. Interested parties should therefore have the opportunity to weigh in on what questions the charge should include. Significantly, EPA's "framework rule" for TSCA risk evaluations emphasizes that "EPA plans to take public comment on the charge questions given to peer reviewers." 82 Fed. Reg. 33744.

6. The Public Should Have the Opportunity to Provide Written and Oral Statements to the Peer Review Panels

The EPA Peer Review Handbook recommends "that the process [for HISAs] should include a public meeting, whenever feasible and appropriate, . . . [at which] interested members of the public can make oral presentations on scientific issues." Handbook, at 86. For the TSCA Work Plan assessments, the Agency convened public peer review meetings and allowed interested parties to provide written comments and oral statements to the reviewers. The SAB implements a similar public participation process for its review of IRIS assessments. The Handbook recommends separating the initial public comment period from the later submission of written materials to the panel – an approach that EPA followed for the Work Plan assessments and uses for IRIS reviews.

This model should be followed for the 10 risk evaluations. In addition to allowing submission of written comments to the reviewers, EPA should schedule sufficient public meeting time to accommodate oral statements by all interested parties who wish to share their views and afford the panel members ample opportunity to discuss the scientific issues among themselves so they can provide meaningful feedback to the Agency.

7. The Panels Should Prepare Informative Reports That Summarize Major Recommendations and Document the Range of Views among Panel Members

Peer review reports are most useful to the Agency and public when they are the outgrowth of dialogue among panel members and, as a result, distill key panel recommendations and capture common themes, areas of agreement and disagreement, and the views of panel members with shared areas of expertise. The SAB follows this model and, to that end, circulates draft reports to panel members for review and comment

and convenes group drafting sessions. This interaction among panel maximizes the likelihood that the Agency receives coherent and thoughtful feedback while ensuring that panel members are able to express and record divergent views. By contrast, where panel members submit their individual responses to charge questions with no give-and-take and group discussion, the resulting report is often a collection of unsynthesized opinions that are difficult for Agency scientists to process and less useful in improving EPA's work product.

For the precedent-setting risk evaluations underway under TSCA, we strongly urge EPA to assure that peer review panels have sufficient time for internal dialogue and to develop reports that are thoughtful and thorough, coherently address all the issues, summarize key panel recommendations and fully present panel member views, including both majority and dissenting views. Final peer review reports should be immediately made available to the public.

8. EPA Should Seek the Advice of its Children's Health Protection Advisory Committee on the 10 Evaluations

Children are explicitly identified as a "potentially exposed or susceptible population" in section 3(12) of TSCA and EPA risk evaluations must specifically address whether a substance presents an unreasonable risk of injury to such populations under section 6(b)(4)(A). EPA's Children's Health Protection Advisory Committee (CHPAC) is a body of external researchers, academicians, health care providers, environmentalists, state and tribal government employees, and members of the public with expertise on children's health issues. It is the preferred source of advice within the Agency on regulations, research, and communications related to children's health. Its input will be vital given the central role of children's health protection in TSCA risk evaluations. EPA should explicitly request the CHPAC's review of the 10 risk evaluations and ask for its views in writing.

9. EPA's Final Risk Evaluations Should Respond to All Public Comments and Peer Review Recommendations

The final stage of the peer review process is the Agency's response to the panel's recommendations and revisions to its scientific work product to reflect the panel's feedback. This part of the process must be fully transparent. As explained in the EPA Handbook:

The credibility of the final influential work product is likely to be enhanced if the public understands how the Agency addressed the specific concerns raised by the peer reviewers. Therefore, for HISAs, EPA offices should prepare a written response to comments in the peer review report explaining (1) the Agency's agreement or disagreement with the views expressed in the report; (2) the actions that have been or will be taken to respond to the report; and (3) the reasons that the EPA office believes those actions satisfy any key concerns or recommendations in the report. Any responses also should be posted in the SI website database.

Handbook, at 87. EPA should fully implement these steps when finalizing its 10 risk evaluations.

10. EPA Should Extend the Deadline for Completing the Evaluations by Six Months

Section 6(b)(4)(G) of TSCA gives EPA up to three years to complete a risk evaluation but allows this deadline to be extended for an additional 6 months. EPA should take advantage of this provision and extend the completion date for the first 10 risk evaluations until June 30, 2020.

This extension would provide additional breathing space for the public comment and peer review process, increasing the likelihood that EPA receives high-quality comments and giving the reviewers the time

necessary for an in-depth examination of draft evaluations and preparation of detailed reports. It would also give EPA scientists more time to consider the public comments and peer review reports, revise the draft evaluations to incorporate this input and develop a detailed response to the recommendations of the commenters and review panels.

For the four Work Plan assessments completed under the old law, the average amount of time from the start of the public comment period to publication of the final assessment was 19 months. Comparable stages in the IRIS process have been even more protracted, averaging 3 years for recent assessments. The TSCA risk evaluations will be more complex than the Work Plan assessments and the public comment and peer review process will therefore require greater time and effort. It would be a serious mistake for EPA to cut corners on these steps and to rush final evaluations out the door before EPA scientists have carefully considered the expert advice they receive. EPA should thus take the additional six months provided by law to complete the evaluations.

In sum, we believe the above recommendation for the public comment and peer review process for the 10 evaluations are necessary to meet the requirements of TSCA and assure credible, science-based judgments about chemical risks and urge EPA to adopt them. We look forward to discussing the details of the upcoming process with your staff.

Please contact SCHF counsel Bob Sussman with any questions at bobsussman1@comcast.net.

Respectfully submitted,

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