

August 24, 2016

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Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

**RE: Docket ID EPA-HQ-OPPT-2016-0400
Processes for Risk Evaluation Under the Amended TSCA
SIRC Comments on TSCA Chemical Evaluation Process**

To Whom It May Concern:

The Styrene Information & Research Center¹ (SIRC) appreciates the opportunity to provide comments on the Environmental Protection Agency's (EPA's) implementation of the Toxics Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA). SIRC provided oral remarks at the EPA's August 9 public meeting on the TSCA chemical evaluation process, but given the limited speaking time at that meeting, submits these written comments to provide elaboration, given our organization's strong interest in the effective implementation of this important Act.

SIRC would like to congratulate the EPA for its work to secure the passage of the TSCA Modernization Act. There is a strong need for a robust Federal program that can separate out and manage the unreasonable risks potentially posed by various uses of chemicals, from the majority of other uses that are safe. This new program will be good for both the public and for those who manufacture and use chemicals throughout our economy. SIRC further appreciates that EPA has reached out to stakeholders to seek comments and recommendations in initiating TSCA implementation.

¹ In North America, the Styrene Information & Research Center (SIRC) serves as a resource for industry, federal and state governments, and international agencies on issues related to the potential impact of exposure to styrene on human health and the environment. Headquartered in Washington, D.C., SIRC was formed in 1987 as the principal focal point for public information and research on styrene. SIRC is a non-profit organization consisting of voting member companies involved in the manufacturing or processing of styrene, and associate member companies that fabricate styrene-based products. Collectively, SIRC's membership represents approximately 95% of the North American styrene industry.

SIRC's primary comments focus on three approaches that SIRC hopes EPA will adopt in the implementation of the new TSCA:

1. To make progressive use of "crowdsourcing"² in its approach to public participation and information gathering;
2. A recommendation that, for the new TSCA, the Agency does not need to "reinvent the wheel" in terms of hazard and risk assessment options, as well as risk management options and;
3. The need for EPA to consider all available data – especially new data – for evaluations, and not to rely on point-in-time assessments by an EPA office, or another federal agency, as providing a definitive hazard assessment conclusion.

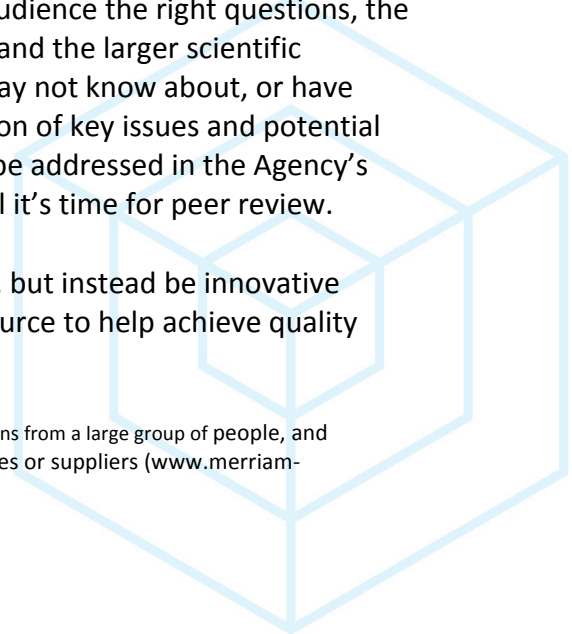
Crowdsourcing

We know that the new Act gives EPA years to complete its risk evaluation and risk management tasks. However, it's clear that the deadlines defined in the new Act will prove challenging for the agency to meet, and to address all that the Act requires in a timely fashion. We understand that it took 10 years from start to finish to promulgate the TSCA Section 6 asbestos rule in the 1980's. Certainly the new Act does not give EPA 10 years to promulgate future risk management rules, nor should it. However, this means that EPA will need to use some common sense management skills to achieve Congress' goals for TSCA.

Crowdsourcing is one of those productive management techniques that the Agency should seriously consider. Some government programs may view public comment periods as time-consuming chores that are necessary because we live in a democracy, but that encroach on the time the agency needs to work on the rule. SIRC suggests that a more modern and effective approach to public participation is embodied in the now popular concept of crowdsourcing. If you ask the right audience the right questions, the public -- including NGOs, companies, trade associations, and the larger scientific community -- can help you find relevant data that you may not know about, or have available. Crowdsourcing can help with early identification of key issues and potential concerns about a chemical, or its uses, that will need to be addressed in the Agency's work; issues that you may not otherwise hear about until it's time for peer review.

In short, do not view public participation as a distraction, but instead be innovative about -- and use -- public participation as a valuable resource to help achieve quality work produced on time.

² The practice of obtaining needed services, ideas, or content by soliciting contributions from a large group of people, and especially from the online community rather than from traditional employees or suppliers (www.merriam-webster.com).



EPA Need Not “Reinvent the Wheel” for Evaluation Processes

SIRC urges EPA not to “reinvent the wheel” in implementing the new TSCA. The science and processes of risk assessment³ and risk management have been around for a long time, and have evolved over the years. EPA itself has published many guidance documents, including the 2005 Cancer Guidelines, for example, which, while perhaps not perfect, are a good place to start, as opposed to starting over with a new evaluation approach. Another good example is the National Research Council’s “Science and Decisions” report, that emphasizes the importance of risk evaluators communicating to risk managers, and the public, the uncertainties associated with any risk evaluation. NRC’s reasons for stressing this are well summarized on page 98⁴ of their report. This recommendation, along with the recommendation in the Council’s May 2014 report on the IRIS program -- that evaluators should present decision makers and the public with a range of values -- can be invaluable to risk managers who may be confronted with less than perfect choices regarding the best risk management approach to take.

This may be because of the risks posed by chemicals that might be substituted for a banned chemical, or the economic impact of various risk management options, or the finding that certain uses of a chemical may be essential for national security or to meet other national objectives.

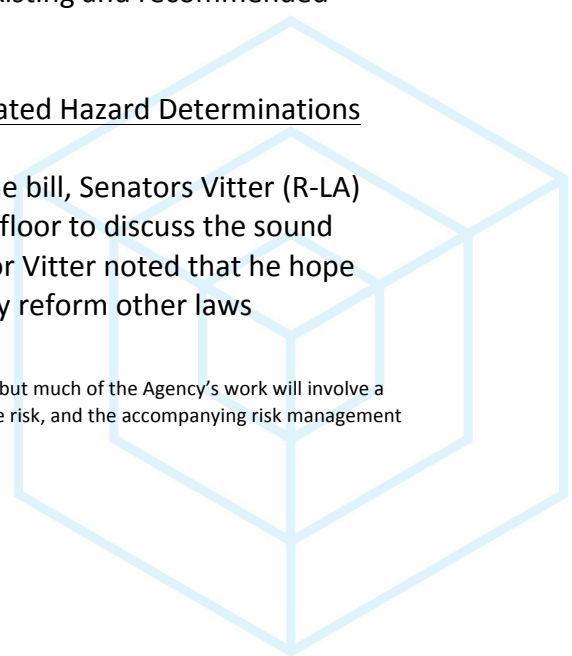
In short, EPA should not be afraid to communicate to its risk managers and the public both what it knows and what it does not know about a chemical, thereby giving subsequent decision makers the broadest amount of information on which to make difficult risk management decisions. This is just one example of the many pieces of advice from both the National Academy of Sciences and the Agency itself that are available for adoption by the TSCA program as already existing and recommended evaluation processes.

Consideration of All Available Data and Not Relying on Dated Hazard Determinations

During final consideration of the conference report on the bill, Senators Vitter (R-LA) and Inhofe (R-OK) entered into a colloquy on the Senate floor to discuss the sound science provisions in the TSCA reform legislation. Senator Vitter noted that he hope the new law will serve "as a model for how to responsibly reform other laws

³ SIRC notes that the TSCA statute refers to “risk evaluation,” not “risk assessment,” but much of the Agency’s work will involve a timely risk *assessment* to reach a safety determination of reasonable or unreasonable risk, and the accompanying risk management implementation decisions.

⁴ See <http://www.nap.edu/read/12209/chapter/6#98>



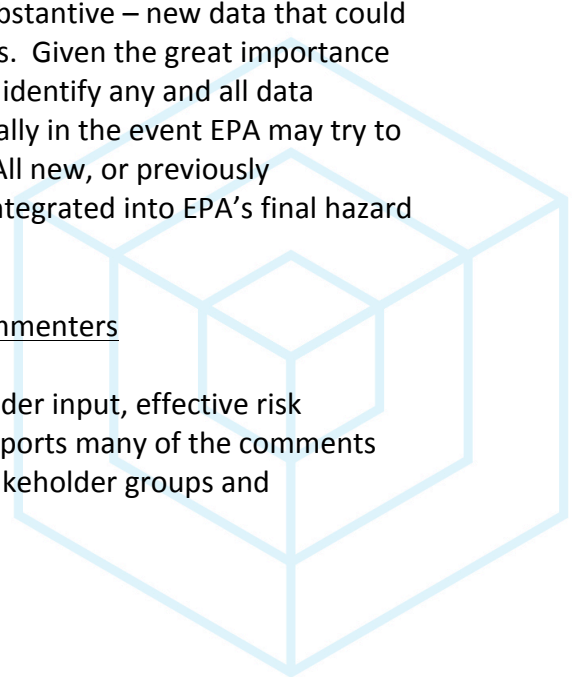
administered by EPA and other federal agencies that are tasked to make decisions based on science." The Louisiana Senator and ranking member of the Environment and Public Works Committee further opined that "for far too long, federal agencies have manipulated science to fit predetermined political outcomes, hiding information and underlying data, rather than using open and transparent science to justify fair and objective decision-making. This Act seeks to change all of that and ensure that EPA uses the best available science, bases scientific decisions on the weight of the scientific evidence rather than one or two individual cherry-picked studies and forces a much greater level of transparency that forces EPA to show their work to Congress and the American public. Congress recognized the need to use available studies, reports and recommendations for purposes of chemical assessments rather than creating them from whole cloth."

Just as importantly, the Senator noted that recommendations in reports of the NAS "should not be the sole basis of the chemical assessments completed by EPA. Rather, the EPA must conduct chemical assessments consistent with all applicable statutory provisions and agency guidelines, policies and procedures. Further, in instances where there were other studies and reports unavailable at the time of the NAS recommendations, EPA should take advantage of those studies and reports in order to ensure that the science used for chemical assessments is the best available and most current science."

SIRC strongly supports the directives coming out of that colloquy, and urges EPA to use the best – and all – available data for its TSCA evaluations. EPA should not solely rely on existing available hazard assessments from EPA program offices, or from other federal hazard assessment programs. Such assessments represent only a point-in-time determination, and may not reflect subsequent – and substantive – new data that could significantly inform and/or change the earlier conclusions. Given the great importance of the TSCA program, EPA should ensure that it works to identify any and all data pertinent to a chemical's hazard evaluation, most especially in the event EPA may try to base a hazard evaluation on an existing determination. All new, or previously unconsidered, data should be thoroughly and carefully integrated into EPA's final hazard evaluations.

Support for Recommendations of Other Stakeholder Commenters

Beyond the above recommendations relative to stakeholder input, effective risk assessment, and use of best available data, SIRC also supports many of the comments offered by the American Chemistry Council and other stakeholder groups and



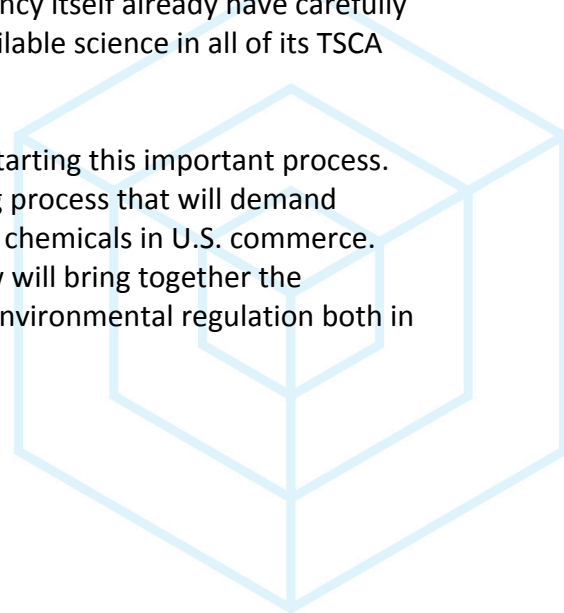
companies, that were briefly outlined during the August 9 public meeting. Some of the most important points offered, which SIRC anticipates will be elaborated on in written comments, included:

- The need for EPA to have a formal plan for systematic review, including problem formulation & scoping, clear parameters for determining data quality, and application of an evidence-based (or “weight-of-the-evidence”) approach to provide credible hazard assessments;
- Integration of stakeholders fully in the TSCA process, and leveraging the resources that stakeholders can offer;
- The imperative need to consider the best available science;
- The need for EPA to provide for robust, independent external peer review of its proposed evaluations;
- The benefits of open scientific dialogue with stakeholders during peer review meetings, including the opportunity for an appropriate public comment period;
- Thoughtful and thorough consideration and application of mode of action data in hazard assessments;
- Taking advantage of data and conclusions already in place under the European REACH program, Health Canada programs, etc., when exposures are comparable;
- The fact that the new TSCA legally mandates EPA’s consideration of science; science considerations cannot be considered “guidance” and,
- Allowing for a 90-day stakeholder comment period versus the current 30-day comment period.

Summary

In summary, SIRC hopes that the Agency will carefully provide for maximum public participation in the new TSCA processes, that EPA also studies and adopts the best recommendations and policies that the NRC and the Agency itself already have carefully defined in past years, and will fully consider the best available science in all of its TSCA evaluations.

SIRC again acknowledge the EPA for its quick actions in starting this important process. We all recognize that updating TSCA will be a challenging process that will demand timely, engaged, and informed evaluations of the exiting chemicals in U.S. commerce. We hope that your implementation of this important law will bring together the country's best minds and best practices on science and environmental regulation both in and outside the government.



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Thank you for the opportunity for SIRC to provide these comments.

Very truly yours,

A handwritten signature in black ink that reads "Jack Snyder". The signature is written in a cursive style with a large, looped "S" at the end.

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