

January 25, 2018

Document Control Office (7407M),
Office of Pollution Prevention and Toxics (OPPT)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW.
Washington, DC 20460-0001

Re: **TSCA § 6(b) Pre-Prioritization Procedures and Decision-making
Comments of the Styrene Information and Research Center
Docket Id. No. EPA-HQ-OPPT-2017-0586**

Ladies and Gentlemen:

The Styrene Information and Research Center, Inc.¹ (SIRC) appreciates the opportunity to provide comments on approaches the Environmental Protection Agency (EPA) may use to identify potential candidates for prioritization for risk evaluation under § 6(b) of the Toxics Substances Control Act, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA). The Agency's pre-prioritization procedures are important because they will determine which substances will undergo risk evaluation for the foreseeable future.

EPA must articulate organizing principles for pre-prioritization, whose purpose is to identify potential candidates for prioritization. Because TSCA § 6 implementation, including pre-prioritization, must fully implement statutory requirements and goals, those factors must be fundamental to the pre-prioritization process.

The statute and the agency's prioritization rules serve as a starting point for developing a pre-prioritization process.

TSCA § 2605(b)(1) states, "The process to designate the priority of chemical substances shall include:

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. SIRC was formed in 1987 as the principal focal point for public information and research on styrene. SIRC is a nonprofit 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.

- a consideration of the hazard and exposure potential of a chemical substance . . .
- the conditions of use or significant changes in the conditions of use . . . , and
- the volume or significant changes in the volume of the chemical substance manufactured or processed.”

In its prioritization rule, 40 C.F. R. § 702.5(a), EPA describes its general objectives for high-priority and low-priority candidate selection.

High-Priority Substance: “substances with the greatest hazard and exposure potential first, considering reasonably available information on the relative hazard and exposure of potential candidates.”

Low-Priority Substances: “substances with hazard and/or exposure characteristics under the conditions of use such that a risk evaluation is not warranted.”

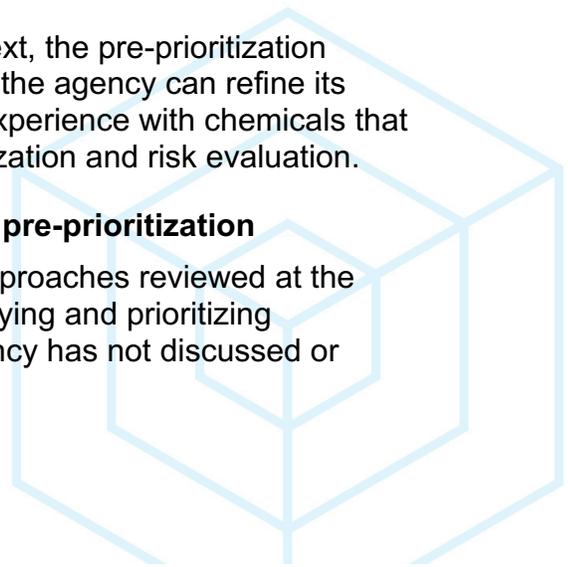
These general objectives are supplemented with need for readily available information that will allow the agency to meet statutory time and numeric deadlines.

SIRC’s comments focus on these and several other themes.

- Pre-prioritization procedures should be designed to encourage broad, voluntary information submissions from stakeholders to support informed, transparent, science-based, decision-making.
- Stakeholder support will be encouraged by early notice of EPA’s plans.
- Alternative chemical assessment is not part of pre-prioritization, Prioritization, or Risk Evaluation.
- To be workable, pre-prioritization must not be an exhaustive information search and analysis, but predicated on readily available information and tentative evaluations.
- Given the new statutory and procedural context, the pre-prioritization process should be adaptable and iterative so the agency can refine its processes and procedures based on future experience with chemicals that have moved through pre-prioritization, prioritization and risk evaluation.

1. EPA must articulate organizing principles for pre-prioritization

The Discussion Document and the six alternative approaches reviewed at the public meeting each described techniques for identifying and prioritizing candidates for prioritization and review, but the Agency has not discussed or



identified preferred organizing principles or goals for candidate substance selection. As we saw at the meeting, without an organizing principle, one can review many innovative alternative approaches, but there is no basis for comparison without articulated clear principles.

Particularly given the time horizon for completing a significant fraction of the chemical evaluations contemplated by TSCA § 6(b), EPA's approach to candidate selection should focus first on initiating substance reviews that will most effectively and efficiently enable the agency to fulfill the policy and intent of Congress for the "risk-based screening process" of prioritization described in 15 U.S.C. § 2605(b)(1)(A).

As expressed in 15 U.S.C. § 2601 (b) and (c):

[A]dequate information should be developed with respect to the effect of chemical substances

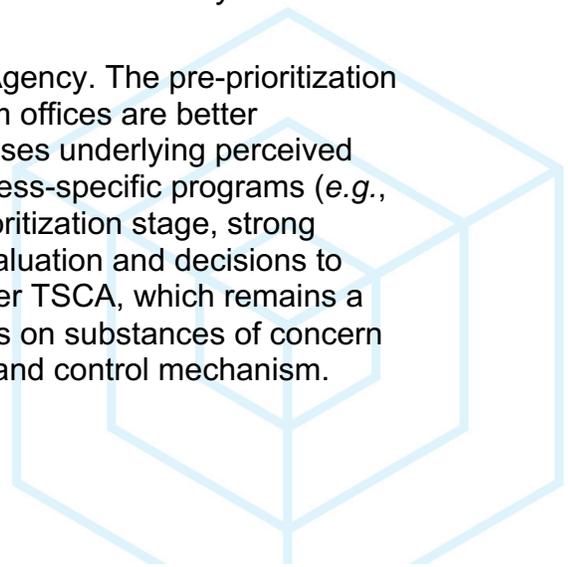
[A]uthority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

It is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action

The availability of sufficient data is an important consideration for launching formal prioritization, but pre-prioritization should focus on identifying substances that should be reviewed first in accord with the prioritization goal, and then determining whether available information can support a timely prioritization determination. This, of course, must respect the statutory deadlines for numeric priority determination goals.

a. Prioritize candidates with potential risks best addressed by a TSCA regulation, rather than other authorities

TSCA is one of many statutes administered by the Agency. The pre-prioritization process should consider whether other EPA program offices are better positioned to address potential risks. If the primary uses underlying perceived risk could be regulated under other industry- or process-specific programs (e.g., air, water, or occupational standards), at the pre-prioritization stage, strong consideration should be given to referring further evaluation and decisions to other EPA program offices in lieu of proceeding under TSCA, which remains a gap-filler statute. This frees TSCA resources to focus on substances of concern for which TSCA may be the only practicable review and control mechanism.



b. Pre-prioritization should consider existing regulations as part of the risk or safety projections

Some substances have been well studied and subject to risk management controls by EPA and other agencies for years. The Agency's risk-based considerations include the "nature and extent of any existing regulation that is intended to mitigate the hazards of a chemical substance." Prioritization Rule, 82 Fed. Reg. at 33,754.

c. Selection criteria should focus on exposure, not production volume

In evaluating risk, production volume is an important consideration, but primarily as an input for estimating release and exposure. Pre-prioritization should focus on the extent of actual exposure as a key mediator of risk. Substances with large manufacturing volumes but low exposures generally should not be priorities. This approach is consistent with TSCA § 2605(b)(1) ("The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical")

2. Alternative chemical assessment should not be part of pre-prioritization, prioritization or risk evaluation

The claimed value of some of the alternative prioritization approaches discussed at the public meeting included their utility to support chemical product comparisons and potential product substitutions, *e.g.*, the functional category approach and Health Canada approach. Alternatives analysis may be useful during risk management proceedings (if unreasonable risks for a substance are identified), but it is an extra-statutory distraction and should not be considered in pre-prioritization, prioritization, or risk evaluation proceedings.

3. EPA's public pre-prioritization actions should include sufficient context to send appropriate signals to industry and prevent unwarranted stigma

The identities of a range, perhaps a large range, of potential prioritization candidates may be public long before even a pre-prioritization decision is made. This is likely an unavoidable consequence of the agency's efforts to collect information. There is a substantial risk that lists of substances in the pre-prioritization pool will be treated as a "SIN" list and that listed substances will be targeted for purposeful but unwarranted deselection and substitution. When such lists are made public, the Agency should provide context for the basis for listing and confirm the absence of any judgments or agency determinations about risk prior to rule making findings.

4. Pre-prioritization procedures should include timely public notice and information requests

The Agency must carefully plan and manage data to assure that appropriate information is available to satisfy TSCA's statutory imperatives to employ best



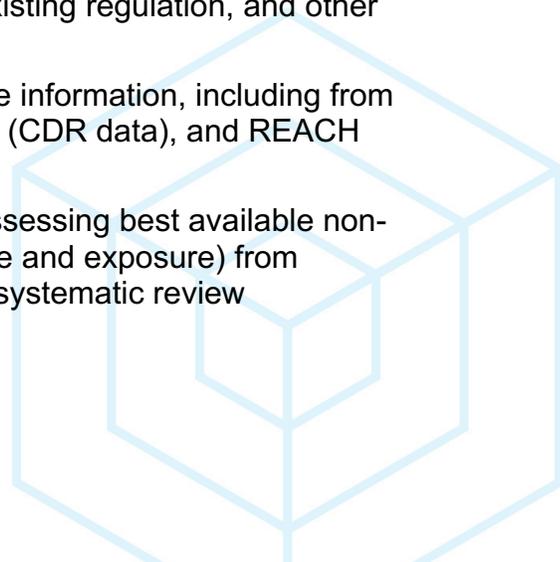
available science and weight of the evidence / systematic review in decision-making under TSCA § 26(h), (i), coupled with the short time frames for assembling, developing and assessing data under § 6(b) after formal prioritization commences.

At the pre-prioritization stage, EPA needs a streamlined, systematic system to ensure there is enough reliable data available to support timely determinations. This should include consideration of information quality and systematic review principles, such as consideration of the quality and comprehensiveness of readily available information. For example, a concise spreadsheet describing readily available information on toxicology, exposure and primary uses may be constructive. The goal is to avoid unwarranted risk conclusions (either overly conservative or under protective) in subsequent deadline-driven decision making based on inadequate data that will not meet statutory requirements.

While discretionary, pre-prioritization should be transparent and avoid the perception as a 'black box' or arbitrary system, which will undermine public confidence and increase apprehension and suspicion among all stakeholders.

Neither the Discussion Document nor the public meeting presentations indicated when EPA would request chemical data and others' assessment information during pre-prioritization. The regulated industry and the public will have helpful information on use, exposure, and health and environmental effects. Properly done, EPA could be effective in obtaining needed assessment information voluntarily during the pre-prioritization period. Pre-prioritization data collection and assembly procedures should include:

- Adequate lead time notice of substances of interest to allow industry sectors and value chains to organize to develop and provide relevant information;
- Notice of the Agency's existing database and detailed information on perceived information gaps relevant to fit-for purpose reviews and consistent with systematic review methods;
- Points of contact and opportunities for engagement on use assumptions, information gaps, data development plans, existing regulation, and other relevant topics;
- Leveraging existing hazard, use and exposure information, including from Chemical Data Reporting, 40 C.F.R. Part 711 (CDR data), and REACH robust study summaries; and
- Data quality information needs for properly assessing best available non-guideline study data and information (*e.g.*, use and exposure) from stakeholders in anticipation of weighting and systematic review procedures.



5. Low-Priority Designations and Conditions of Use

By December 2019, EPA must have prioritized and designated 20 substances as “Low-priority” and not warranting review. TSCA § 6(b)(2)(B). This may be difficult to achieve because a substance will be designated “High-priority” if either: (a) it is determined that any one condition of use “may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use,” or (b) there is insufficient information to rule out such risks. 40 C.F.R. § 702.9(e).

EPA must consider this programmatic risk in developing its pre-prioritization approach. For example, the agency cannot rely solely on the TSCA Work Plan as a pre-prioritization tool because the listed chemicals may have one or more conditions of use that will trigger a high-priority designation.

The challenge of meeting the statutory quota for Low-priority designations supports the agency’s position in the final rules for prioritization and risk evaluation regarding the scope of conditions of use. Had EPA expansively defined “conditions of use,” it may have made it practically impossible to make any low-priority designations, and, in doing so, create conflicts with other statutes the agency administers.

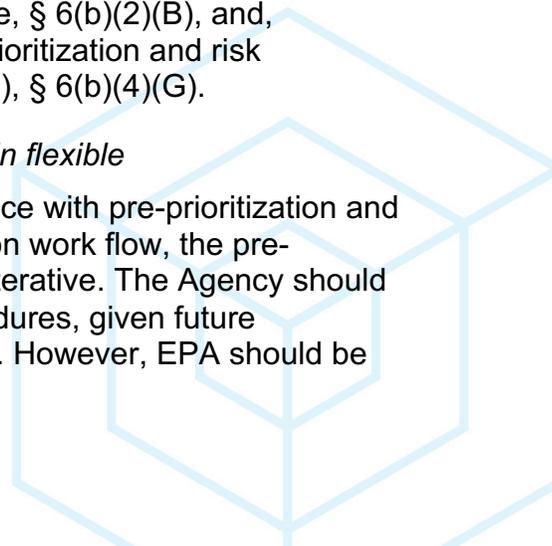
6. Additional Considerations for Selecting Pre-Prioritization Approaches

a. Pre-prioritization must be tailored for amended TSCA

The Agency must recognize that no existing approach was designed to meet the statutory requirements or longer term policy objectives of TSCA as amended by the Lautenberg Act. EPA must develop a new, purpose-built approach to pre-prioritization designed for this new framework. Key framework elements include the intent to review all chemicals on the TSCA Inventory over an extended period, § 6(b)(3)(C), discretion to determine which “uses” will be reviewed during risk evaluation or deferred, § 6(b)(4)(D), the requirement to draw prioritization candidates first from the 2014 Work Plan, § 6(b)(2)(B), with preference for Work Plan chemicals with high persistence and bioaccumulation scores, or are both known human carcinogens and have high chronic and acute toxicity, § 6(b)(2)(D), the obligation to maintain a certain pace, § 6(b)(2)(B), and, importantly, the limited time available to complete prioritization and risk evaluation once the process has started, § 6(b)(1)(C), § 6(b)(4)(G).

b. Pre-prioritization procedures should remain flexible

Given the Agency’s and the public’s limited experience with pre-prioritization and its central role in defining the Agency’s risk evaluation work flow, the pre-prioritization process should remain adaptable and iterative. The Agency should retain the freedom to refine its processes and procedures, given future experience with the program and changing priorities. However, EPA should be



intentional and transparent about any changes to procedures and priorities, to encourage planning and avoid the perception of arbitrary action.

c. EPA needs a pre-prioritization off-ramp for chemicals under consideration

EPA faces a formidable task in evaluating all existing chemicals. When EPA staff undertakes a pre-prioritization review, the process needs a defined exit or off-ramp if the chemical does not appear to be a good prospect for a prioritization rule making. Obvious examples include lack of sufficient information or existing regulations. In other contexts, we have witnessed bureaucratic inertia that results in misdirected effort stemming from an unstated interest in seeing preliminary work progress through the process, rather than determining that further work is not needed or should be formally deferred. The Agency must be a careful guardian in allocating its resources.

* * * * *

SIRC appreciates EPA's careful consideration of these comments and would be pleased to provide additional details or elaboration. Thank you for the opportunity to provide these recommendations on the important process of implementing section 6(b) of TSCA.

Sincerely,



Ray Ehrlich
Executive Director
Styrene Information & Research Center
1750 K Street NW, STE 700
Washington, DC 20006
(202) 787--5997
ray.ehrlich@styrene.org

