

Comments to OIRA Regarding its Review of EPA's Proposed TSCA Risk Evaluation Rule

We are smaller companies using chemicals to make products such as wind turbine blades, fuel-saving automotive components, and non-rusting lightweight structures for highway bridges. In 2014, our industry was identified by the President's Council of Advisors on Science and Technology as a high national priority transformative manufacturing technology.

Styrene (a substance on EPA's TSCA Work Plan) is an essential component of our raw material systems. Our industry has safely used styrene to make composite products since WW II. Every WOE-based assessment of styrene has concluded that our use of this chemical does not present a significant risk to our employees and plant neighbors. By contrast, every shortcut- and default-driven assessment has concluded that styrene does pose a health risk to exposed people. This illustrates the danger of a TSCA program driven to satisfy mandated deadlines without formal commitment to sound science principles. (Common assessment flaws include: Critical concepts not defined or defined *ad hoc*. Tautological listing criteria. Non-transparent study evaluation. Negative and null data ignored. "Plausible" AOP without supporting evidence given weight over AOP with supporting evidence. Peer review charge discouraged consideration of legitimate scientific controversies. Responses to public comment prepared only after publication of final assessment.)

Uncertainty regarding the regulatory status of our materials and operations will stifle investment and innovation, threaten our viability as small companies, and in turn curb employment in and the economic well-being of the communities in which we operate.

Based on our experiences, we suggest that the following policies and practices need to be included in EPA's TSCA Risk Evaluation Rule.

- EPA's rule must provide sufficient information to provide clarity and certainty regarding what a risk evaluation will look like. EPA's rulemaking must explicitly incorporate the Section 26 science requirements.
- Key concepts must be defined, including weight of evidence, sentinel exposures, susceptible populations, best available science, reasonably foreseeable, and EPA must specify in advance how these will be interpreted and implemented in a risk evaluation. Because this is a proposed rule, EPA should consider proposing alternative options for each of these important definitions and seek input on these definitions.
- The new statutory requirements for transparency and best available science can only be satisfied with systematic review. The rule needs to include criteria for evaluation of data and studies. The rule should commit to incorporating these elements in a transparent and objective manner.
- EPA's rule should specify the key stages of a risk assessment at which the agency will solicit and respond to public comment before proceeding. Key stages should include issuance of a scoping document, identification of relevant studies, evaluation of relevant studies, and evidence integration.

- The rule must commit EPA to conducting its own WOE-driven hazard assessments for TSCA and not rely on those performed for other purposes.
- Independent peer review of a draft risk assessment should include peer review of EPA's responses to public comments. The peer review panel should also respond to public comments submitted to the panel.

Under the best of circumstances, our industry of smaller companies will be hard pressed to effectively and constructively participate in the many complicated parts of a TSCA process to evaluate risk and reach safety determinations. **If EPA's procedures and policies are developed in an entirely iterative and *ad hoc* manner, the moving target will impair our ability to effectively participate, and the resulting uncertainties will stifle innovation and job growth.**

EPA's TSCA rules will have significant impacts on the thousands of small companies using chemicals to make products and employ people in their communities, and the development of these rules should be subject to the small business flexibility reviews under SBREFA.