

March 15, 2017

Ms. Sheila Canavan  
Mail Code 7405M  
U.S. Environmental Protection Agency  
Office of Pollution Prevention and Toxics  
William Jefferson Clinton Building  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

**Re: Comments on the U.S. Environmental Protection Agency's Initial 10 Chemicals for Risk Evaluation**  
EPA-HQ-OPPT-2016-0723, EPA-HQ-OPPT-2016-0725, EPA-HQ-OPPT-0732, EPA-HQ-OPPT-2016-0733,  
EPA-HQ-OPPT-2016-0735, EPA-HQ-OPPT-2016-0736, EPA-HQ-OPPT-0737, EPA-HQ-OPPT-2016-0741, EPA-  
HQ-OPPT-2016-0742, and EPA-HQ-OPPT-0743

Ms. Canavan:

The undersigned organizations represent a broad spectrum of American businesses throughout the manufacturing and distribution supply chain that have aligned in an effort to better understand and communicate the impacts of legislative and regulatory chemical management issues at the federal, state, and local levels. The undersigned supported passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), amending the Toxic Substances Control Act (TSCA), and are committed to working with EPA to achieve the full, timely and reasonable implementation of the Act.

The undersigned have a broad understanding of the uses of chemicals in the U.S. marketplace. They provide these general comments relevant to EPA's February 14, 2017, Public Meeting on Risk Evaluation Scoping under TSCA for Ten Chemical Substances and the Preliminary Information on Manufacturing, Processing, Distribution, Use and Disposal documents EPA has included in the docket for each of the initial ten Work Plan chemicals. These comments are also intended to inform EPA's approach going forward for the development of preliminary Information of chemicals beyond the first 10 that are prioritized for Risk Evaluation under TSCA.

EPA has an historic opportunity to implement the LCSA in such a way that it becomes a model regulatory program for regulatory bodies around the world. The potential of the new law can only be realized if the Agency follows the science and risk-based approach Congress intended. Lawmakers and countless stakeholders supported the new law because its risk-based framework and requirement for strong scientific standards will ensure protection of human health and the environment while preserving opportunities for innovation. It is critical that EPA implement the LCSA with regulations and processes that are consistent with the intention of the law, workable within the timelines prescribed by the law and provide transparency and certainty in support of ongoing innovation in the market. The following comments are offered with these goals in mind.

### *Iterative or tiered approach to scoping informed by the supply chain*

Risk evaluations will benefit from a tiered or iterative approach to scoping that is based on high quality Preliminary Information. Input from industry sources along the supply chain during the collection of preliminary information and prior to scoping is necessary to ensure the highest quality preliminary information are used as the basis for scoping decisions and will improve the accuracy of hazard and exposure assessments and thereby improve the scoping and risk evaluations.

The undersigned strongly recommend that EPA include a tiered approach to risk evaluation. EPA has up to six months following the initiation of the risk evaluation to prepare and publish the scope. Congress intended this time to be used to allow the EPA to identify the hazards, exposures, conditions of use, and the potentially exposed or relevant susceptible subpopulations the Administrator expects to consider in the risk evaluation.

In order for EPA to conduct risk evaluations consistent with the quality scientific standards required by the LCSA and within the timeframes required, EPA should conduct screening level evaluations during the scoping phase of the risk evaluation to identify uses with low potential for risk. Tools exist to allow the Agency to conduct quantitative screening level analyses of multiple exposure scenarios, as appropriate for consumers, sensitive subpopulations, and the environment. This will allow EPA to have a more tailored focus on those populations and exposures of greatest concern during a refined risk evaluation process. That said, it is imperative that all uses identified during scoping that do not undergo full risk evaluation are nevertheless addressed and identified as not presenting unreasonable risk in the final Risk Evaluation for the chemical.

### *Conditions of Use*

The undersigned are concerned that EPA intends to evaluate every condition of use in a risk evaluation. LCSA does not require the Agency to conduct full risk evaluations based on all conditions of use and nowhere in the law is "conditions of use" preceded by "all". It is view of the undersigned that EPA's interpretation, as described at the public meeting on February 14, 2017, goes beyond the intentions of Congress and may distract from and negatively impact EPA's ability to conduct meaningful risk evaluations on high priority substances in a timely manner.

The definition of "conditions of use" in Section 3 of the LCSA, stresses the need for EPA to determine relevant conditions of use: "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."<sup>1</sup> This definition suggests conditions of use that are known or readily foreseeable and for which adequate information exists.

The Agency should use its discretion to scope risk evaluations to exclude particular uses regulated by other agencies or under other Federal laws. For example, EPA should not include exposure scenarios identified during the scoping exercise that are adequately regulated under other federal laws, such as exposure scenarios under the jurisdiction of the Occupational Safety and Health Administration (OSHA).

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<sup>1</sup> § 3 (4)

In addition, the Agency should not include exposure scenarios that are inconsistent with labeling requirements for safe use, or exposures that are the result of product misuse. An intentional or unintentional misuse of a substance is not reasonably foreseen and should not be considered a condition of use<sup>2</sup>.

#### *Scientific Standards*

The underpinning of LCSA is effective risk evaluation of high priority chemicals considering their potential hazard, exposures, and conditions of use. The Agency must analyze substances and exposures using the best available science and the full weight of scientific evidence. Under Section 26 (h), it clearly states that the Administrator shall make decisions based on science and shall use scientific information, technical procedures, measures, methods, protocols, methodologies or models, employed in a manner consistent with the best available science.<sup>3</sup>

Under 26(i) of the LCSA, EPA is required to make decisions using the weight of scientific evidence. In order to promote clarity and consistency in applications. EPA must adhere to Congress' stated intent that weight of evidence be based upon the systematic review method. Systematic review approaches use a pre-established protocol to comprehensively identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate.

#### *High Quality Data*

The undersigned are concerned that EPA may gather information about uses from sources, such as the Internet, without verifying the reliability and credibility of the information. EPA's decisions should be made based on the highest quality and verified information and should involve direct consultation with principal stakeholders, known to the Agency, that manufacture, import, process or use the specific chemical substance under review.

LCSA requires the Agency to scope the risk evaluation on each of the 10 chemicals by June 19th and complete risk evaluations within three years. The prescribed timeframe should motivate the Agency to engage with industry stakeholders early and often, as they are likely to have the most accurate and reliable and up-to-date information available about potential hazards and exposures under a chemical's conditions of use.

#### *Focus on Risk Evaluation not Alternative Assessment*

At the public meeting on February 14, 2017, EPA specifically requested feedback on the consideration of alternatives for the initial 10 chemicals during scoping and risk evaluation. LCSA specifically requires that EPA conduct risk evaluations "without consideration of cost or other non-risk factors". Therefore, all activities related to the risk evaluation of high priority chemicals, including prioritization, scoping and risk evaluation should be focused on the risk of the chemical in question. The existence of an alternative is not relevant to whether the chemical presents an unreasonable risk in its conditions of use. Consideration of alternatives may be relevant during risk management if an unreasonable risk determination is made.

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<sup>2</sup> Ibid.

<sup>3</sup> § 26 (h) 1 through 5

*Transparency*

In order to maintain public trust in the scoping and risk evaluation processes, EPA must ensure that the data and information used and basis for all decisions are transparent and publicly available.

The undersigned will continue to share comments and concerns during the rulemaking process. We look forward to working with the Agency to craft efficient and effective rules to manage TSCA chemicals in a way that promotes innovation and protects human health and the environment.

Respectfully Submitted,

Adhesive and Sealant Council  
Alkylphenols & Ethoxylates Research Council  
American Apparel & Footwear Association  
American Chemistry Council  
American Coatings Association  
American Fuel & Petrochemical Manufacturers  
American Petroleum Institute  
Association of Home Appliance Manufacturers  
Biotechnology Innovation Organization  
Consumer Technology Association  
CropLife America  
Fashion Jewelry and Accessories Trade Association  
Flexible Packaging Association  
Grocery Manufacturers Association  
Hardwood Plywood & Veneer Association  
Institute of Makers of Explosives  
International Fragrance Association North America  
IPC- Association Connecting Electronics Industries  
National Association of Chemical Distributors  
National Association of Manufacturers  
National Council of Textile Organizations  
National Oilseed Processors Association  
Pine Chemicals Association  
Plumbing Manufacturers International  
Rubber Manufacturers Association  
Society of Chemical Manufacturers & Affiliates  
Styrene Information & Research Center  
U.S. Chamber of Commerce