

November 29, 2016

Honorable Gina McCarthy  
Administrator  
Environmental Protection Agency  
1201 Constitution Avenue, NW  
Washington, DC 20460

**RE: Improving Implementation of the Lautenberg Chemical Safety Act**

Dear Administrator McCarthy:

The American Alliance for Innovation (AAI or Alliance) is a group of over 200 trade associations representing 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. AAI believes that the Agency's efforts to implement the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act (LCSA) in several key areas warrants your particular attention. AAI supported passage of the LCSA, and is committed to working with EPA to achieve the full, timely and reasonable implementation of the Act.

**Initial 10 Chemicals.** AAI believes that a sound scientific basis is required when selecting the first 10 chemical substances to undergo risk evaluations. The Alliance strongly encourages the Agency to base its decision making on the best available science and provide stakeholders with adequate notice. Given that the LCSA requires the risk evaluation scope for these chemicals to be developed before the revised risk-based screening rule is made final, a well-developed problem formulation docket with stakeholder input for is critical for the first 10 substances.

**Priority Chemicals.** The LCSA requires EPA to establish a science-based process for identifying priority chemicals for risk evaluations, and apply it throughout the implementation process. As implementation proceeds, adequate advance notice is necessary so that manufacturers and processors can avoid costly disruptions to the supply chain.

The LCSA established a new process for risk evaluations by amending section 26 of the Toxic Substances Control Act (TSCA) to require that the "Administrator shall make decisions under sections 4, 5, and 6 based on the weight of scientific evidence." Moreover, the LCSA requires the Administrator to "use scientific information, technical procedures, measures, methods, protocols, methodologies, employed in a manner consistent with the best available science." How these important amendments will be implemented must be clearly articulated in EPA's forthcoming risk evaluation process rule. It is imperative that EPA set the direction and necessary framework for all risk evaluations under LCSA by announcing its intent to adhere to the new standards.

Using the best available and highest quality scientific information, as required under the statute, will enhance transparency and result in reproducible and unbiased evaluations. We therefore encourage the Agency to engage early with industry stakeholders to fully understand the relevant downstream uses and obtain information on the hazards and potential exposures of substances throughout the supply chain. The LCSA rulemakings currently in progress will have an immediate and lasting impact on American manufacturing and consumer confidence in myriad products used every day. The Alliance is concerned that any regulatory determination based upon data that is not supported by a robust risk evaluation or a proper and unbiased

weight-of-evidence approach will erode the public trust in American products and the agencies responsible for protecting public health and safety.

**Section 5 New Chemicals Review.** The LCSA made a number of discrete changes to section 5 of TSCA, which governs the review and regulation of chemical substances new to the market. In adopting the LCSA, Congress reiterated the view that the new chemicals program was considered to be a success. Indeed, the single largest change to section 5 was a mandate the EPA explain its decisions, especially in the case of new chemical substances that do not warrant additional review (on the basis that they are “not likely to pose an unreasonable risk”). We are pleased that EPA has announced a public meeting on section 5 implementation for December 14. EPA should not delay making any improvements to the new chemicals program until that meeting, however.

In the few short months since enactment of the LCSA, the new chemicals program has ground to a virtual standstill. Upon enactment, EPA unilaterally extended the review period for all pending PMNs by an additional 90 days, despite the lack of statutory authority for such an action. Since then, very few final decisions have been made on PMN submissions. The vast majority of new chemical reviews are slated for section 5(e) orders, marking a far more onerous and extensive regulatory burden for new chemistries. In the Alliance’s view, section 5 practice as previously implemented by EPA has been turned on its head, such that the ability of chemical companies to bring new and innovative products to market is jeopardized. We encourage you to immediately review implementation of the new chemicals program to ensure that the program implements Congressional intent to support innovation in U.S. chemical manufacturing, processing, and use.

**Confidential Business Information.** Congress made modest changes to the provisions of TSCA that govern the protection of confidential business information (CBI) in the LCSA. Claims for CBI protection must be accompanied by an upfront substantiation, CBI claims are now limited to 10 years (but can be renewed for similar periods), and while all CBI claims must be asserted, a subset of those claims do not require substantiation (e.g., sales and marketing information). For example, under section 14(g)(1)(c)(i), information such as production volumes, marketing and sales information, customer and supplier information, is generally not subject to substantiation requirements.

Unfortunately, CBI practice since the enactment of the LCSA appears to have become far more onerous, well beyond what Congress anticipated in making the amendments. Companies making CBI claims are routinely asked to substantiate their claims, even though the original submissions contain the appropriate justification to protect the information from disclosure. This practice certainly requires the expenditure of more EPA resources than would otherwise be expected, and has resulted in confusion among the regulated community. It is also apparent that uniform guidance to CBI claimants has not been made available. The Alliance strongly recommends that EPA temporarily halt all CBI claim reviews until such time as a clear and consistent review process, and appropriate guidance, are made available. The Alliance believes that the temporary halt, and subsequent policy review, can be done quickly and effectively without materially affecting the 90-day review period for CBI claims made under the LCSA.

AAI members are committed to developing, manufacturing, distributing, and marketing products that are safe for their intended conditions of use, meet or exceed government safety requirements, and are protective of human health and the environment. We look forward to

continuing our work with the Agency to protect public health and the environment, promote sound chemicals management policy, and preserve innovation and U.S. jobs through effective and efficient implementation of the LCSA.

Adhesive and Sealant Council	IPC–Association Connection Electronics Industries
Alkylphenols & Ethoxylates Research Council	Motor & Equipment Manufacturers Association
American Apparel & Footwear Association	National Association of Chemical Distributors
American Chemistry Council	National Association of Manufacturers
American Cleaning Institute	National Industrial Sand Association
American Coatings Association	National Marine Manufacturers Association
American Coke and Coal Chemicals Institute	National Mining Association
American Composites Manufacturers Association	National Retail Federation
American Feed Industry Association	National Stone, Sand and Gravel Association
American Fuel & Petrochemical Manufacturers	National Tank Truck Carriers
American Petroleum Institute	North American Metals Council
Association of Home Appliance Manufacturers	Oregon Women in Timber
Auto Care Association	Outdoor Power Equipment Institute, Inc.
Battery Council International	Personal Care Products Council
Biobased and Renewable Products Advocacy Group (BRAG®)	Pine Chemicals Association International
Biotechnology Innovation Organization	Plumbing Manufacturers International
Color Pigments Manufacturers Association	PVC Pipe Association
Consumer Specialty Products Association	Recreation Vehicle Industry Association
Consumer Technology Association	Resilient Floor Covering Institute
Council of Great Lakes Industries	RISE, Responsible Industry for a Sound Environment
Ecological & Toxicological Association of Dyes & Organic Pigments Manufacturers, North America	Society of Chemical Manufacturers and Affiliates
Fashion Accessories Shippers Association	Specialty Graphic Imaging Association
Fashion Jewelry & Accessories Trade Association	SPI: The Plastics Industry Trade Association
Gemini Shippers Association	SPRI, Inc. (representing the Single Ply Roofing Industry)
Grocery Manufacturers Association	Styrene Information and Research Center
Institute of Scrap Recycling Industries, Inc.	The Chlorine Institute
International Fragrance Association North America	Toy Industry Association, Inc.
International Minerals Association-North America	Travel Goods Association

cc: Jim Jones  
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