

Office of the United States Trade Representative
600 17th Street, N.W.
Washington, D.C. 20508

October 31, 2012

Re: Promoting U.S. and E.C. Regulatory Compatibility; Docket: USTR-2012-0028

Dear Sir or Madam:

On behalf of the Society of Chemical Manufacturers and Affiliates (SOCMA), we appreciate the opportunity to provide input on promoting regulatory compatibility between the United States and the European Union. SOCMA is the only U.S. based trade association dedicated solely to the [batch, custom and specialty chemical industry](#). Over 70% of SOCMA members are small businesses.

SOCMA appreciates the work of the U.S. and E.U. on the High Level Working Group on Jobs and Growth. With such large trade flows between these economies, eliminating tariff and non-tariff barriers would benefit both economies and our members. Through greater cooperation we hope to see efficiencies for business and government regulators and a reduction in the cost of doing business at a time when resources are scarce in public and private sectors.

Chemical Regulations Should be Based on Sound Science and Risk

SOCMA fundamentally supports approaches to regulating chemicals that are based on sound science and risk. Such approaches factor the hazard, or intrinsic characteristics, of a chemical with the potential for exposure. In contrast, approaches based more on the precautionary principle would be detrimental to our industry and not achieve the shared goals of the U.S. and E.U. on facilitating trans-Atlantic trade and enhancing protection of human health and the environment.

SOCMA finds that current European REACH regulations are disproportionately burdensome to small, U.S. manufacturers. We are aware of instances in which U.S. chemical manufacturers are unable to enter the European market because of testing costs and regulatory burden. The impact of this trade barrier is not limited to U.S. manufacturers; it also affects the accessibility of chemicals and innovative products in the E.U. market.

Still, SOCMA supports the basic goal of regulatory compatibility between the U.S. and E.U. with the understanding that there may be areas where this is more appropriate than others.

The following recommendations outline opportunities for greater regulatory cooperation:

- Permissible use of data that has been generated for regulatory purposes and information sharing, provided that confidential business information (CBI) is adequately protected. The U.S. Environmental Protection Agency (EPA) and the European Chemicals Agency (ECHA) should establish a formal data-

sharing agreement, given the breadth of information being submitted under REACH and likewise for the U.S. to share domestically conducted work.

- Increased transparency on chemical information and evaluation processes with the understanding that protection of CBI is critical to promoting innovation and the vitality of our members' businesses. Since the EPA and European Chemicals Agency (ECHA) do not have comparable practices, this is an area that will need to be further explored.
- Seeking regulatory harmonization on emerging issues and new regulations in areas where relevant.
- Prioritizing chemicals in commerce in a rigorous risk-based and transparent fashion.
- Reducing or eliminating duplicative standards and protocols by using uniform definitions and guidelines, such as OECD definitions and test guidelines, and ISO standards.
- Sharing of cost-benefit-risk assessment methods.
- Globally Harmonized System of Classification and Labeling of Chemicals (GHS) classifications set in sound science.

Conclusion

Today the U.S. and E.U. take divergent approaches to regulating chemicals. As a result, unfortunate trade barriers have been created and disadvantaged U.S. chemical manufacturers, especially small and mid-sized U.S. chemical manufacturers. However, there are opportunities for greater regulatory cooperation in the future. We encourage continued conversations between regulatory bodies in the U.S. and E.U., in particular, between the U.S. EPA and ECHA. Additionally, any future coordination on regulations should be transparent and allow for input from U.S. and E.U. stakeholders. Thank you for considering our comments. Feel free to contact me with any questions or comments at 202 721 4100.

Sincerely,



William E. Allmond, IV
Vice President, Government & Public Relations