July 24, 2013

The Honorable Lee Terry
Chairman, Energy and Commerce Committee
Subcommittee on Commerce, Manufacturing and Trade
US House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Jan Schakowsky
Ranking Member, Energy and Commerce Committee
Subcommittee on Commerce, Manufacturing and Trade
US House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Terry and Ranking Member Schakowsky,

The Society of Chemical Manufacturers and Affiliates (SOCMA) respectfully submits this letter for the record regarding the hearing on the US-EU Free Trade Agreement: Tipping Over the Regulatory Barriers. We appreciate the Subcommittee hosting a hearing on this issue, which is of great interest and importance to our membership.

SOCMA supports a comprehensive Transatlantic Trade and Investment Partnership (TTIP) with the European Union. The transatlantic economic relationship is already the world's largest, accounting for one third of total goods and services trade and nearly half of global economic output. Transatlantic trade and investment currently supports 13 million jobs on both sides of the Atlantic. Europe is the top export market for US chemical manufacturers, comprising 20.2% of exports valued at $53 billion in 2012. In 2011 $600 million was paid in tariffs; eliminating tariffs alone would have a significant impact.

With such large trade flows between these economies, eliminating tariff and non-tariff barriers would benefit both economies and SOCMA's 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.

Today the US and EU take divergent approaches to regulating chemicals. As a result, unfortunate trade barriers have been created and disadvantaged US chemical

manufacturers, especially small and mid-sized US companies. However, there are opportunities for greater regulatory cooperation in the future.

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 US and EU on facilitating trans-Atlantic trade and enhancing protection of human health and the environment.

Additionally, regulations should not be disproportionately burdensome to small US manufacturers. The impact of trade barriers like REACH is not limited to US manufacturers; it also affects the accessibility of chemicals and innovative products in the EU market.

SOCMA supports the basic goal of regulatory compatibility between the US and EU with the understanding that there may be areas where this is more appropriate than others.
The following recommendations outline opportunities for greater regulatory cooperation:

Data Sharing between US and EU agencies

- Permissible use of data that has been generated for regulatory purposes and information sharing, provided that confidential business information (CBI) is adequately protected. The US 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 US to share domestically conducted work.
- However, it should not hold up the development of an efficient mechanism for sharing non-CBI data. Also, data could be shared in an aggregated manner to improve modeling accuracy (i.e. hazard, risk), reduce testing costs, and improve regulatory outcomes. Model development based upon improved data must be more transparent and involve user input. This will ultimately lead to reduced administrative and testing efforts.

Increased transparency in the evaluation process

- Increased transparency of 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.

- Companies should also have access to regulators to ask questions and aid in their compliance efforts.
- Currently our members have seen their chemicals nominated for inclusion on SVHC lists based on old and erroneous data, which has resulted in the filing of law suits. Ideally, there would be a way to appeal to the agency prior to this escalation so that the SVHC listing can be reevaluated based on current data. A more formal mechanism to submit updated data to allow agencies to make regulatory decisions on the best available science might be a solution, in addition to a mechanism to appeal when agencies do not.
- Globally Harmonized System of Classification and Labeling of Chemicals (GHS) classifications set in sound science.

Continued regulatory dialogue with goal to minimize differences between systems

- EPA, ECHA, and any other appropriate agencies should have a regular dialogue to be aware of each other's rules, minimize differences when possible, and harmonize regulations on emerging issues and new regulations in areas where relevant.
- Where relevant agencies should seek mutual recognition of standards.
- Additionally, the US and EU should seek to align different approaches to change management of active pharmaceutical ingredient (API) manufacture & control, agreeing on annual reportable changes as a first step.
- Additionally, any future coordination on regulations should be transparent and allow for input from US and EU stakeholders.

Streamlined work between agencies

- Work can be streamlined by 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, and consideration of work, where it exists, in international organizations like APEC or the OECD.
- Agencies can share cost-benefit-risk assessment methods.
- For finished drug products and active pharmaceutical ingredients (APIs), the US and EU could sign a mutual recognition agreement on inspections. This would eliminate duplicate inspections of the same site using the same standard and be an immediate saving in inspection resources in EU and US. Importantly, this would permit re-deployment of saved resources to inspect sites in 3rd countries. Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) is also an option.
- The US and EU could also recognize the equivalence of their GMP standards for APIs. The process has already begun; ideally Step 1 will be complete by July 2013.

- SOCMA supports harmonization of the Pharmacopoeia. This would eliminate unnecessary, costly, multiple testing of raw materials & products. EU-US harmonised monographs will revitalise the goal of a global standard for all pharmacopoeia

We look forward to working with you and other members of the House, as well as the other stakeholders towards a successful conclusion of this agreement.

Kind regards,

William E. Allmond, IV
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Society of Chemical Manufacturers and Affiliates (SOCMA)