SOCMA
Society of Chemical Manufacturers & Affiliates

Honorable Lisa Barton
Acting Secretary of the Commission
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

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Re: Hearing on Trade Barriers that U.S. Small and Medium-Sized Enterprises Perceive as Affecting Exports to the European Union (Inv. No. 332-541)

Good morning. My name is Bill Allmond and I am Vice President of Government and Public Relations at the Society of Chemical Manufacturers and Affiliates (SOCMA) in Washington, DC. Thank you for the opportunity to testify before you today. For 91 years, SOCMA has been and continues to be the leading trade association representing the specialty chemical industry. SOCMA's 200 member companies employ more than 100,000 workers across the country and produce some 50,000 products – valued at $60 billion annually – that make our standard of living possible. From pharmaceuticals to cosmetics, soaps to plastics and all manner of industrial and construction products, SOCMA members make materials that save lives, make our food supply safe and abundant, and enable the manufacture of literally thousands of other products. Over 80% of SOCMA's active members are small businesses.

The EU-28 is the largest trading partner of the U.S. and a significant producer, importer, and exporter of chemicals. As such, we welcome the announcement of a comprehensive trade agreement, but also understand the significant challenge of the undertaking given the different regulatory schemes. We have experienced the ongoing implementation of REACh - the Registration, Evaluation, Authorization and Restriction of Chemicals (REACh) which became law on June 1, 2007. It was designed to streamline and improve the former legislative framework on chemicals of the European Union (EU). REACh places greater responsibility on our industry to manage the risks that chemicals may pose to health and the environment. It was created in an effort to comply with the WSSD 2020 (World Summit on Sustainable Development) goals. Founded on the precautionary principle rather than the US risk-based approach to regulation, it has had a significant impact on the way companies operate in the EU market and the resources devoted to testing and compliance. Bloomberg Government estimated that the regulatory costs add 22.2% to the tariff on chemicals.[1]

REACh is and has been very expensive and time consuming for all chemical companies doing business in the EU. This "no data, no market" approach has forced SME companies to either incur large testing costs or exit the market. Other alternatives included reducing substance production volumes to lower tonnage bands which requires less testing or withdrawing SVHCs from EU

[1] Source: BGOV Analysis, August 6, 2013. US-EU Trade Talks. Ken Monahan. **Bloomberg Government calculations of trade-weighted tariffs based on Ecorys Holding BV regulatory tariff equivalent estimates, and tariff and trade data reported by the Department of Commerce, World Bank and Global Trade Information Services, Inc.

markets. This is potentially forcing fewer available substances with more concentrated producers, with questionable benefits to downstream users or the general public. With less than 5% of dossiers being inspected, according to ECHA, this is a high price to pay to collect hazard data.

REACh is the largest barrier SOCMA companies face with respect to exporting to the EU. Even the European Commission's REACh review concluded that the impact on SMEs was disproportionate. This issue is magnified by the EU's very restrictive definition of what constitutes a SME. SOCMA members understand this is the regulatory reality and this legislation will not be repealed. However, there are ways to make this legislation more workable. There are several key issues that impact the ability of our members to export:

1) Costs, the largest being for testing, followed by obtaining an Only Representative (OR), and translating and reformatting material safety data sheets (MSDS), as well as producing/compiling and distributing ESD Sheets and complying with the CLP regulations.
2) Ability to communicate with ECHA
3) Transparency

Costs

Many SOCMA members have decided to continue operating in the EU market and have various lessons to offer from their experience. Companies that have fared the best have taken a proactive approach, both internally and with their customers, and had the resources or margins to compensate for the additional costs associated with REACh compliance.

During the pre-registration process in 2008 many SOCMA members made the decision to proactively pre-register chemicals. Some chose not to, based on cost expectations, including the costs of hiring an Only Representative (OR). Still others pre-registered with the intent to drop some of their pre-registered chemicals before the necessary registration deadline.

As an example, one SOCMA member company decided to drop a chemical because they could not justify the expense of testing costs relevant to the market size. This decision was made in advance of the 2010 deadline, since a business case could not be made to justify the costs involved in completing the registration process.

Some SOCMA members have had chemical products with a deadline in 2010 or 2013. ECHA noted that 25% of Phase 2 registrants (5/31/2013) were anticipated to be SMEs, many of which will not have been through the process before.[2] But the majority of our members products exported to the EU will fall in the 2018 deadline when the quantity threshold falls to 1 metric ton (MT) per year. This smaller quantity threshold makes it much more difficult to amortize compliance costs at a rate that will make sense, even though the data requirements are lower. It is highly unlikely that our member companies will be able to follow through with registration dossiers on all of the substances that they initially pre-registered.

While ECHA has tried to scale registration fees for SMEs, this is by no means the largest expenditure with respect to REACh and there are no plans to address testing costs, which are the largest

[2] http://www.icis.com/Articles/2013/04/12/9658741/insight-data-quality-still-an-issue-in-reach-registrations.html

expenditure followed by retaining and OR, and MSDS translating and reformatting. Some members were spending $100,000 before registration even commenced. SOCMA member companies anticipated spending between $200,000 to $250,000 to register chemicals in 2010. One company estimated that assuming no data is available they would spend $120,000 for testing, dossier preparation and fees for chemicals in the 1-10 tons per annum range and approximately $430,000 for testing, safety report, dossier preparation and fees in the 10-100 tons per annum range. Another estimated in total this would be $2 million over a five year period. In addition, on-going costs can also be an issue. Even after a registration is completed, there is an on-going requirement to remain involved with SIEF activities, as well as to have auditable records available in the EU.

Additionally, Substance Information Exchange Forums (SIEFs), which companies are legally obligated to join if registering the same substance, are not addressing cost issues and reduced replication. Looking ahead to the 2018 deadline many substances will be registered by only one company and splitting costs will not be an option.

Registration costs also impact the innovative materials that companies would like to market in the EU. One member company developed a new family of chemicals from renewable raw materials, but based on registration costs in Europe, which were prohibitive for a medium sized company, was forced to limit sales to the US, Asia, and South America. The irony is REACh is supposed to spur replacement of certain chemicals with safer alternatives. It is likely that a risk based approach, which in this instance would have greatly reduced the costs of registration, which need to be fully funded pre-marketing, would have allowed our member to market this family of materials in the EU.

Ability to communicate with ECHA

For those that have submitted dossiers, one of the most common complaints heard is the inability to communicate with ECHA. Their guidance has been unclear at times and trying to discuss your dossier with an ECHA regulator is difficult to impossible.

While ECHA has held Stakeholders Days in Helsinki, this is often not feasible for U.S. SMEs. The time and cost to travel is often too great, knowing that the chance of actually being able to talk to someone at ECHA about their case is small. There are REACh help desks in Member States, but often the response time was too slow or inadequate. Additionally responses come back from a general mailbox and not an employee of ECHA which makes it extremely difficult to follow up if additional questions need to be asked.

From ECHA's own statements and statistics it is clear the agency needs to do a better job communicating. They have continued to say the quality of dossiers submitted is an issue. According to ECHA for Phase 1 in 2010 of the 5,500 intermediate substances, about 2,388 dossiers were not fully compliant.[3] "According to the agency's 2012 progress report on evaluation under the REACh legislation, ECHA was able to close the books on just 33% of the 354 compliance checks that it carried out during 2012." This leaves companies in a place of uncertainty.

[3] http://www.icis.com/Articles/2013/04/12/9658741/insight-data-quality-still-an-issue-in-reach-registrations.html

ECHA and the member states have provided little oversight with respect to SIEFs. Members have found that they are forced into SIEFs inappropriately because the chemical is not truly the same because of impurities. This has implications for hazard classification and incorrect categorization. As of December 1, 2010 all companies offering "the same product into the EU" had to agree on classification and labeling in compliance with the CLP directive. Some of our member companies have had a difficult time communicating with the agency on this process as well as to appeal erroneous categorizations, some of which can have worldwide implications.

Even when a company's products are included on the Substance of Very High Concern (SVHC) list, communication is difficult. One SOCMA member's chemicals were added to the list by the Dutch government. The addition was based on old and erroneous data. Rather than allowing a dialogue between the consortium and ECHA to appeal this addition, the consortium was forced to file a law suit against the agency. The listing will no doubt have a negative effect on sales of the product to Europe and U.S. customers shipping polymers to Europe manufactured from the monomers.

Moving toward the 2018 deadline, there is also a concern that there will be an influx of dossiers with first time SME registrants seeking guidance who would benefit greatly from the ability to dialogue with the agency.

Transparency

There is currently minimal transparency with respect to communication between competent authorities and companies and in decision making by ECHA. The agency has also been uncooperative when asking for additional information on statistics the agency puts forward, such as enforcement information, and asking for guidance on how Member States enforcement actions. All of this information would be useful to aid with compliance as only 1/3 of the dossiers evaluated in 2012 were deemed "not of poor quality" and satisfactory to the agency.[4]

ECHA has a lengthy and complex procedure for evaluating dossiers. It took ECHA two years after the 2010 registration deadline to issue its first Statements of Non-Compliance (SONCs). SONCs are related to dossiers of insufficient quality; details provided by the agency on enforcement actions have been limited.[5]

Several of our members have chemicals that are on the Community Rolling Action Plan list (CoRAP). One of our small company members was very surprised to learn that the preliminary report on a product that they produce, and have pre-registered for REACh would not be made available to them because they had not completed a registration dossier. They will only be able to review the details when the final decision is reached and publically released. In this, and likely soon to be many similar instances, ECHA will be taking an action on substances which will have worldwide implications, without any input from U.S. Companies. This is especially egregious in this instance since our member is the only producer of this particular chemical in the Western World.

We strongly support science based decision making. However, in these instances the decision-

[4] http://chemicalwatch.com/14672/the-enforcement-of-reach-registration-dossier-quality?q=echa%20staff
[5] http://chemicalwatch.com/14672/the-enforcement-of-reach-registration-dossier-quality?q=echa%20staff

making process for adding chemicals to the SVHC listings, and the CoRAP list need to be made more clear and transparent, since the mere addition of a material to one of these lists has worldwide implications.

Recommendations

Create Small Business Ombudsman

It would be helpful going forward to create a small business ombudsman within ECHA, and all other EU regulatory bodies impacting the chemical industry, to evaluate the potential impact of such legislation on SMEs. Such ombudsman should also assist SME's in compliance activities and be reachable during US business hours (or at the very least morning hours), to help US small chemical companies as they work to comply. (Note – Helsinki is 7 time zones different than DC – so 9:00 AM in DC is 4:00 PM in Helsinki – their quitting time.) While this would not remove the need for an "OR", it would reduce the costs of compliance because US companies could do more of the work themselves without having to do everything through their "OR".

Increase ECHA staff availability

SMEs would find it useful to have the opportunity to get additional support and advice from ECHA. During the Authorization process ECHA offers potential applications pre-submission information sessions (PSISs).[6] This type of dialogue would be useful to SMEs in all phases of the registration process to ask case-specific questions and if necessary further clarifying questions. Potentially, these types of interactions would also aid ECHA in bolstering compliance rates.

Increase Transparency

Going forward, transparency in nominating chemicals to the various lists along with transparency in enforcement across Member States would be useful. Future regulations should be promulgated in a transparent manner and allow for input from US and EU stakeholders. If done properly, harmonization on emerging technologies on standards and regulation by the US and EU could hopefully be pushed into third country markets making it easier for SMEs and all companies to have a global standard, decreasing the barriers to trade. In addition, "pre-decisional" papers in all of the EU's environmental programs should be made available to all US companies with an interest in the material under review. This is vitally important since many such decisions, taken in the EU, have worldwide implications.

Follow Up on Regulatory Review

The European Commission (EC) published a review of REACh May 2, 2013.[7] In that document the EC published a list of eight recommendations "with the aim to reduce the administrative burden of REACh by SMEs while maintaining their ability to fulfill all REACh obligations." In summary, these recommendations were:

1. For ECHA to provide more specific guidance on transparency and cost sharing in SIEF formation and operation
2. To review the Fee Regulation
3. For ECHA and industry to develop more user-focused with special attention to SMEs
4. For ECHA and industry to collaborate on intellectual property protection in the context of

[6] http://chemicalwatch.com/15413/authorisation-begins-echa-readies-itself?q=echa%20staff
[7] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52013DC0049:EN:NOT

mandatory exchange of information in the value chain.

5. For ECHA to develop better guidance, specifically for SMEs and less experience companies, in the use of the Use Descriptor System
6. For ECHA and REACh Helpdesks to develop guidance in integrating REACh processes early into the R&D and innovation process.
7. For the Commission to use the Enterprise Europe Network and national REACh Helpdesks to increase awareness and communication along the supply chain.
8. For the Commission to continue to monitor administrative costs of implementation of REACh by SMEs and the technical and legal support for SMEs provided by implementing institutions.

We would like to know how ECHA responded to the EU Commission's requests and any plans to address these challenges in advance of the 2018 deadline.

We are not alone in our concerns about REACH. "34 World Trade Organization (WTO) members, including developing countries, have raised 27 specific trade concerns about REACh, mostly pertaining to its registration/data gathering and notification obligations."[8] While REACh is a regulatory reality, there are ways to make the regulation and future regulations more workable for SMEs.

[8] http://chemicalwatch.com/13297/is-reach-a-trade-barrier?q=reach%20and%20SME