

## **CEFIC-ACC JOINT PROPOSAL ENHANCING EU-US CHEMICAL REGULATORY COOPERATION**

The business of chemistry in the United States and the European Union are strong supporters of transatlantic cooperation and therefore welcome the joint statement between Commission President Juncker and President Trump on 25 July. This statement includes chemicals as one of the sectors for which both sides will work to reduce barriers and increase trade.

Enhanced regulatory cooperation has the potential to significantly address non-tariff barriers and increase reciprocal trade in chemicals, while maintaining high levels of protection for human health and the environment. An effective regulatory cooperation will improve standards, open markets and increase investment and jobs.

Industries on both sides of the Atlantic recognise the fundamental differences in both regulatory approaches to chemicals, and uphold REACH and TSCA as well as their respective implementation. These differences will not allow for mutual recognition. Within these parameters, and while maintaining the highest standards of chemicals safety and the right to regulate of each side, there are areas of common interest worth pursuing through EU-US regulatory cooperation. Cooperation efforts on these areas are already ongoing either bilaterally or at international level. Their inclusion in the regulatory talks will accelerate this process. Moreover, harmonized approaches to regulatory cooperation between the US and the EU could serve as a global blueprint.

This document therefore suggests three priority areas for Cefic and ACC for which work is already underway and that would be enhanced through EU-US regulatory cooperation. Finally, ACC and Cefic support a cooperation on a voluntary, transparent and accountable basis.

### **Promoting alignment in classification and labelling of chemicals**

This is an area with great potential for co-operation given that an international standard already exists, which is the UN GHS, Globally Harmonised System of Classification and Labelling of Chemicals. GHS follows a “building block” approach to facilitate implementation. The different take up of building blocks and the variation in interpretation has led to differences between EU and US classifications. EU and US authorities could commit to work towards convergence when implementing the GHS, by seeking alignment on the use of the same building blocks. This would be in line with a UN GHS initiative to develop a global list of agreed GHS classifications. While respecting each other procedures, an enhanced EU-US co-operation on classification of chemicals could serve as a model for other countries adopting GHS requirements and become a good basis for a global list. This would help facilitate trade and provide a level playing field for business on both sides of the Atlantic. Companies would also benefit from harmonised safety data sheets and labelling of chemical products. This is particularly relevant for SMEs.

## **Co-operation in prioritising chemicals for assessment and assessment methodologies**

EPA and ECHA already cooperate in the area of methods for assessment and evaluation of chemicals. This cooperation can be intensified, in particular in the development and integration of new scientific developments. The already existing Statement of Intent signed between ECHA and EPA could be a good basis for developing further co-operation activities.

The OECD programme for assessment of chemicals could be used as a model. This programme evaluates the hazardous properties and hazard characterization of high volume production of chemicals and generates OECD-agreed assessments. Similarly, evaluations by EPA or EU Member States could be shared and considered as a common basis. This would avoid redundant work and limit the time for authority examination and approval. The risk evaluation should remain separate as the models of exposure in the two regulatory systems differ. While benefits will mainly accrue to the authorities (reduction of the administrative burden), industry - including downstream customers - would also benefit by having quicker access to market for innovative products.

## **Information sharing and protection of IP rights & confidential business information (CBI)**

US and EU authorities exchange data and information on chemical substances, such as summaries of test or study results, on a regular basis. This information is sometimes made public. A proper mechanism for data and information sharing that includes adequate safeguards to ensure the protection of commercial and proprietary interests is crucial for industry.

ECHA and EPA have already started a dialogue on data sharing. Agreeing on a common format like IUCLID (The International Uniform Chemical Information Database) as the basis for exchange on safety studies would significantly facilitate data sharing. IUCLID is a database co-developed by ECHA and the OECD to record, store, maintain and exchange data on chemical substances. It provides harmonised templates for results of studies and allows full exchangeability of datasets. Finally, this initiative would be in line with calls from several animal welfare organisations to increase data exchange between regulators to avoid duplication of tests involving animals.