

Brussels, 10 November 2015

Geert Dancet
Executive Director
European Chemicals Agency (ECHA)
P.O. Box 400
00121 Helsinki
Finland

Re: AmCham EU concerns regarding the September ECJ ruling on the definition of an article within REACH

Dear Mr Dancet,

The 164 member companies of the American Chamber of Commerce to the European Union (AmCham EU) have systematically sought to comply with the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. This is a priority for us and requires sustained human and financial resources.

Our members base their tools, processes and certification systems on legal certainty and existing guidance from the European Commission to ensure compliance with all aspects of REACH. They have put in place systems to get information on substances of very high concern (SVHC) in products as supplied, at the level of 0.1% of that finished product, or ‘article’, even in the case of complex and of imported products such as automobiles, gas turbines and medical devices. This approach was confirmed by the European Commission’s own Legal Service opinion in 2007.

This interpretation of the definition of an article was not accepted by a number of Member States and, after it had been challenged in the European Court of Justice (ECJ), the Court in September provided clarification on the current definition in the REACH regulation¹.

The result of the ruling is that every single component in a product which can be defined as an article according to the REACH definition will now have to be assessed. This poses an enormous challenge to many manufacturers, whether they make complex articles that contain tens of thousands or hundreds of thousands parts, or many different articles containing fewer parts, such as personal care products and toys.

This significant change will impact the way in which importers/manufacturers and regulators work together to ensure compliance with REACH. **Not only will businesses need to radically refocus their compliance programmes and processes expending considerable financial and human resources to do this, but they also need to have updated guidance from ECHA to ensure that there is a consistent approach from regulators across the EU on how the revised interpretation of an article should be applied.** Business wants, and needs, to be able to comply with REACH in an efficient and effective manner.

¹ [Case C-106/14](#) Substances of very high concern present in articles — Duties to notify and provide information — Calculation of threshold of 0.1% weight by weight), 10 September.

To achieve this aim, we urge the European Commission and ECHA to:

- **Set out its planned next steps** for coordinating with Member States and interested parties to update compliance guidance;
- **Thoroughly evaluate the practical implications and costs** of assessing and reporting to customers and compliance authorities at a ‘component-article level’ instead of on a ‘product-level’;
- **Ensure industry involvement:** Stakeholders that will have to implement this change must be engaged from the beginning and included in the whole consultation process for updating the compliance guidance;
- **Define an appropriate timeline** to adapt the industry’s processes to the recent ruling;
- **Clarify key definitions** as part of the guidance update exercise, including the definition of a ‘component-article’ and of industrial or professional users or distributors. AmCham EU members will continue to work on this internally to provide input during the guidance update exercise; and
- **Consider the development of scenarios** for reasonable exceptions to the component-article level restriction, such as the case for inaccessible components.

New compliance guidance will necessarily affect international trade and supply chains - which often weave in and out of Europe during the production of a product. Deciding how and when to put a new and proportionate compliance regime into place is critical to making sure that new compliance rules allow authorities and business to focus their efforts on efficient and effective compliance.

AmCham EU members look forward to cooperating with ECHA and the Commission and to providing input on the concerns listed above.

In the meantime, please do not hesitate to contact Stéphanie Brochard (Tel: +32 2 289 10 15; email: stephanie.brochard@amchameu.eu) from the AmCham EU Secretariat if you have any questions.

Yours sincerely,



Meglana Mihova
Chair of the Environment Committee of the American Chamber of Commerce to the European Union