

Brussels, 13th April 2017

COMMENTS ON DRAFT ECHA GUIDANCE ON REQUIREMENTS FOR SUBSTANCES IN ARTICLES (version 4.0)

Orgalime thanks the European Chemicals Agency (ECHA) for its efforts in ensuring an inclusive and transparent process of updating the current Guidance on Requirements for Substances in Articles following recent jurisprudence of the European Court of Justice (ECJ). As a member of ECHA's Partner Experts Group (PEG), Orgalime in its role as the umbrella organisation of European engineering industries has thoroughly commented on the previous draft updated ECHA guidance documents. Our previous comments are available [here](#).

In the context of the finalisation of the guidance document and the ongoing consultation of CARACAL, we wish to reiterate the following key points in the interest of a workable and proportionate implementation of article 33 REACH:

- The interpretation of article 33 REACH by the European Court of Justice and the need to provide information at the component and sub-component level must not create a system that would be disproportionate to the explicitly stated objective of article 33 REACH, namely to ensure the safe use of articles. Otherwise, this would lead to imposing a substantial burden on European manufacturers and importers of very complex articles, as well as on market surveillance and enforcement authorities that would outweigh any benefit. This is particularly true for our industry, which produces highly complex articles consisting of thousands of components, often in small batch sizes, and which works with very long and multi-tiered, global supply chains.
- We understand that ECHA's intention is to provide general and overall guidance within the limits of the ECJ ruling and that it cannot address specific, detailed issues. As a result, the draft guidance provides scenarios and indications that can indeed be applied to "simple" articles. However, when it comes to very complex articles, the current draft remains somewhat insufficient and inappropriate in comparison to the proportionate, pragmatic and workable solutions that will have to be applied to daily operations. We have taken note of ECHA's intention to initiate a dialogue between industry and authorities to address these issues and we look forward to participating in these discussions.
- Any information collected along the supply chain and transferred to the final recipient must be effective in helping to identify risks and ensure the safe use of the article. Communicating details on SVHC potentially contained in parts sealed inside very complex articles and with no risk of exposure are in our view not necessary for this purpose, while they create confusion

Orgalime, the European Engineering Industries Association, speaks for 41 trade federations representing the mechanical, electrical, electronic, metalworking & metal articles industries of 24 European countries. The industry employs some 10.9 million people in the EU and in 2015 accounted for more than €1,900 billion of annual output. The industry accounts for over a quarter of manufacturing output and a third of the manufactured exports of the European Union.

and potentially even hinder the identification of relevant information. This is also an issue that industry and authorities will need to further discuss.

- Chapter 5 on ‘Obtaining information on substances in articles’ still includes numerous paragraphs that suggest obligations which do not stem from either the legal text of the REACH Regulation or the new interpretation of article 33 based on the ECJ ruling. While we fully recognise the principle of due diligence, we stress that REACH is not a CE marking regulation under the New Legislative Framework and as such, no documenting obligations should be put forward by the guidance. Suggesting additional voluntary obligations is misleading and can cause unnecessary burden on companies, especially SMEs. Given the wide diversity of different articles and industrial sectors affected by article 33 REACH, companies should be given the necessary flexibility to organise information gathering and verification as best suits their case rather than being forced to follow one particular approach over another. This is particularly true for as diverse a sector as the electrical and electronic industry, where many different tools for communicating in the supply chain exist and need to exist, including for competition reasons. Therefore, we call for rewording this chapter to stick to the legal text of the REACH legislation.
- To avoid unnecessary actions and investment, companies require an official ECHA guidance document. Once the official ECHA guidance is finally adopted and released, companies will have to study the implications, adapt their internal systems and accordingly inform all of their suppliers, review all information already available and reassess their current declarations according to the previous interpretation of article 33. The time needed for each of these actions will vary depending on the number of products/components, their complexity, the awareness of the particular supply chain, among many other factors. Enforcement authorities should support industry in this transitional phase and in their effort towards meeting their legal obligations.