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JBCE contribution of Inception Impact Assessment / Revision of CLP

Japan Business Council in Europe (JBCE) welcomes the feedback opportunity regarding Inception Impact Assessment/Revision of CLP. JBCE supports the EU's aims at ensuring both a well-functioning single market for chemicals and a high level of protection of human health and of the environment. As a cross-sector association with member companies operating in different industries and stages in the supply chain, JBCE is eager to contribute to the legislative process of revision of CLP.

New hazard classes

EU Commission suggested that several new hazard classifications should be included in CLP Regulation, such as Endocrine Disruptor, PBT/vPvB, PMT/vPvM, immunotoxicity and neuro-toxicity. With recognizing that the CLP Regulation is a regulation in the EU and the EU has a full autonomy of its legislation, JBCE is concerned that these new inclusions would deviate from the internationally coordinated classification system, i.e., the Globally Harmonized Standard (GHS). It must be noted that chemical supply chains do not remain only in the EU but actually are connected globally. The potential significant difference between the EU legal scheme and the rest of the world would hinder smooth material supplies in and out of the EU. We would like to remind the European Commission that the EU and Japan have the EPA to promote trades of goods between the two regions, and are concerned that the different classification system would hinder the implementation of the EPA.

In particular, we are of the opinion that persistence and 'mobility' as well as 'bio-accumulation' are not classified as 'hazard' classes, and but concepts which allow further and detailed risk assessment of certain chemicals. Inclusion of the 'PMT/vPvM' as well as PBT/vPvB in CLP Regulation would make deviation from the international framework. In our view, 'mobility' should be considered as a part of exposure assessment when risk management of certain chemicals is (to be) considered. Likewise, persistence and bioaccumulation as well are considered as pathways of exposure of a chemical compound to human body and the environment, but are not hazard of the substance per se.

Given the above assessment, including 'mobility' as part of the SVHC listing criteria, and justification for REACH restriction seems nonetheless disputable and premature. In particular, the German UBA is concerned with certain substances existing in the drinking water source ('mobile substances') and suggests using solely LogKoc as proxy for mobility. JBCE, however, recognizes that there are different opinions on the concept, scientific justifications, screening methods and parameters among

the Member States and stakeholders, and it seems that German UBA's simplistic application of LogKoc is inappropriate and could make over-classification. JBCE hopes to see that responsible EU authorities assess classification criteria proposals, including classification methodologies, and validate them together with dedicated contributors from industry (such as CEFIC), civil society and academia based on sound science, so that a reasonable, balanced and agreeable approach can be found.

Last but not the least, we would like to highlight that immunotoxicity and neuro-toxicity are currently not defined as hazard class under REACH or CLP Regulations. Therefore, these potential new classes should carefully be considered and clear criteria for the classification should be established through thorough scientific discussions at the international level.

ABOUT JBCE

Founded in 1999, the Japan Business Council in Europe (JBCE) is a leading European organization representing the interests of about 90 multinational companies of Japanese parentage active in Europe. Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, textiles and glass products.

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