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## **JBCE contribution of Inception Impact Assessment / Revision of REACH**

Japan Business Council in Europe (JBCE) welcomes the feedback opportunity regarding Inception Impact Assessment/Revision of REACH. JBCE supports the objectives of the Chemicals Strategy for Sustainability are to better protect citizens and the environment against hazardous chemicals and encourage innovation for the development of safe and sustainable alternatives. 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 REACH.

### **Grouping Approach**

EU Commission suggested extending the generic risk approach to restrictions. In JBCE's view, risk assessment is a core principle of chemicals management that needs to be retained.

Under the REACH Regulation, hazard and risk assessment are to be made based on the scientific information obtained by the registrations, in order to determine sound and reasonable management of the chemical compounds, with consideration of socio-economic impacts. At the same time, we recognize the European Commission's needs to speed up the process of chemical management to achieve the EU Green Deal targets. With noting such needs, we would like to ask the Commission to ensure the transparent and science-based methodologies of grouping of chemical compounds; should it be done by use or sector, by hazard classification, or by chemical structure?

The proposed grouping approach, as is already under discussion for PFAS, to skip all of these steps and simply jump to a conclusion on the basis of mere assumption – all PFAS are persistent and toxic, in case of PFAS - , without considering the information gathered in the registrations and differences of chemicals and each use of such compounds. You could make a big chemical family, but it does not necessarily mean that all chemicals categorized in the family are hazardous in the same manner.

JBCE therefore would like to strongly encourage the relevant EU stakeholders to consider whether there is really a need to completely abandon REACH's science and fact-based approach, replacing it with broad, rapid and sweeping actions based on suppositions and which group dissimilar substances together, in contradiction to the facts collected in the REACH registration process.

### **Essential Use**

The concept of essential uses for substances is being discussed beyond the special case of PFAS and in conjunction with other concepts in the Chemical Strategy for Sustainability. When implemented alongside so-called "generic risk assessments", which are essentially simplistic hazard-based bans in which the real risks of individual uses are not considered at all, the "essential use" concept would mean that individual risk assessments would only be acceptable for uses that were already known and already considered to be essential. This would have an extreme chilling effect on innovation in the EU.

JBCE believes that the essential use discussion should take place only after the risk of a substance (or a category of substances) is identified based on the sound science as defined under REACH Regulation. It is not appropriate on the basis of mere hazards before a serious risk has been identified. Furthermore, in line with the EU's Better Regulation guidelines, open and transparent consultation, involving all stakeholders, a comprehensive impact assessment of introducing an essential use concept into any regulatory framework is needed.

### **“One Assessment for One Substance”**

Industry is struggling to cope with different regulations which are relevant to chemicals. An obvious example is the overlap between RoHS Directive and REACH Regulation. It is understood that the objectives of each legislation are different, therefore in principle two different rules are required. With that in mind, it is often complex for the industry – especially SMEs – to understand different requirements under these rules. Daikin is of the opinion that it would be very helpful if there was a database where one could see all the requirements for a substance – for example, REACH, WEEE, biocides, etc. – because then the industry would have a better understanding and predictability of what needs to be done.

That being said, it should be noted that one substance could be used in many different ways and risk assessment of the substance must be conducted based on all of the possible scenarios. The comprehensive data collected under REACH and the clear criteria under CLP now provide a firm basis for the assessment of substance hazards, so the assessment and identification of hazards, especially substances of very high concern, should be done under these legislations. In order to maintain coherence and to ensure predictability as EU law, the consistency between chemical and chemical-related legislations at the EU-level is essential. When mere suspicions of hazards exist, the risk cannot be precisely assessed, and as a result proper socio-economic impact analysis is not possible. Such uncertainty would hamper assessment more and more at the later stages of the study. In particular, the need for any restriction and/or thresholds should be decided after assessing both possible risk to human health and environment and risk to be reduced by the legislative proposal. To effectively reduce real overall risks, it is important to focus on the main sources of risks, and not simply to tighten requirements on minor risk components. Doing otherwise merely adds cost without significant risk reduction. If regulators already set a default scenario and allow a substance to be used only in the said scenario, it would strictly limit (or even ‘hinder’) innovation for that substance in the future

### **Registration of polymers**

JBCE would like to remind the European Commission that monomers consisting of polymers have to be registered under the current regime. Undertakings in and outside the EU have to gather information and register monomers consisting of polymers by various tests required under REACH Regulation already. If polymers have to be registered, even if not all, we would be interested to know how these existing datasets will be utilised for reduction of risks coming from polymers. At the same time, we would like to express our view as follows:

- only minimum information on polymers should be requested to fill the gap of information which cannot be obtained through the information existing in the monomer registration dossiers;
- if only certain polymers have to be registered, the selection criteria of such targets and reasons should clearly be communicated with industry;
- substance evaluations can be considered as a method to request for certain information on certain polymers to consider risks coming from polymers, instead of default registration requirements for all polymers.

On top of it, we would like to encourage the Commission to consider additional burdens on SMEs and to propose proportionate and balanced approach to polymer registration.

## **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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