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JBCE's views on the updated rules on classification, labelling and packaging

Being a cross-sector association with member companies operating in different industries and stages in the supply chain, JBCE welcomes the opportunity to submit its views on the updated rules on classification, labelling and packaging (CLP) of the Draft delegated regulation.

1. Introduction

Chemical substances enrich human life by being properly used with clear understandings. JBCE strongly supports the concepts and objectives of REACH and CLP to contribute to human health and the environment. JBCE also believes that a risk management approach should be used when regulating chemical substances. This is fundamentally important to the handling of chemical substances in international supply chains in terms of feasibility and practicality. As for the feedback call on the updated rules of CLP, JBCE would like to share its views and insights as follows.

2. Details

(i) Consistency between CLP and UN GHS

Our concern arises from the expected consequences of the resultant lack of consistency between the EU legal framework and the Globally Harmonized System of Classification and Labelling (hereinafter GHS). This international system is the main tool to ensure that information on physical hazards and toxicity from chemicals are available in order to enhance the protection of human health and the environment during the handling, transport, and use of these chemicals. The GHS also provides a basis for the harmonisation of rules and regulations on chemicals at national, regional, and global levels, an important factor also for trade facilitation.

These updated rules on CLP introduce new hazard classes (ED, PMT, vPvM, PBT and vPvB), and JBCE is concerned that the introduction of new hazard classes would deviate from the internationally coordinated classification system, i.e. the GHS. It must be noted that chemical supply chains are not limited to the EU but 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.

As noted above, chemical substances and products are not only manufactured, placed on the market and used in Europe, but are also exported and used in countries and regions around the world. Many countries and regions have implemented GHS and aligned their domestic legislations with GHS. We are concerned that the European Union now intends to add new hazard classifications in CLP without alignment with the GHS. This would damage the spirit of GHS as pictograms will be used without the agreement of the GHS. Furthermore, even though new hazard classifications would be introduced in advance, the EU would need to potentially revise them to implement the revisions of GHS in the near future. As a consequence, major legislations changes will occur at least twice, and industrial stakeholders will have to implement both changes involving huge resources.

In order to avoid confusion in the global supply chain, we would strongly suggest that these issues be fully discussed in a transparent manner from an international perspective.

(ii) Transition Period

Setting up a criterion in the new CLP hazard classes takes time because it should involve scientific discussion involving experts from all stakeholders. The criteria must be clearly defined and guidance on how to assess chemical substances based on these additional criteria should be made available before the adoption and enforcement of the legislation. If a new hazard class is introduced, stakeholders will need to reclassify all substances and adopt and apply new labels. Hence, enough time should be given to the global supply chain to make sure alignment is achieved and to prevent confusion at international level.

Labels and SDS for chemical products must comply with all relevant domestic regulations of the destination (i.e. country/region). As both imports into the EU and exports from the EU to other regions are relevant, the cost and efforts required for preparation of product labels, packaging and SDSs that comply with the destination's legislations will be tremendous. Even though there are domestic languages and compulsory classification due to the regional regulations, industrial stakeholders would like to minimize cases where the label design, packaging materials, and SDSs for products would have to be changed around the world. This is related to the reduction of waste for sustainability purposes. Although there are many cases where SDSs can be provided through websites, the packaging materials and labels of the products must be aligned and compliant with national and/or regional legislations. A huge amount of work such as new label design, paste-ups creation, printing, packaging materials, repacking in warehouse and label replacement will be required. Industrial stakeholders have implemented detailed and complex inventory management procedures in order to minimize the use of materials. If the EU takes the lead and implements changes without prior alignment with GHS, a significant amount of materials would be used and additional unnecessary waste will also be generated. This is obviously not aligned with the overall objective of the development of a more sustainable society.

Based on the above, and as already stated, we would strongly suggest that the European Commission issue clear guidance documents addressing these critical issues prior to the adoption of the legal text.

(iii) Hazard Classes

The objective of the introduction of new hazard classes is to maintain a science-based approach and emphasize the need to evaluate the various properties of chemicals and compounds based on reliable data. In addition, we support the consistency with global systems such as GHS, as already mentioned. For EDs, we support the definition of the WHO. They are already fully established in the European Union. In addition, and although there are some minor differences, we would like to remind that PBTs Global Standards are POPs Convention Screening Standards. As for the proposed mobility criteria, it is necessary to consider the risk management of specific chemicals as part of the exposure evaluation.

Additionally, P (Persistent) and vP (very persistent) themselves are not hazards. Regulatory countermeasures are necessary only when persistency is associated with toxicity.

The mobile criterion (M) and the very mobile criterion (vM) have not been defined, and there needs to be consensus among experts in the field before adopting these criteria for regulatory purposes. The report of REACH "Improvement of guidance and methods for the identification and assessment of PMT/vPvM substances" which was made by German Environment Agency in our view still raises many challenges that should be further discussed. Concerning the inclusion of B (bioaccumulative)

and vB (very bioaccumulative), we believe a consensus based on the scientific evidences available globally should be obtained. If EU-CLP introduces B and vB as new hazard categories, the scientific criteria of BCF(the bioconcentration factor in fish) should also be discussed with experts of GHS for consistency.

(iv) Impact of CLP changes on other manufacturing sectors

We are concerned that the introduction of new CLP hazard classes will affect various downstream sectors. Discussions are currently underway on the GRA (generic hazard-based approach to chemical management) of the REACH revision and the substances of concern in the draft Ecodesign Regulations. This expansion of the CLP will affect these discussions. It is therefore a concern not only for the chemical sector but also for the downstream sectors.

If not properly implemented, this could lead to the restriction of market-relevant products that do not pose a risk for human health or the environment, without previous risk characterisation or socio-economic assessment. We believe that the determination of risk should be a pre-requisite for assessing the proportionality of any regulatory action and for cost/risk benefit analysis.

Another conern relates to the impact on products already placed on the market. If the new classifications were introduced in EU CLP at this time, all existing chemical products would need to be reclassifed according to the newly identified criteria. Furthermore, it could be assumed that these toxicity end-points might be recognized as new SVHC and/or subjects to authorization in the future. The impact on mixtures should also be taken into consideration, according to the OECD guideline, the testing and evaluation of P (persistency = degradation) and B (accumulation) are usually conducted on individual chemical substances. Mixtures are sometimes tested, but each chemical substance must be evaluated individually associated with data regarding the structure and content of each chemical substances. For example, chemical substances having branched and complicated alkyl chains might be assessed by the evaluation of more simple chemical substance having straight alkyl chain. The remaining compositions might be assumed by analogy. In this case, it would be less reliable than the evaluation of a single chemical substance. Chemical products are hardly used as a single chemical substance, and are provided as a mixture or incorporated into articles. If the classification and regulation based on the evaluation of individual substances takes precedence, there is a risk that deviation from the actual situations of using and specifications of the product would increase.

3. Conclusion

JBCE supports the risk management approach based on chemical substances and mixtures. Although the use of higher-hazard substances and mixtures should be restricted, a sufficient scientific evaluation and transition period should be considered. In addition, in order to avoid confusion in the global supply chain, these evaluations should be made with consideration of practicality and feasibility from an international perspective, and we would expect clear guidance documents to be presented to avoid wrong and inadequate interpretations of the newly introduced proposed criteria. When chemical products are used correctly, EU citizens are safe and do also benefit from their uses.

About JBCE

Created in 1999, the Japan Business Council in Europe (JBCE) is a leading European organisation representing the interests of more than 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, steel, textiles and glass products.

Building a new era of cooperation between the European Union (EU) and Japan is the core of our activities, which we perform under several committees focusing on: Corporate Policy, Corporate Social Responsibility, Digital Innovation, Environment & Energy, Standards and Conformity, and Trade.

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