JBCE inputs on the public consultation on REACH Revision for the additional comments

JBCE supports the REACH regulation to protect human health and the environment and would like to contribute to its revision. Please find attached our additional input on this public consultation.

Increased information on critical hazard (CMR)

We agree with the necessity to amend the REACH Regulation in such a way that would ensure a better safeguard and protection of the human health from hazardous substances. We support the need to achieve the goals of Europe's Beating Cancer Plan and the additional obligations for the registrants in terms of information requirements on carcinogenicity (Q. 1, points 1&5). However, some additional specifications need to be made.

we would like to underline the need to maintain a science-based approach and to evaluate the different natures of chemical compounds, based on reliable data. Additionally, before being able to provide an informed response to this question, it is needed to determine which substances will specifically follow within the excessively broad and undefined category of "more chemicals".

In regard to the possibility to achieve a complete transition to non-animal testing methods (Q.1, points 2,3 & 4) 'even to the detriment of international harmonisation', 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 the national, regional, and global levels, an important factor also for trade facilitation. JBCE is well aware of the need to limit animal testing as much as possible and is in favour of the initiatives that can foster this transition process. However, this shift should not happen to the detriment of international harmonization, which might generate burdens to trade, compromising not only the European but the entire global market in the field of chemicals.

Any changes to the REACH Regulation in terms of testing methods should be enforced gradually and carefully, and should also include a precise cost-benefit assessment to industry as a consequence of those variations (e.g., staff training, purchase of new types of machinery for testing). For instance, a Roadmap could be established under the Transition Pathway document expected to be published in Q2 2022, including supplementary incentives and opportunities to facilitate such transition.

Information on the lowest tonnage band

Introducing additional information requirements into REACH also for low tonnage substances (below 10 tonnes) might result in a considerable additional burden for the industry, especially for SMEs, who generally do not have the resources, in terms of workforce or testing facilities, to face such obligations. It is the Impact Assessment on the REACH revision itself that states '*for industry, it is anticipated that stricter registration requirements, in particular for substances at lower tonnages and for certain polymers, will increase the administrative burden and related compliance costs*[1]'.

In this regard, for example, it is worth recalling the cost estimate run by the European Commission in parallel with the work on the CSS and published in the Staff Working Document (SWD) "*Review of certain provisions of the REACH Regulation as laid down in its Article 138*".[2] In the document, the European Commission assessed that the costs for manufacturers and importers of drawing up the chemical safety reports for 1-10 tonnes CMRs was estimated at € 3,203,691, whereas that for downstream users was € 1,779,963, for a combined total of € 4,983,654. Although it was concluded that the measure is "*economically justified*", as well as "*affordable, both for larger and smaller companies*", the document specifies that "*it cannot be excluded that the costs carried by manufacturers or importers could be impacting competitiveness, especially if a substance is marketed only by one or few registrants. Thus, withdrawal of some substances from the market cannot be excluded*".

According to the above SWD, the European Commission assessed the necessity of expanding the obligation to develop a CSR to CMR substances in the lowest tonnage band. For the purpose of managing risks coming from CMR substances in more concrete way, it might make sense to introduce such obligations to these specific substances, which can also be in line with the obligation for phase-in CMR substances. However, the obligation to develop a CSR to other substances than CMR substances must carefully considered due to the above reasons.

Information requirements on polymers

We are very concerned about the recent changes to the concepts that were prepared for a CARACAL subgroup meeting scheduled for April 1. These changes would overburden both authorities and industry. For the following discussion, JBCE assumes a reversion to the more pragmatic concepts that had been discussed previously.

In question 7, it is unclear what 'certain chemicals' would be subject to polymers requiring registrations (PRR) status, which leaves too much room for interpretation. It is unclear what data would be required: the data requirements should be

[1] Inception Impact Assessment on Revision of EU legislation on registration, evaluation, authorisation and restriction of chemicals, European Commission 2021 (Ref. Ares(2021)2962933 - 04/05/2021)
[2] https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_article_138.pdf

appropriate to polymers, not a “copy-paste” of requirements for substances. The definition of reactive functional group is also unclear and ambiguous.

In this regard, it is worth mentioning that fluoropolymers have thermal, chemical, photochemical, hydrolytic, oxidative, and biological stability, as well as negligible residual monomer and oligomer content and low to no leachables. Also, they are practically insoluble in water and not subject to long-range transport. With a molecular weight well over 100 000 Da, fluoropolymers cannot cross the cell membrane

In question 7b, the questionnaire asks what kind of polymers should be registered under the new registration requirements. We would like to suggest that the EU refers to the currently available OECD’s criteria of ‘Polymers of Low Concern’[3], and that polymers meeting these criteria be kept exempted from the PRR obligations. In particular, regarding the specific bullet point naming particular types of polymers ‘*Fluoropolymers and perfluorinated polymers’*, it is not only disproportionate and unfair but also would open the door to the possibility that the European Commission can impose registration obligations on any polymers without scientific and neutral justification, even if these any other polymers are identified as polymers of low concern in the OECD definition. In this regard, it is worth mentioning ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals)’s Conceptual Framework for Polymer Risk Assessment (CF4Polymers) in 2019[4], supporting the PLC approach as a means to accomplish polymer risk assessment and support the findings of Henry et al[5]. They are ‘*unaware of scientific evidence to justify generally assigning fluoropolymers the same level of regulatory concern as other PFAS*.’

Secondly, not all the cationic polymers are harmful and carcinogenic. Cationic polymers like divertive of acrylamide for example, which is often used as a water adsorbing resin of diaper. Natural polymer Poly(L-Lysin) is used as a food preservative.

If any criteria are to be set to identify PRR, it should be done in a scientific manner, not in a way to ‘name and shame’ certain particular polymers. If some fluorinated polymers are not in the scope of OECD polymers of low concern or any scientific and neutral criteria set by the revised REACH Regulation, then these fluorinated polymers would have to be registered. Our position applies to any other types of polymers.

<u>Information on environmental footprint</u>

The CARACAL document on the environmental footprint in REACH (Doc. CA/18/2022) addresses this aspect. It already identifies several relevant legislation, such as the Eco-design for Sustainable Products Regulation (extending the scope of

[3] https://www.oecd.org/env/ehs/oecddefinitionofpolymer.htm

[4] TR 133-1 – THE ECETOC CONCEPTUAL FRAMEWORK FOR POLYMER RISK ASSESSMENT (CF4POLYMERS). ECETOC, 2019. (https://www.ecetoc.org/publication/tr-133-the-ecetoc-conceptual-framework-for-polymer-risk-assessment-cf4polymers/)

[5] A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers, Henry et al, 2018 (https://setac.onlinelibrary.wiley.com/doi/10.1002/ieam.4035)

the Eco-design Directive) and a proposal for a Corporate Sustainability Reporting Directive (CSRD). The ultimate goal of introducing this environmental footprint is, in our view, to make transparent the impact from production and sale of goods on and their environmental performance in relation to climate and water use etc.

The introduction of mandatory reporting requirements on the environmental footprint of substances/products as part of REACH registrations will unavoidably entail considerable complication across several regulations; not only the above-mentioned legislation but also, for example, the so-called Fit-for-55. Collecting information on the environmental footprint at the substance level would extremely be difficult, especially for intermediates and those substances which are further incorporated into articles and products. Therefore, information requirements on environmental footprint should not be required for intermediates.

As we stated in our position paper on the Carbon Boarder Adjustment System (CBAM)[6], it is imperative to conduct a thorough impact assessment with the industry in terms of feasibility in day-to-day business and cost-efficiency. Any extension of scope beyond the initial items (namely, iron & steel, aluminium, cement, fertiliser and electricity) of the Commission's proposal would entail much more complex calculation methods. In particular, the calculation methods for the chemicals and polymer, as proposed in the ENVI amendment, are hugely more complex than those for steel or cement as highlighted by the Commission's impact assessment report. In our view, it is currently premature to include goods with complex calculation methods such as chemicals and polymers or downstream products in the scope of the CBAM. As a consequence, we are of the opinion that the environmental footprint should not be included into REACH at this stage.

Although the preservation of the environment is rightfully one of the European priorities, the increment of the legal obligations should take place gradually, guaranteeing the necessary balance between the goal to achieve a climate-neutral and circular economy and the need to preserve the competitiveness of the European chemical industry on a global scale. Therefore, REACH is not 100% fit for the purpose of introduction and use of the environmental footprint, and reporting requirements should not be made obligatory under REACH until the appropriate tools and guidance (i.e., Safe- and Sustainable by Design) are implemented.

<u>Information on requirements on uses and exposures</u>

As regards information requirements on use and exposure, JBCE believes that the information requirements on use and exposure should not be exclusively the responsibility of manufacturers and importers of chemicals, but also actual downstream users. The downstream users' obligations are already stipulated in the current REACH legal text (TITLE V: DOWNSTREAM USERS). Therefore, more emphasis should be made on strengthening communication along the entire supply chain.

[6] Joint Industry Recommendation on the proposal of Carbon Border Adjustment Mechanism (CBAM)

Moreover, the obligation to provide information in regard to exposure should not apply to downstream users in cases in which substances are not intended for release.

Simplifying communication in the supply chain

In general, JBCE endorses the better communication of hazard and risk management measures in the supply chain through (extended) safety data sheets, although in the questionnaire there is no detailed explanation of the 'harmonised electronic tools'. It must be emphasised that such communication through such tool should be maintained and limited within the supply chain.

Changes to the provisions on the evaluation process

JBCE agrees with the need to establish a zero-tolerance policy aimed at ensuring the maximum level of compliance of the registrants with the obligations set in the REACH regulation. However, it should also be noted that the operators in the sector should be granted sufficient time for adjustment to ensure compliance with the upcoming new information requirements or any requests from the competent authorities upon compliance check, in order for registrants to re-organise the internal review planning of their dossiers (especially since those changes might entail increase and/or training of the personnel) and to bring missing information and data with a certain quality. Thus, JBCE supports for the authorities to request specific information provided that sufficient time is provided and the 'the right to be heard' is secured during the REACH compliance check process.

Essential uses concept

Please refer to the separate document uploaded together with JBCE's response.

Reform of authorisations and restrictions

In the Authorization process in REACH, the candidate list of substance is published and information is communicated in the process. This process contributes to the realization of risk management and systematic communication throughout the supply chain to prevent adverse effects on human health and the environment.

Substitution of hazardous substances in articles begins with the chemical manufacturer completing the necessary alternatives. However, in the final product, it is necessary not only to substitute for harmful substances, but also to carefully evaluate the performance, quality, reliability, safety and durability of the product. Since the evaluation requires huge cost and time, it is important to convey information in the supply chain. As a result, the current Authorization process helps to obtain early material risk information across the supply chain and contributes to the environment and human health.

We are convinced that the authorization process is a valid process for all stakeholders in this supply chain, so we recommend choosing Option 1. However,

simplification alone may not be sufficient. For example, fairness is required for all stakeholders, such as certainty of plans and competitiveness with non-EU manufacturers. This could be further improved. In addition, we recommend that the restriction process incorporate scientific requirements and clear, detailed procedures similar to the authorization process, as well as the authorization process.

Generic Risk Management Approach

The application of the Generic Risk Management Approach (GRA), as established under Article 68(2), currently applies only to CMR substances in consumer products and is planned to be extended to other hazard classes and professional uses. According to this simplified process, there is no need to run a use-related risk assessment before the restriction or prohibition of the use of substances.

First of all, regarding the said 'other hazard classes', JBCE would like to remind that not all the aspects mentioned in the questionnaire are currently identified as hazard classes.

- Endocrine disruptors (ED) with effects for human health – not a hazard class;
- ED with effects on the environment – not a hazard class;
- Persistent, bioaccumulative and toxic substances (PBT) – not a hazard class;
- Very persistent and very bioaccumulative substances (vPvB) – not a hazard class;
- Substances with specific target organ toxicity, single exposure (STOT SE), differentiated based on target organ;
- Substances with specific target organ toxicity, repeated exposure (STOT RE), differentiated based on target organ;
- Immunotoxic substances – not identified or defined under UN GHS;
- Neurotoxic substances – not identified or defined under UN GHS;
- Respiratory sensitisers.

Particularly, JBCE is aware that the European Commission is aiming at identifying ED and PBT/vPvB as hazard classes under CLP, and supports the position presented by Japan Chemicals Industry Association (JCIA) in the public consultation on the CLP revision.

Now, JBCE would like to emphasise that the GRA approach does not distinguish between hazard and risk. If not properly implemented, this could lead to the restriction of market-relevant products that may 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.

Next, JBCE does not support the extension of the GRA to professional uses. The tasks carried out by the professionals are not comparable to the use that consumers make of products. In addition, it should be noted that there is currently no definition of professional uses under the REACH Regulation. Specific criteria should be applied when developing such a concept, taking into consideration the level of

training of the workers as well as the existing containment measures put in place in the professional environment where they operate. Also, the scope of the GRA lacks justification because other protection measures could be further investigated under the EU-OSHA legislation.

Coherence with other legislation

Regarding the relation between the REACH regulation and other EU legislations, we strongly believe that double regulation should be avoided. We welcome that the assessments on substances are made by ECHA and shared across the EU legislations under the principle of “one substance one assessment”.

However, we strongly believe that the assessment of final products should be done based on sufficient knowledge about each product groups and it should not be done only from a chemical perspective. For the products which are regulated under New Legislative Framework (NLF) with CE marking, this existing framework functions well on the EU market. Thus, product specific legislations under NLF should be respected and the double regulation by the REACH regulation should be avoided.

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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