Japan Business Council in Europe

1st June 2022

JBCE additional inputs on the further survey on REACH Revision

JBCE is a unique association with a wide range of industrial sectors from upstream to downstream suppliers.

JBCE supports such initiatives for the REACH regulation and would like to contribute to its revision and further survey with additional input. Please note that JBCE responded to the official "Have Your Say" consultation on the REACH revision.

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 by the European Commission to be extended to other hazard classes and professional uses. According to this simplified process, there would be no need to run a use-related risk assessment before any regulations on the use of substances.

(1) Pre-conditions of GRA – New hazard classes

If the assessment made only by hazards approach at first, not by risk assessment, it may have negative impact on products which contribute to the entire social-economic. It means the restriction or ban of substance that are properly risk managed and contribute to the function and reliability of the product. Having a substitute for a substance or mixture does not mean that there is a substitute for an article.

JBCE would like to remind that not all the aspects mentioned in the questionnaire are currently identified as hazard classes. Particularly, JBCE is aware that the European Commission is aiming at identifying ED and PBT/vPvB as hazard classes under the CLP regulation, and supports the position presented by Japan Chemicals Industry Association (JCIA) in the public consultation on the CLP revision. For 'immunotoxic substances' and 'neurotoxic substances', there are not even criteria or classification methodologies; we wonder how industry and the Commission could assess potential impact on the inclusion of these categories into the GRA scheme, without knowing how to identify these substances in the first place.

(2) Hazard = Risk?

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 prior risk characterisation or subsequent socio-economic assessment. We believe that the determination of risk should be a pre-requisite for assessing the proportionality of any regulatory actions and for cost/risk benefit analyses.

Evidently, even low-hazardous chemical substances may cause serious concerns for the human body if these were used in a very large quantities and by, inappropriate ways of handling, and disposals. For example, nail polish removers (usually contain acetone) may cause faint and dizziness in case they are used in poorly ventilated areas. However, in reality, nail polishes are sold and used in a small amount and disposal of the leftover are communicated with consumers; we can say that risks are properly controlled. The impact on the human body and the environment can be minimised and properly controlled by appropriate ways of using and knowledge for the risk of chemicals. Even natural products are not always safe. Potatoes could cause food poisoning in case of inappropriate storage (exposed to the light). We believe that chemicals are to be managed and risks coming from chemicals should controlled by a good understanding of the scientific properties of the chemical substances.

(3) Extension of GRA to “professional uses”

As mentioned in our contribution to the previous consultation, 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.

In this further survey, questions with unclear definitions and information under such a premise are difficult to answer. In such a case, we would answer with “N/A”, “I do not know” or “no opinion”.

Reform of authorisations and restrictions

As mentioned in our contribution to the previous consultation, JBCE support keeping both Authorisation and Restriction with improvement of procedures in the REACH regime (option 1).

Step	Substances	Baseline (No changes to REACH)	Option 1	Option 2A	Option 2	Option 3
Candidate List		CMR, PBT, vPvB substances + ELoC for other substances	Add ED, PMT, vPvM to hazard classes where no ELoC is necessary; Add requirements for downstream users to provide information on use, exposure, alternatives and waste management Add fees linked to this notification obligation linked to the SVHC use			
Type of restriction applying by default (i.e., unless there is a derogation or authorisation)	SVHC on Annex XIV	Authorisation requirement/ Annex XIV	Authorisation requirement/ Annex XIV	Restriction/ Annex XIV bis[1]	Restriction/ Annex XVII (integration of ex-Annex XIV)	None
	Other substances	Restriction/ Annex XVII	Restriction/ Annex XVII	Restriction/ Annex XVII		Restriction/ Annex XVII
Derogation proposed by authorities	SVHC on Annex XIV	Art 58(2) Only for uses where risks are properly controlled by other legislation	Art 58(2) Only for uses where risks are properly controlled by other legislation	Part of restriction proposal	Part of restriction proposal	n/a
	Other substances	Part of restriction proposal	Part of restriction proposal	Part of restriction proposal		Part of restriction proposal
Derogation of general applicability[2] on industry request		None	None	Possible where foreseen in restriction	Possible where foreseen in restriction	none
Authorisation	SVHC on Annex XIV	For substances in Annex XIV	For substances in Annex XIV	Possible where foreseen in Annex XIV bis, no upstream applications	Possible where foreseen in Annex XVII, no upstream applications	none
	Other substances	none	none	Possible where foreseen in Annex XVII		none

(1) SVHC list

Currently some of substances fulfilling one or more of the criteria defined in Article 57 of REACH are identified as SVHC and these are on the candidate list for authorisation. According to the Article 33 of REACH, if a SVHC is present in an article with a concentration of 0.1% (w/w) or above, any supplier of the article has to provide the name of the substance and if necessary sufficient information for the safe use to the recipient/consumer. We would like to point out that additional (presumably mandatory) requirements for downstream users to provide information on use, exposure, alternatives and waste management would be a huge burden. Especially for the manufacturers of final complex articles, it is very challenging to collect the correct information from very long and complex supply chains across the world, especially from the outside of the EU where the duty on communicate information in the REACH Regulation does not apply. For the complex articles such as Electric and Electronic Equipment (EEE), containing SVHC more than the above-mentioned threshold does not necessarily mean to pose the risk for the health and environment when such articles are integrated in devices, users do not get in contact with such articles during their service time and wasted as instructed under WEEE Directive. In some cases, substitution might not be so simple in final products level and chemical manufacturers and/or downstream users need to keep using the SVHCs paying attention to the obligation of supply chain communications. It should be carefully assessed whether such burden on the downstream users proportionate to the benefit which chemicals and final products deliver to the society.

In addition, the introduction of annual fee to use of SVHCs is not considered proportionate either. SVHCs on the Candidate List are, under the current regime, not banned substances, therefore the use of such substances is not subject to penalties. If this fee is not penalty fee, then it can be considered as taxation. In our understanding, the EU Treaty makes no explicit provision for legislative competences in the area of direct taxation, and that legislation on the taxation of companies has usually been based on Article 115 of the Treaty on the Functioning of the European Union (TFEU), which authorises the Union to adopt directives on the approximation of laws, regulations or administrative provisions of the Member States which directly affect the internal market; these require unanimity and the consultation procedure[1]. In this aspect, it appears very difficult to justify for collection of such fees which are effective (presumably) directly in the EU. Additionally, we do not think that ECHA has such remit to impose taxes, without clear purposes of such fees - who will benefit from fees for what? - and the intended uses of collected taxes. Indeed, they collect fees from registrants and applicants for authorisation, but it is considered that these are paid for actions by registrants and applications to compensate resources (manpower and actual expense) at ECHA.

(2) Authorisation

We are convinced that the authorisation process is fair and appropriate where proportionality of risk to human health and the environment is considered. Article 58(2) in REACH offers the possibility to give derogations adapting the scientific and technical progress of the time. With this future innovation with authorisation substances is possible. Therefore, we support Option 1 to keep the authorisation.

(3) Restriction

With Option1 of Authorisation and Restriction reform, we suggest a sufficient transition period is necessary for the restriction on a case-by-case basis: Substitution must be proven whether it can also be a substitution for final product. Having a substitute for a substance or mixture does not mean that there is a substitute for an article. For final products, it is necessary to carefully evaluate whether the required performance, quality, reliability, safety and durability of the final products can be achieved with alternative substance. After alternative chemical substances are available on the market, it will take 1-2 years for research and feasibility study on alternative materials, 1-2 years for scale-up and manufacturing process, 1-2 years for evaluation by customer, and over 2 years for certification. Depending on the product group, 12-15 years may be required to replace chemical substances to alternatives[2].

[1] European Parliament,https://www.europarl.europa.eu/factsheets/en/sheet/80/direct-taxation-personal-and-company-taxation,(accessed May31st, 2022)

[2] For example, US TSCA has regulated PIP(3:1) without well considering sufficient evaluation and information sharing (Application 6th of January, 2021, Effective date: 5th of February, 2021, Regulatory compliance date:

Supply chains of complex articles are worldwide and very long. Since the evaluation requires huge cost and time, it is important give sufficient time for the whole supply chain to react. Otherwise, it would make further administrative burden and confusion of supply chain.

In addition, we suggest establishing a process to apply derogation for the substances which are already on the Annex XVII. Currently additional application for derogation at the later stage is not possible. There should be a chance to prove whether the derogations correspond to the state of art, otherwise it might hinder EU citizens from benefitting from innovation which is available outside of the EU.

(4) Our opinion on option 2 and 2A

Option 2 and 2A suggest to marge Authorisation into Restriction, however, the concept is unclear especially for imported articles from outside of the EU. Thus, we select “no opinion” in question 32.
Imported articles are not in scope of the Authorisation. However, in the future, if the substances in Annex XIV are included in Annex XVII and the Restriction is applied for imported articles which contain substances listed in Annex XIV, there will be a big confusion. Sufficient transitional period is needed. During the time “Annex XIV bis” is still valid within EU, a similar chance for such derogations should be provided also for imported articles. Without this process, it might affect manufacturers in Europe which use imported articles as components.

Conclusion

Society takes various benefits when chemical substances are properly assessed for potential risks based on consideration of hazard and exposure, and are used safely in products. When a chemical compound is regulated, it should be done so step-wisely. Complex articles, such as EEE, are made up of very long supply chains. Unclear restriction including blunt ban would disrupt the supply chain and not have a positive impact on the society after all.

On top of our opinion in the application of GRA, we would like to emphasise that double regulation with other legislations such as Cosmetics Regulation and Food Contact Materials Regulation should be avoided. To ensure the best possible inter-relationship among different chemical legislations and to avoid contradictions, we welcome documents such as “*REACH AND DIRECTIVE 2011/65/EU (RoHS) A COMMON UNDERSTANDING*” by European Commission published in 2014. Such consideration reduces administrative burdens and contribute to Better Regulation.

JBCE supports the option 1 in the reform of authorisation & restriction of the REACH Regulation. This is particularly the case, if the upcoming REACH revision will include other drastic changes such as expansion of GRA and introduction of the essential uses concept. If such changes are applied and implemented at once, in our view, it would definitely cause more legal uncertainty and confusion among the regulators, enforcement authorities and industry (not only chemicals but also OEMs), if not

March 8th of March in 2022), Downstream had to take immediate action without well recognition whether the article and equipment contains PIP(3;1). This has been causing huge confusion at many industrial sectors.

forever, in the first three to four years at least until specific guidance documents are developed and adopted. If possible, we would appreciate very much if the European Commission organises an open stakeholder workshop, so that the Commission can explain more about its reform idea and collect reactions and opinions from the relevant stakeholders.

We would like to ask for rational and realistic consideration by the European Commission. We thank you again for the opportunity to participate in this survey, and are open to further dialogue.

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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