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JBCE's response to the EU COM discussion paper on 'Essential Uses'

As a cross-sector association with member companies operating in different industries and stages in the supply chain, JBCE welcomes the opportunity to provide input on the European Commission discussion paper on 'Essential Uses'.

1. **Have there been efforts in your Member State / Association to define a concept of essential uses or a similar concept to address REACH restrictions or authorisations or in the framework of another legislation? If yes, please explain.**

The term 'essential uses' is increasingly being heard in relation to PFAS, and the Call for Evidence initiators intend to propose a REACH restriction to the group of PFASs, with aiming for all uses except 'essential uses'. It must however be noted that there is no definition of 'essential uses' in anywhere in the REACH Regulation. There have been individual views and opinions proposed by NGOs and a few academics, but JBCE members are of the opinion that inclusion of 'essentiality' into the REACH restriction regime must require a broad legal and political consideration, which results in the amendment of REACH Regulation, i.e. amendment of the conditions for REACH restriction (Article 68), as these criteria would apply across the board to every substance and every end use and would shift the EU in the direction of a "planned economy", in which major product innovations would need to be sanctioned by government officials.

2. **Are you aware of scientific or other kinds of documents that address the concept of essential uses and that have not been referred to in this document or its annex?**

JBCE members are not aware of such.

3. **Are you aware of legislation or other regulatory procedures that use a concept like essential uses and that are not referred to in this document?**

The notion of essential uses already existed in international law prior to the ongoing PFAS debate but had a very narrow definition and application. It was introduced in the Montreal Protocol in order to foster the minimisation of the usage of ozone-depleting gases. The Montreal Protocol on Substances that Deplete the Ozone Layer was a global agreement to protect the Earth's ozone layer by phasing out the chemicals that deplete it. This phase-out plan included both the production and consumption of ozone-depleting substances. We, however, believe that this example of the concept is unlikely to be directly applicable within the framework of REACH. Essential use as defined by the Montreal Protocol is not a basis for immediate read across to REACH.

When we look at REACH, the assessment under REACH authorisation scheme can be referred. 'Essentiality' of a substance is assessed on the balance between hazard & risks derived from the substance and societal needs to it. This is carried out by the socio-economic analysis in accordance with Article 60 (4-5) REACH Regulation. Therefore, we would like to ask the need to define 'essentiality' for the purpose of REACH.

4. **What are the challenges for the use of the concept? Who will decide on essentiality for society and how can this decision be made?**

Some say that 'essentiality' is already proposed and established by Montreal Protocol. However, it must be pointed out that the purposes of Montreal Protocol and REACH Regulation are different - climate action and management of chemicals -, and an easy and simple application of a concept from one regime to the different regime would surely hamper the future development of new products and new technologies. (The substances targeted by the Montreal Protocol also only had a limited range of uses and the risk was well-defined.)

According to the Montreal Protocol, the essentiality is recognised only if it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects), and there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health. It might be easy to identify the purpose of protection of human lives, however 'functioning of society' can depend on what kind of society the EU would like to be. For example, we understand that fluoroelastomers (e.g. for o-rings and sealing) and fluoroplastics (e.g. for wire and cable) are required to automobiles functioning to comply with the emission regulation as well as running safe on the road. How would the essentiality be applied to this case? Would road safety be considered 'protection of human safety', or a critical part of the functioning of society?

5. **Could you think of examples (ideally with a short justification):**

    a. **where it may be easy to define whether uses are essential or not (or likely to be essential or not)?**

    JBCE has reservations about the usefulness of a broad general definition of 'essential uses' in absence of a specific case, and thus believes it does not make sense to give a few "easy examples" such as medical vs. cosmetic uses. In fact, we think that defining 'essential' cannot avoid being a subjective and emotional discussion.

    b. **where you believe it would be important to work on applying the concept on essentiality?**

6. **To what degree shall decisions be taken on the basis of pre-defined essentiality criteria only and to what degree do decisions still need case-by-case assessments?**

In the first place, one should consider whether the essential use discussion is really necessary if there is no real risk of a substance (or a category of substances) that has been identified. 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.

Last but not the least, the present perspective cannot define essentiality forever. Consider the the development of mobile phones, in which European manufacturers played a key role. Back in the 1970s, we would have considered mobile phones an interesting idea from science fiction, but by no means "essential", as we all lived perfectly well without them. Even thirty years ago, still not many people used or needed mobile phones; they were expensive and there were other viable means of communication, such as public phones and landlines. Now, how many people will claim "mobile phones are not essential"? They will be "not essential" to very few, but definitely "essential" to most people. Certainly, they are essential to the current functioning of society. A static definition of "essentiality" would lead to a static society.

7. Are there aspects that you would consider important to investigate during the development of an essential use concept and that have not yet been mentioned?

One important point is that the European Commission would have to demonstrate that the European Commission or the European Union has a mandate or authority to define 'essentiality', which would have a major impact on the society in all the EU Member States under the Treaty of Functioning of the European Union.

Compensation and financial aid for companies that would have to change their products and businesses or release employees.

Another aspect to consider is the impact of such a concept on innovation in the EU and resulting downsides for industry in the EU. The current categorization presented by Cousins et al 1 focuses primarily on products that already exist on the market today, while inventors and entrepreneurs focus on developing new products that address future needs of society.

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.

At the beginning of a development, both speed and the protection of intellectual property, the latter including the definition of the development goal itself, are extremely important for the inventor. In deciding where to develop products, inventors and entrepreneurs consider where the development can be done speedily without publicizing the product idea prematurely. Any public discussion of the potential essentiality of a truly innovative product would take time and resources, disclose the idea prematurely and in most cases also lead to an initial verdict of "not essential". Thus, any inventor with an idea that might require the use of a hazardous substance, even at extremely low risk level, would be strongly motivated to conduct the development outside the EU, for example in Japan, China, the US or now also the UK. As a result, EU consumers would get useful and "essential" products much later and EU industry would likely never catch up to non-EU competition. To return to the example of mobile phones, which contain some hazardous substances at a risk level people generally consider acceptable, would it have been likely or even possible to develop mobile phones in the EU, if the essentiality of their use had to be proven at the very beginning, before even a prototype were made?

8. **Do you have initial ideas on criteria or definitions that might help to decide whether a use might or not be essential?**

In order to indicate how complicated the discussion and the concept could be, JBCE would like to indicate factors to be considered to determine the 'essentiality' of a chemical compound and end applications in the CSS, for example:

- Whether safety of users of a product as well as workers who are at the production site of a product can be ensured without the substance;
- Whether the product contributes to safety and health of human being (i.e. used in the medical applications, such as devices and pharmaceuticals);
- Whether material efficiency would be achieved without the substance;
- Whether energy efficiency would be achieved without the substance;
- Whether there are available alternatives and/or are alternative technologies to produce a product without the substance;
- Whether a product performs reliably without the substance;
- Whether durable and sustainable products can be produced and placed on the market without the substance;
- Whether t a product produced without the substance is accessible by general public (with reasonable cost and efforts);
- Whether a substance is needed in critical industries researching and developing innovations pivotal for the European Green Deal and an economy focussing on sustainability.

We would note however, that at least at the Member State level, some existing law already requires the use of the least hazardous substance that achieves the desired performance. Rather than attempting a generally applicable definition of "essentiality", "least hazardous viable alternative" requirements might be a better approach to some, if not all of these aspects we have listed.

9. **What would you consider the most appropriate way to develop the concept, definitions and criteria further**

    a. **A study**

    b. **CARACAL discussions**

    c. **A CARACAL sub group**

    d. **other**

In JBCE's view, it would not be appropriate to leave the development of such a broad concept to such a small and specialized group as CARACAL. The concept of 'essentiality' will be a subjective discussion, not objective, therefore it should be a policy or even a broad societal discussion, and that would be far beyond the remit of Competent Authorities for REACH and CLP: "What is essential to you might not be essential to me". What is essential to the EU might not be essential to Japan – because we are living in the world of diversity and views can be – or should be – diverse. Resulting differences in interpretation of 'essentiality' could lead to dispute and risk the essential use concept being considered as a technical barrier to trade.

JBCE and its members support to promote for human health and environment in a realistic manner and on the basis of profound evaluation, and are willing to contribute to bring these ideas forward together with the European Institutions and other interested stakeholders.

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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