JBCE REACH WG – Essential uses task force
(15th Apr 2022)

JBCE's position for Essential Uses Concept

JBCE is welcome to contribute to the European Chemicals Strategy, which manages chemical substances appropriately and contributes to human health and environmental protection. We also believe that streamlining processes that place an administrative burden on all stakeholders can help us determine restriction and bans on hazardous substances in a short period of time. Therefore, We are happy to contribute to the discussion of the essential concept of use.

1. Introduction - Essential Use Concept

First of all, it must be noted that there is no definition of 'essential uses' anywhere in the REACH Regulation. Among various views and opinions stakeholders including several academia, JBCE members are of the opinion that inclusion of 'essentiality' into the REACH restriction & authorisation regime must be based on a broad legal and political consideration which results in the amendment of REACH Regulation. Amendment of the conditions for REACH restriction (Article 68 by simple inclusion of 'essential uses' concept, in particular to apply to every substance (whether as a single substance or a group of substances) and every end use, would make 'chilling effects' on innovation in EU, which consequently might cause the loss of EU global competitiveness.

2. History of a concept like essential uses

(1) Montreal Protocol

The notion of essential uses already existed in the Montreal Protocol in order to foster the minimisation of the usage of ozone-depleting gases. This is a very narrow definition and application. 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.

(2) REACH restriction

'Essentiality' of a substance is assessed on the balance between the risks derived from the substance and societal needs to it. Today, part, but not all, of this consideration is implicitly covered in the socio-economic analysis done in accordance with Article 60 (4-5) REACH Regulation (i.e. by the Committee for Socio-economic Analysis (SEAC), ECHA). The economic value of the benefits of the substance are weighed against the cost of the **scientifically identified** risk. In some cases this analysis is actually a proxy for assessing essentiality, but this can lead to problems if "essential" aspects of a use cannot be reduced to a monetary value.

An example of the difficulties with socio-economic assessment being used as a proxy for "essentiality" can be found in the Opinion on the proposed REACH restriction (ban) of microplastics as infill for sports pitches, which was vigorously opposed by numerous sports clubs and associations. ECHA's SEAC was unable to perform the cost-benefit analysis according to REACH Article 60 and said that the decision on this restriction should be based on policy. This is an example that SEAC could not perform the quantitative assessment of the value of sports community and businesses.

3. Challenges for the use of the essential use concept

As mentioned above, purposes and goals of Montreal Protocol and REACH Regulation are different - climate action and management of chemicals –, and an easy and simple transfer 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 (1) it is necessary for '*human health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects)*', and (2) 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 fuel hoses, O-rings and sealing used in harsh conditions) and fluoroplastics (e.g. for wire and cable in industrial equipment and E&E products) are required to automobiles functioning to comply with the emission regulation as well as running safe on the road in the future traffic environment with electric vehicles. 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?

In light of the on-going discussion on the grouping approach under REACH revision, the essential uses concept and application would also be another challenge, in particular when 'grouping of substances' can be made in different manners: grouping by chemical structure, by uses or by hazard classification. If the essential use concept and assessment would be applicable to the group of substances, it must clearly be stated how the Dossier Submitters and the relevant authorities guarantee the same level of assessment to each grouping of substances.

4. Decision-making process under the essential uses assessment: What degree on decisions be taken on the basis of pre-defined essentiality criteria, or case-by-case assessment still needed? Who will be accountable after all?

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 sound science as defined under REACH Regulation. It is not appropriate on the basis of mere hazard considerations and before a serious risk has been identified. It can be said that the consideration of 'essentiality', in other words, consideration of balance among hazard, risks and societal needs, is already included in REACH authorisation and restriction. If the European Commission wishes to add another layer 'essential uses' into those regimes, it would require rather substantial changes to REACH authorisation and restriction.

Despite the above concerns, in case the EU will go ahead with setting up the concept and criteria, we are of the opinion that it should primarily be addressed and used under REACH Regulation in terms of 'essentiality' assessment of substances to produce products (if not one product, numerous products). Who will be the evaluators and the decision-makers are to be identified, and these can be different depending on the essential uses procedures which the EU will set up. If the assessment will be a part of socio-economic assessment which is required for a REACH restriction proposal under Article 68, it will be SEAC or other ECHA body where necessary or available. If ECHA would not like to take up this task, the actual implementation should then be made by the accountable decision-maker, which consists of, for example, the European Commission, the Members of European Parliament and/or the Council of the European Union.

5. Aspects that you would consider important to investigate during the development of an essential use concept

(1) Generic Risk Assessment

When implemented alongside so-called “generic risk assessments”, which are in essence simplistic hazard-based bans, the “essential use” concept might prevent case-by-case assessment of essentiality of substances for certain (most probably only “known” uses) and certain substances or groups of substances could not be used at all in the future, even if extremely low exposure to human and the environment is identified, just because of assessment and restriction.

(2) Intellectual property rights – inventions and innovation

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 publicising the product idea early, endangering patent rights or disclosing an inventor’s plans 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.

In addition, the present perspective cannot provide a definition of essentiality valid forever. Consider 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. It would also have to be mentioned that introduction of this ‘essential uses’ concept and implementation should not hinder the future development of a new substance and a new application of the existing substances.

(3) Definition of ‘most harmful substances’

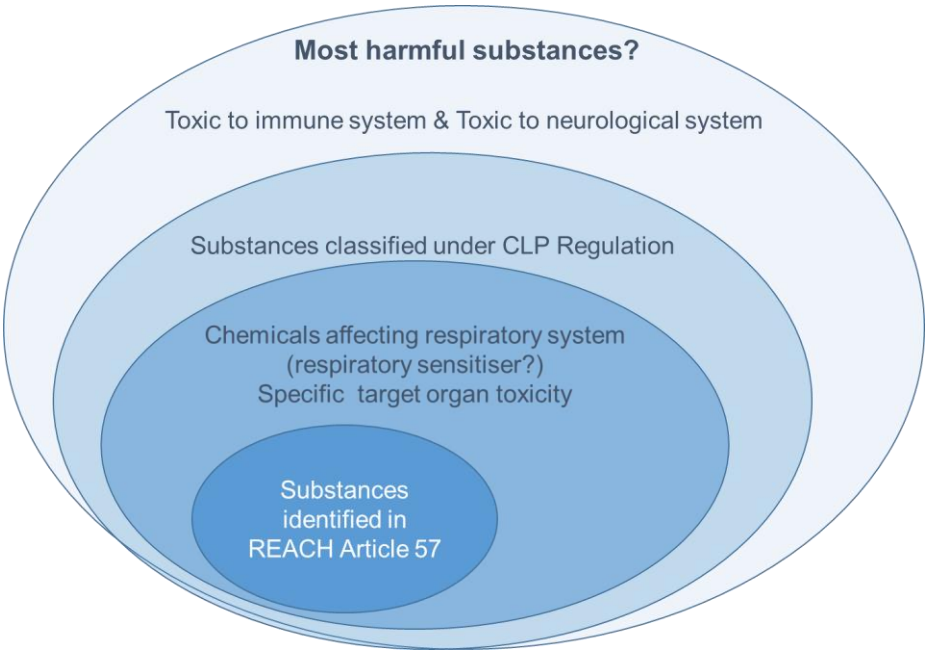
During the Essential Use Workshop held on 3rd March 2022, there were many refences to the term “most harmful substances” many times. Although the background document defines it as “*Most harmful substances are defined in the Chemicals Strategy for Sustainability as chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative; chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ*”, we see several challenges to incorporate it into the REACH framework to implement it in Authorisation and Restriction.

- Substances to be regulated under Annex XIV REACH (Authorisation) have to be identified as carcinogenic 1A or 1B, mutagenic 1A or 1B, toxic to reproduction 1A or 1B, PBT, vPvB, endocrine disruptive and/or having equivalent level of concern to PBT or vPvB. This identification process is defined according to well established scientific criteria.

- UN GHS and EU CLP have certain criteria to identify CMR properties, effects on respiratory system and toxicity to specific targeted organs (STOT). Although UN GHS and EU CLP do not have specific classes flagging endocrine disruptors (ED) immunotoxicants and neurotoxicants, they already provide the tools to flag these hazards, R or STOT classification for EDs and STOT classification to immunotoxicants and neurotoxicants. However, there is no scientific defined criteria as to what "most harmful substances" are. This term needs to be clearly defined and agreed on by the scientific community and all stakeholders before being implemented into any EU or international chemical classification.

- The meaning of "most harmful substances" is entirely unclear. Which hazards, which thresholds? Does it mean some arbitrary "toxin of the month"?

As we have seen, setting up a criterion in the CLP and REACH Regulations take time, because it should involve scientific discussion by experts and the criteria and guidance must be clear and agreed on by relevant stakeholders.



(4) Role of "Safe use of chemicals"

JBCE noticed that many workshop participants asked about the role of 'safe use of chemicals' in the Authorisation and Restriction procedures, with the essential use concept, to decide on derogation to use of chemicals.

We noted that some European Commission officials apparently think that "essential use" and "safe use of chemicals" are unrelated. Indeed, discussing the essentiality of substances to produce a certain product and assessing safe use of chemicals at the production site require different expertise; the former requires technical expertise in the functionality of materials for specific products, while the

latter assesses the risks to workers and downstream users. However, in our view, safe use of chemicals should substantially be considered in the assessment of application for authorisation and of derogation proposals in restriction dossiers. Particularly, Article 68 of REACH Regulation has the condition, “an unacceptable risk to human health and the environment”, therefore it is logical to give a weight to “safe use of chemicals”.

(5) Definition of “End use of chemicals”

This aspect was not discussed in the background document, but attracted attention from the participants during the workshop. JBCE would like to reflect our thoughts and questions as follows.

This term was explained by using the example of “roller-coasters”, in which the presenter said “the concept would assess not the societal need of roller-coaster, but the essentiality of a (hazardous) substance for the safe operation of the roller-coasters”. What was said is clear, but we suspect that still some important considerations are missing in this statement.

For example, a hazard-classified substance (“substance A”) is used to produce a coating material. This coating material (“material A”) is used to protect materials (“material B”) of materials consisting products (“material C”), such as roller-coaster and spinner at funfair, personal protection aid (PPA) for professionals, or cars, because the substance A provides durability, resistance to corrosive chemicals for products as technical function. The first question is “what is the end use here?”: the coating material, for production of which the substance A is used (“material A”), the coating material for certain material (“material B”), or the coating material (“material C”) for certain final products (e.g., roller-coaster, spinner, PPA, car and so on)? Depending on the cases that the essentiality is assessed for, the impact of the assessment results would vary significantly.

If the assessment is applied to the coating material (“material A”) and results in "non- essential", then that coating material (“material A”) would be regulated and could not be used for any final products mentioned above. If the assessment is made on each product (“material C”) and results in "non-essential for roller-coaster and spinner" but "essential for PPA for professional use", then the use for roller-coaster and spinner would be regulated, but at least use for PPA for professional would be derogated.

It is not a very special case that the function fulfilled by a substance used at the part level, especially in complex articles, may or may not meet the criteria of essentiality, depending on the final application.

If this ‘end-use’ concept should play a role in the essential use regime, we would like to ask the Commission to define it the well and to give a clear guidance to all the stakeholders.

6. 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 Chemical Strategy for Sustainability (CSS).

There are several open options in the future criteria and methodologies. For example, we could propose the process as follows:

> The assessment of essential uses from the perspective of chemicals may take place following a decision tree in three main, consecutive steps: (1) establishing whether unacceptable risks are associated with the chemical substance, (2) assessing the essentiality of the chemical substance for the final product and, (3) assessing the essentiality of the final product for society.

This following proposal is based on the assumption that ECHA will include the consideration of 'essential uses' in authorisation and restriction processes, but can also be applied by different decision-making bodies as mentioned above.

It seems appropriate to operate with a list of questions, rather than pre-established lists of sectors or criteria.

Step 1: Risks associated with the chemical substance

- What is the hazard profile of the substance?
- Is the substance an SVHC?
- Is the substance already regulated under other EU frameworks?
- Has the substance already been assessed under REACH (e.g. evaluation or RMOA)?
- What is the level of exposure to the substance along the life cycle?
- Are there risk management measures already in place?

ECHA RAC may identify an unacceptable risk associated with the chemical substance, based on the above criteria. In that case, the assessment process should continue with Step 2 and Step 3, so as to establish whether the chemical substance or the product(s) it is used in should be deemed essential and should therefore benefit from a derogation. If RAC cannot identify or demonstrate any unacceptable risks connected to the chemical, the substance should be considered out of scope for a restriction for further essential uses assessment.

Step 2: Criticality of the chemical for the product (non-exhaustive list)

- Whether or not the 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 or not resource efficiency would be achieved without the substance;
- Whether or not energy efficiency would be achieved without the substance.
- Whether or not there are available alternatives and/or are alternative technologies to produce a product without the substance, with an expected favourable impact on human health and/or the environment.
- Whether or not a product is reliable in performance without the substance.
- Whether or not durable and sustainable products can be produced and placed on the market without the substance; and

Should ECHA take up the responsibility, RAC and SEAC should evaluate whether the chemical substance is critical for the product(s) it is employed for and whether viable alternatives exist; availability of alternatives should also be considered whether or not the 'viable alternatives' are available in the EU, in order to secure the supply of the said alternatives and be independent from external factors (e.g. restrictions to sources based on sanctions, trade wars, export ban by the exporting country, etc.). The assessment process may take into consideration the future Safe and Sustainable-by-Design criteria, as well as the ecological profile methodology. The latter would demonstrate the cost-benefit ratio of using a substance in a product, based on a holistic assessment. If the substance is critical

and no viable alternatives are available, step 3 of the assessment should begin. Step 3 should be under the responsibility of a dedicated multi-stakeholder committee complementary to RAC and SEAC.

Step 3:

For cases where essentiality of uses are being considered, it will be important to define a process that involves all stakeholders and truly considers all effects of a potential ban, both direct and indirect. Below a non-exhaustive list of criteria JBCE would consider as critical when assessing application that require the use of a substance that has undergone the aforementioned assessment (Steps 1 and 2):

- Impact of the application on sustainable development which includes consideration on climate neutrality, circular economy, energy supply and energy efficiency.
- Health and disease controls, including but not limited food and water supply and quality.
- Innovation in a broad sense, with a focus on major sectors linked to policy priorities such as the future EU implementation of the Green Deal and Digitalisation.
- impact on the EU industrial autonomy and the potential increase of its dependence to non-EU countries.

Another option is that a simpler 'ranking' system is set up for the essential uses assessment for the above Step 2 and/or Step 3. Based on the elements mentioned above, essential uses assessment methodology should be developed. The methodology should be simpler (but not too simple) and enable experts and decision-makers (whoever they are) to categorise substances and uses of the substances for products in three different ways: low, medium and high (essentiality). This categorisation could also define the degree of burden of proof on industry or any stakeholders; for example, the uses categorised 'high' do not require intensive assessment with lots of data and justifications by industry, while defence of the uses categorised as 'low' would need case-by-case studies and more quantitative (when impossible, qualitative) data which are to be assessed by experts and decision-makers.

7. Legislative process to set up 'essential uses' in the EU

In JBCE's view, it would not be appropriate to leave the development of such a broad concept to such a small and specialised 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 a world of diversity and views can be – or should be – diverse. Resulting differences in the interpretation of 'essentiality' could lead to dispute and risk the essential use concept being considered as a technical barrier to trade.

In any case, JBCE would support the inclusion of 'essential uses' in the REACH revision, if the essential uses concept must be included in EU legislation. This is because the revision of REACH will be discussed and voted on by the Members of the European Parliament and the Council, who will be accountable for any legally binding decision in the future.

8. Application beyond REACH regime

In the background document, various EU legislation are identified as 'legislation that may benefit from the essential use concept'. These are:

Toys Safety Directive

Cosmetic Product Regulation

Food Contact Materials Regulation

RoHS Directive

Among these, Cosmetic Products Regulation, Safety of Toy Directive and RoHS Directive function well under New Legislative Framework on the EU market, and CE marking on these products guarantees that the products fulfil all requirements of these laws. Some of product specific requirements, such as safety and reliability, have higher priority than the existence of chemicals in the products which are not released during their lifetimes. Therefore, if applying the essential use concept to legislation other than REACH Regulation, the impact and effects need to thoroughly be proven in detail and in advance. The introduction of essential use concept may complicate the current process and cause confusion.

Particularly, JBCE would like to emphasise on RoHS Directive. Regarding substance restriction assessment for Annex II, a better alignment of RoHS Directive and REACH Regulation would be helpful. Here the so-called 'one substance, one assessment' principle should be, and substance that are not classified as hazardous' under the REACH and CLP Regulations should not be considered for possible restriction under the RoHS Directive.

Furthermore, the introduction of the essential use concept to the exemption process (Annex III and IV) will bring more confusion than benefit, In RoHS Directive, Electrical and Electronic Equipment (EEE) are classified into 11 categories. Currently exemptions are given to electrical/electronic components or elements for some categories. The essential use concept does not fit this current categorisation. The necessity for health and safety, the criticality for the functioning of society as well as the existence of alternative are already proven during the current process. "Essentiality" is not a „common factor" of these, but another additional factor. Thus, it does not help simplifying the current process. If the concept is applied to the exemption process, the administrative burden of European Commission as well as industries would increase. The exemptions' description would be more subdivided and detailed, and it would be much harder for manufacturers to identify which exemption apply to which product.

End