

Workshop background document

Study supporting the Commission in developing an essential use concept

European Environmental Bureau Comments

21 March 2022

The EEB would like to welcome the proposal to develop and implement the essential use concept as we consider it can be a useful tool to speed-up regulatory processes and advance towards a toxic-free environment. The implementation of this concept has been committed by the Chemical Strategy for Sustainability which has been supported both by the European Parliament and Council.

Below we include our comments to the questions raised in the “Workshop background document. Study supporting the Commission in developing an essential use concept” by Wood.

From Table 3.1, p. 11 in the Wood report

Assessment of necessity for health and safety and of criticality for the functioning of society

- What are key elements required to assess if the use of a substance is necessary for health and safety?
- What are key elements required to assess if the use of a substance is critical for the functioning of society?
- What are key elements to be considered to include cultural and heritage aspects in the decision on whether the use of a substance is critical for the functioning of society?

To be able to assess the necessity/criticality of using a hazardous chemical in an article or a product the necessity/criticality of the final use of the article or product needs to be assessed together with the necessity/criticality of the function of the hazardous chemicals in the final product.

E.g. the level of hardness of different airplane metal pieces may be completely different, depending on its final uses, landing gear, engine, seats, stairs, etc. Existing aviation safety standards could support the assessment in this and other similar cases.

We consider it may be easier to assess the necessity for health and safety and the criticality for the functioning of society by establishing a list of functions, uses/product categories that can be considered as non critical. This would be the case for the majority of consumer products including toys; textiles; furniture; clothes, apparel and shoes; food contact materials; personal care; cosmetics; luxury; leisure; decorative articles/purposes; sport products; home maintenance and gardening, etc.

We consider that cultural and heritage aspects should not be considered as necessary for health and safety or critical for the functioning of society.

Assessment of alternatives

What are key elements required for the assessment of acceptability of alternatives from the standpoint of the environment and health?

We consider that the alternatives assessment should be limited to a hazard assessment as the focus of the aim of the essential use concept is to identify which harmful substances should be allowed continued use.

We recommend the [Greenscreen List Translator](#), as a very useful tool to perform a rapid hazard assessment and do a preliminary screen out of hazardous alternatives.

What would be key steps in the assessment of alternatives?

The following are key steps to assess alternatives:

- Definition of the function, final use/product category and sector of the chemical. This would allow scoping the alternatives assessment.
- Describe the market for that function, use/product category to understand the prevalence of alternative substances, materials/products and/or technologies/ services. This would allow a better understanding of the availability of alternatives.
- Identification of existing I&D efforts. This would allow informing the time needed to implement the alternatives.

Which actor(s) should provide information/evidence on alternatives? In what format?

We consider that the main actors to inform the availability of alternatives are downstream users and alternative providers.

Therefore we welcome the proposed new role of the candidate list that would require users of SVHC chemicals to notify their uses to ECHA and pay a fee. Additionally these DU should be requested to perform a substitution plan that would support the identification of alternatives.

Market studies are also needed to understand the availability of alternatives. These studies could be performed by consultants, ECHA and/or a substitution support centre that should be established with the fees from DU.

Additionally, authorities (Commission, Member states and ECHA) should have the power to ask companies to provide information on the market and competitors, mirroring the competition law (Regulation 139/2004).

What are key lessons learnt from analysis of alternatives under REACH and other legislation that could be considered for this step in the essential use concept?

We have learned for analysis of alternatives under REACH authorisation and restriction processes that we need:

- A definition and criteria for establishing what is a suitable alternative.
- To have a better understanding of the market and alternatives upfront of decisions on authorisations or derogations to restrictions.
- Alternative assessment experts to support the regulatory processes.
- To give authorities the power to require information from companies. The competition law should be used as inspiration.

- Most importantly, to support frontrunners to inform regulatory processes about their alternatives.

Application of the essential use concept

Is the terminology used in the concept (e.g. essentiality, necessity, criticality, etc.) sufficiently clear? What areas of the concept remain unclear in terms of definitions? How could these be improved?

Although the terminology is sufficiently clear, clarifications are still needed on the chemical categories and substances that will be considered as most harmful chemicals. We consider that a protective approach should be followed that includes all chemicals of concern.

It was also not clear during the workshop discussions if only the essentiality of the substance's function in the product/article will be assessed or the essentiality of the use including the product category. We recommend sticking to the definition in the Montreal Protocol.

What evidence is needed at each step in the presented assessment above (e.g. data sources/verification process) to prove a use is essential? Who should provide this information?

The evidence needed is the description of function of the substances, final use/product category and sector as well as availability of alternatives.

In the case of SVHCs, DUs should provide this information through SVHC notifications. Additionally, any company requesting a derogation for a restriction should also provide this information. Also market studies on availability of alternatives are needed. This could be done by consultants, a substitution support centre or ECHA.

A list of sectors and product categories that cannot be considered necessary/critical for health and safety and the functioning of society must be established to help filtering uses that should not be considered essential.

What degree of flexibility is required for the application of the criteria? An example would be provisions for emergency uses (e.g. medical circumstances). Can you think of other similar examples where flexibility in the application of the criteria or process would be justified

Flexibility is needed but only for extraordinary circumstances.

From Table 3.1, p. 12 in the Wood report

Feasibility/usefulness of screening steps

Do you think that initial screening steps could in principle simplify and speed up decision-making?

If yes, do you think the two screenings (on criticality/necessity and on alternatives) should be done simultaneously or should they be done one after the other? If the latter, which one should be done first and why?

In principle it should be easier to screen for necessity/criticality given that a list of non-critical sectors/uses/product categories is established. Therefore it may be more efficient to start with this step. However in some cases it may be needed to do both screenings simultaneously.

a. What would be the main benefits of the screening steps?

To filter out cases where a ban is straightforward and where no authorisation or derogations to restrictions should be considered.

b. What would be the main challenges of the screening steps?

The main difficulty is likely to collect reliable information on alternatives, as the requester of the derogation has no financial interest to provide such information. For this reason, it should be ensured that information on alternatives is collected by broad consultation of independent experts, alternative providers, information available in the public domain and consultation of stakeholders.

While claims from industry that no alternatives exist should be checked for their credibility, increased attention should be given to cases where alternatives are present on the market.

c. What would be the information required and expertise needed for the screening on criticality/necessity and on alternatives?

See answers above. Clear criteria for defining non-critical uses are needed.

Would it be possible to determine already in the screening that there are no available alternatives?

Determining *that there are no available alternatives* is generally difficult, and any such decision can only be temporary and preliminary.

Information requirements for proving that a use is essential

What are, in your view, the information requirements needed to make a full assessment of criticality/necessity and alternatives and subsequently take a decision on essentiality of a use? What would be the advantages and disadvantages of these information requirements?

As stated above, the minimal set of information requirements for the assessment of criticality or necessity should be the function, use/product category and sector. However, the proponents of a derogation for essential uses should be incentivised to provide a maximum of information, at least enough to determine criticality/necessity and alternatives transparently and beyond any reasonable doubt. Where a use is not convincingly depicted as necessary or critical, it must be considered as failing on the first condition of the Montreal protocol definition.

Do you think it is feasible to simplify the assessment of alternatives for clearly critical uses (even if no clear alternative has been identified in the screening)? If so, why and under which circumstances? What would be the advantages and disadvantages?

Doing this would equate to distinguishing “critical” uses and “clearly critical” uses. Such a distinction is likely complicating the process unnecessarily. Let us not forget that the assessment can be stopped as soon as the existence of a suitable alternative has been established: it would be more beneficial for the quality and the efficiency of the screening process if it is ensured that no financial interests taint the objectivity of the assessment process.

Do you think that information requirements should be the same in all cases or should there be a possibility to adapt them at the screening stage to allow for simplification and better targeting, in particular for clearly critical uses? What would be the advantages and disadvantages of either approach?

Simplification would be possible only for straightforward cases where the function/use is not critical/necessary.

Feasibility/usefulness of a fall-back mechanism for emergency situations

Do you see a need for an additional fall-back mechanism in decision-making on essential uses for emergency situations (given the possibilities already offered by Articles 2(3) and Article 129 of REACH)? If yes, why and how could it be done?

No. The derogation possibilities in Art. 2(3) and Art. 129 are broad. Such derogations would certainly also apply to decisions taken using the EUC.

From Table 3.2, p. 13 in the Wood report

Benefits from ESU in legislation other than REACH

Do you think the legislation [Cosmetic Products Regulation, RoHS Directive, Safety of Toys Directive or Food Contact Materials Regulation] would benefit from an essential use concept?

We consider that cosmetics, toys and food contact materials should be considered non-essential as there are alternatives for any product/article of these sectors that may contain substances of concern.