

Implementation of the “Essential-use” concept in chemical regulations

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Background

In the **Montreal Protocol**, a use is essential only if **(A)** it is necessary for the health and safety, or is critical for the functioning, of society; and **(B)** there are no available safer, technically and economically feasible alternatives.

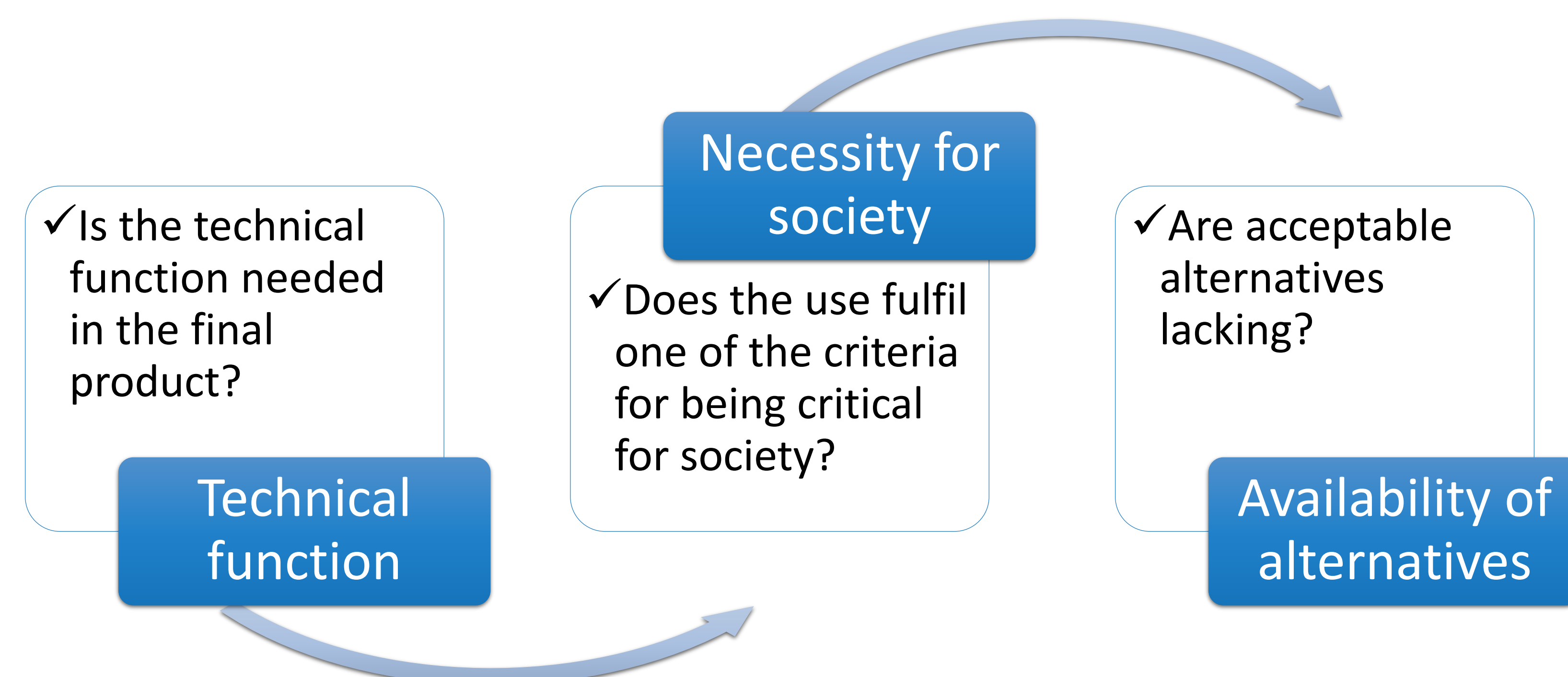
The EU **Chemicals Strategy for Sustainability** stipulates implementation of the essential-use concept under REACH to guide phase-out of the most harmful substances.

Aims of the study

To determine **(1)** whether the existing restriction of uses of harmful chemicals processes refer to elements of the essential-use concept; and **(2)** whether process changes are necessary to implement the concept in the decision-making.

Methods

Analysis of the decisions on derogations to restrictions under Stockholm Convention and REACH processes following the READ approach (Dalglish et al. (2020)) to determine if relevant information to perform essential-use assessment was available.

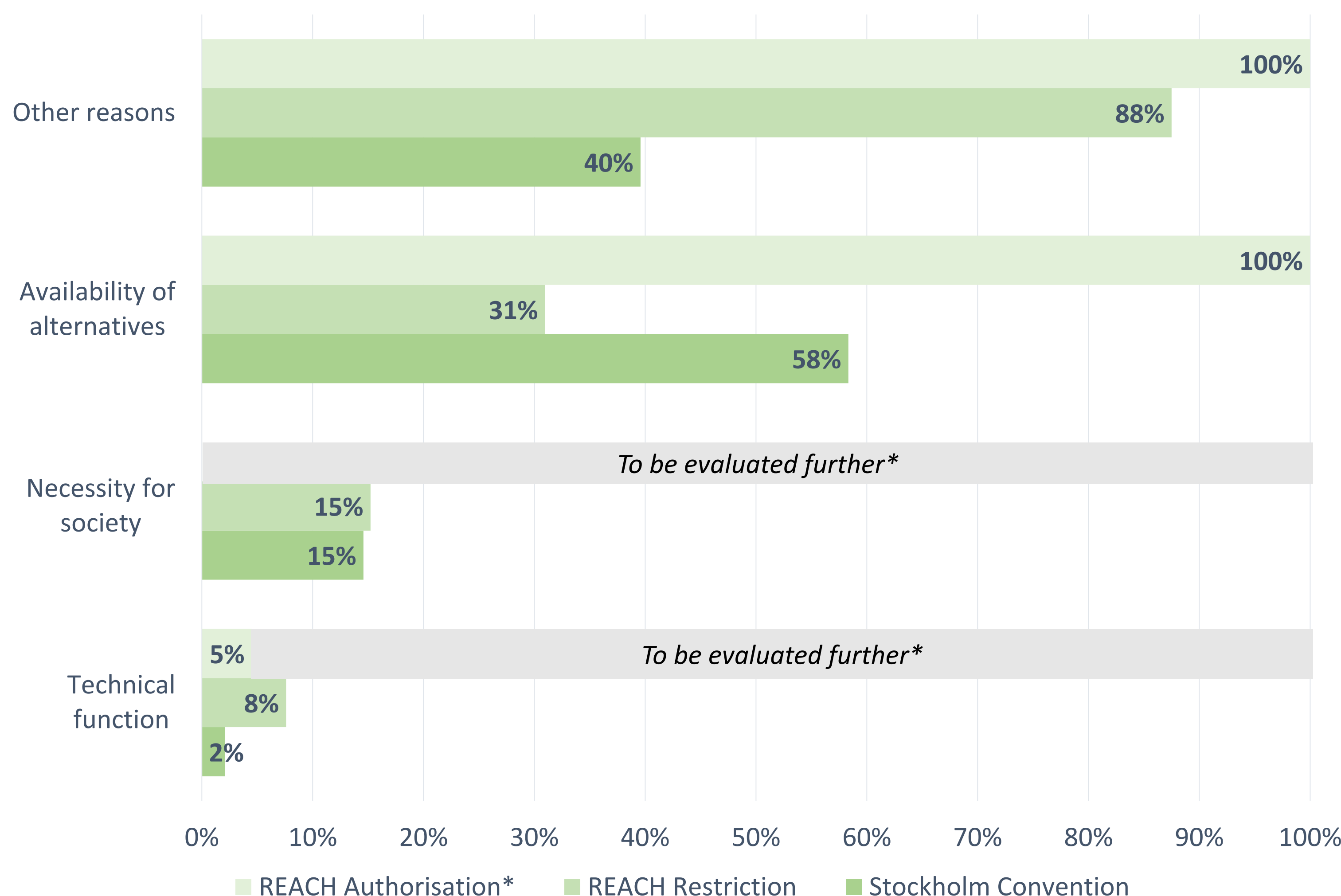


Overview of the assessment of essentiality of a use as proposed by the European Commission

Results

Components of the essential-use concept mentioned in decision-making on derogations to previous restrictions

*: See separate section on REACH Authorisation process



- Derogations refer mainly to the “**availability of alternatives**” component of the essential-use concept.
- Category “**Others reasons**” can be divided into two sub-categories:
 - Reasons for which the **essential-use concept would not affect the regulatory outcome**, i.e., because the use already regulated, the use being out of scope, restriction not enforceable for the specific use, or substance found as impurities in the specific use;
 - Reasons for which the **essential-use concept could affect the outcome**, i.e., because negligible risk from the use, or the restriction costs outweigh the benefits, mentioned for **~20% of the derogations**.

REACH AUTHORISATION PROCESS

- Authorisations are granted if (1a) risk is adequately controlled, or (1b) costs of ceased use outweigh the benefits, and (2) there no suitable alternatives available to the applicant (“**Availability of alternatives**” component)
- Further work is needed** to determine if enough information is provided in the applications to evaluate if the technical function is needed in final products, and whether it would fulfil the criteria to be considered as necessary for society
- For **20 applications**, the European Commission did not grant authorisation for part of the use applied for where “the specified key functionality is not necessary for the use” (“**Technical function**” component)

- All **three components of the essential-use** concept were mentioned in the reasoning for **8 derogations recommended under REACH restriction process** (for uses covered by restrictions on PFOA; D4, D5 and D6; 2,4-dinitrotoluene; PFHxA; and PFAS in firefighting foams).

Lessons-learnt

- No major changes in the REACH Restriction process** are needed to implement the essential-use concept.
- Previous decisions on derogations have been **mainly based on the availability of alternatives**.
- The essential-use concept can bring a **new perspective in decision-making**.

References: EU (2020), <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>; Dalglish et al. (2020), DOI: 10.1093/heapol/czaa064; EU (2024), https://environment.ec.europa.eu/publications/communication-essential-uses-chemicals_en

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Partners

