

Implementation of the essential-use concept within REACH Restriction process

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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 process refers to elements of the essential-use concept; and **(2)** whether process changes are necessary to implement the concept in the decision-making under REACH.

Methods

Analysis of the Restriction processes under REACH following the READ approach as defined by Dalglish et al. (2020).

Reading the material	Extraction and Analysis of the data	Distilling the findings
SEAC final opinions and the European Commission's final decisions of existing restrictions	Reasons for derogations, separated into four categories: ❖ Function needed for health & safety, or functioning, of society; ❖ No alternatives; ❖ Time needed for transition; ❖ Others.	How do the current regulatory outcomes match the essential-use concept?

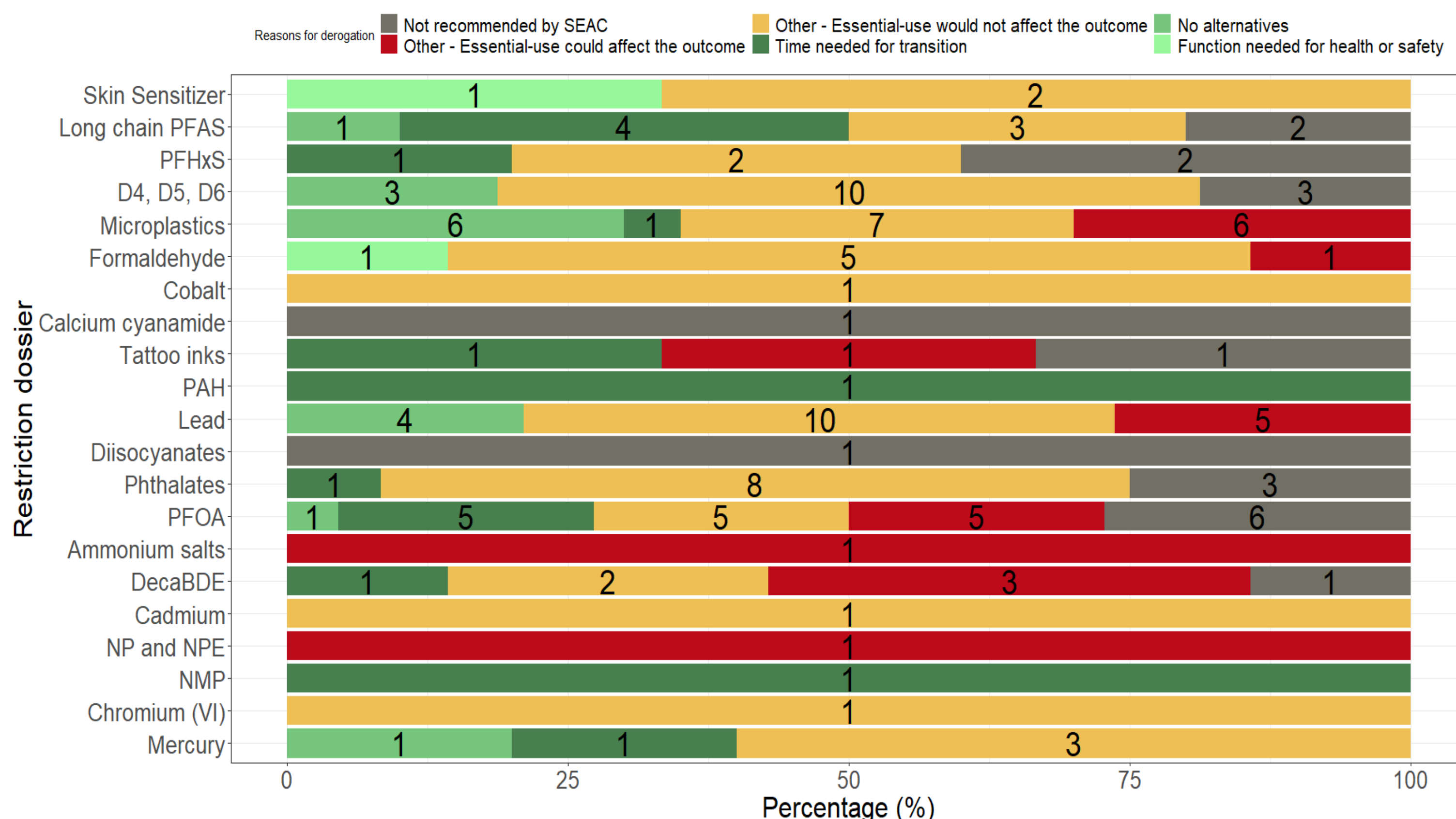
CASE STUDY

Concrete application of the essential-use concept in the restriction of intentionally added microplastics to decide on proposed derogations.

Results

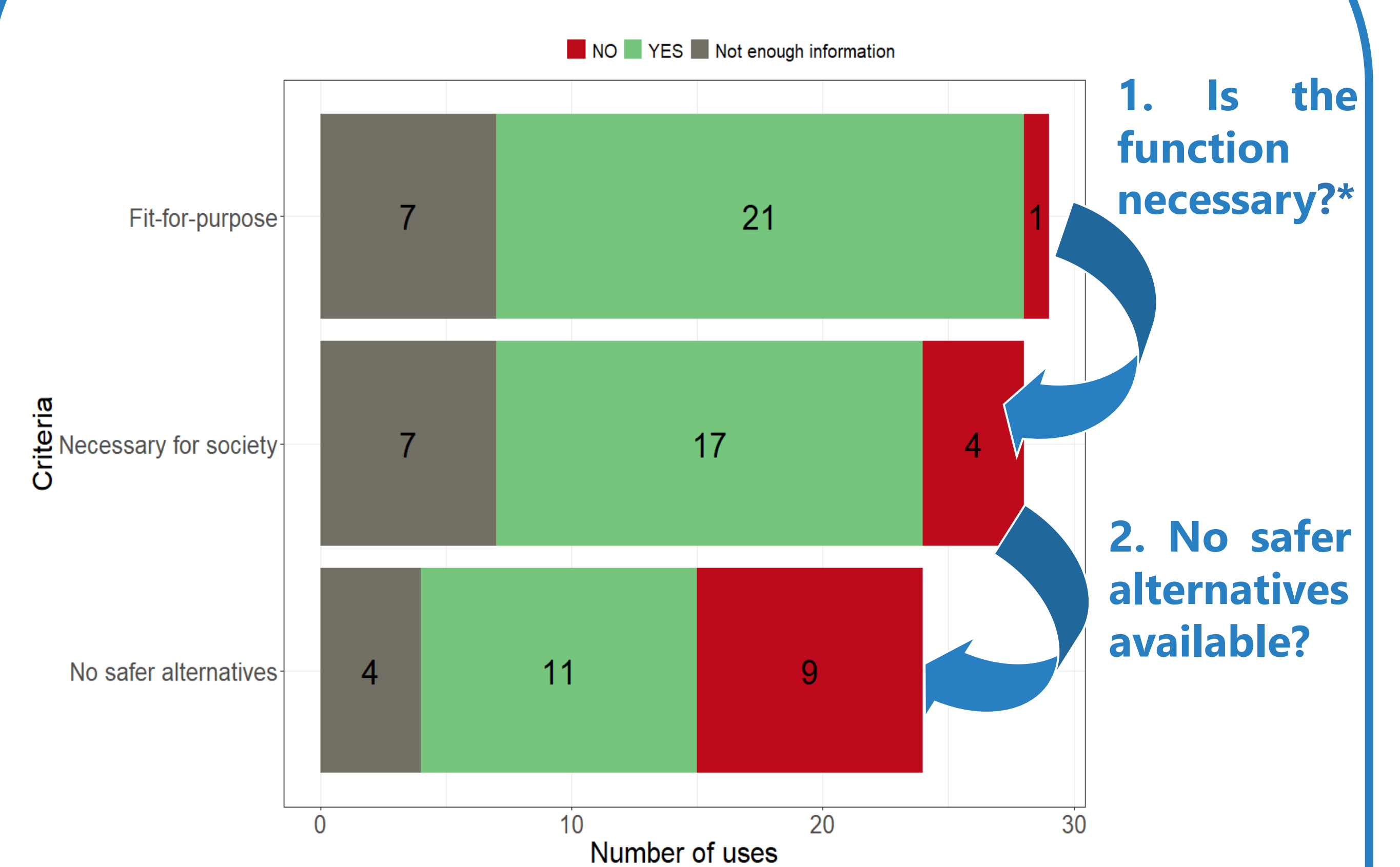
Reasons for granting a derogation in existing REACH restrictions

The numbers indicate the number of derogations granted in each "reason for derogation" category per restriction dossier.



- Derogations refer mainly to the **"alternative"** component of the concept, while the "necessity" component was mentioned only twice.
- Category **"Others"** divided into two sub-categories:
 - derogations granted for 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;
 - derogations granted for 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.
- The concept could have **changed ~20% of the derogations**.

INTENTIONALLY ADDED MICROPLASTICS



*: Is the function necessary for health and safety, and/or is critical for the functioning, of society according to the criteria from WSP (2023)?

- 11 uses of microplastics out of 29 can be considered as essential
- **Enough information available for essentiality assessment.**
- **Safety of potential alternatives barely addressed** in the restriction dossier.

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: Cousins et al. (2021), DOI: 10.1039/D1EM00180A; Dalglish et al. (2020), DOI: 10.1093/heapol/czaa064; EU (2020), <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>; WSP (2023), <https://op.europa.eu/s/yAZM>



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Partners

