ClientEarth

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Demand #3 for REACH reform

A lightened process for restricting the most hazardous groups

The proposed expansion of the fast-track restriction process for consumer uses (Art. 68.2) will be crucial for speeding up the restriction of the most hazardous chemicals that could be used by consumers or professionals. But reforming Art. 68.2 is not enough. The default restriction process (Art. 68.1 and 69-73) must also be revised, for two reasons. First, this is for now the only restriction process that Member States can initiate. Second, some of the most needed restrictions in the coming years will still have to happen under this process:

- ***Situations not covered at all by the fast track restriction process (Art. 68.2)***
    - ***Uses:*** *Industrial use, contamination (non-intentional use), or groups of substances for which there is a wide combination of situations (intentional, non-intentional, industrial, consumer, etc.);*
    - ***Substances:*** *non-classic risks (such as microplastics) or emerging risks,[1] which do not fit the hazard classes covered by Art. 68.2 (even expanded).*
- ***Situations hard to cover under Art. 68.2****: substances in articles from a wide variety of sectors may gain from being addressed together, but may be too complex to handle under Art. 68.2 as one.*
- ***Substances not listed,*** *or listed as category 2 classifications, especially as part of a wide group, might also be more easily handled via a normal rather than fast-track restriction process.*

[1] As for the scope in REACH, see Advancing REACH: Strengthening control of emerging risk (Umweltbundesamt 2021).

What makes the burden too heavy today

A consensus emerges on the sources of burden for dossier submitters:

- Excessive dependency of the authorities on the companies' willingness to provide data on use and hazard, worsened because of the heavy burden of proof carried by authorities.
- Lack of political willingness and capacity from some Member States to propose restrictions, in a context of high opposition from industry.
- Lack of precautionary measures due to lack of political willingness and lack of adapted risk assessment approaches.

The core changes needed

Restrictions must be less resource intensive to prepare. It will reduce burden on the already active States and might encourage more to initiate the process. The necessary changes to Art. 68.1 are detailed below. They are part of a coherent risk management approach together with Art. 68.2 and the authorisation regime (see the other two briefs on Demand #3). The proposed changes rely on the wealth of knowledge developed in the last years on what has bogged restrictions down. They aim to:

Set the end-goal

Include an explicit common goal to eliminate the most hazardous chemicals, starting with a time-bound target for substances that could be used by consumers, and rooted in the fundamental right to a clean, healthy and sustainable environment.

Equip the dossier submitter with the information needed

Strengthen the existing way to get information from the companies:

- More targeted registration requirements, especially for the most hazardous chemicals.
- New obligation for downstream users to notify information on use (quantity, function, alternatives, etc.) triggered by new entries to the Register of Intentions or the Candidate List.

Create new avenues to get accurate information

- Dossier submitter has the power to address a request for information to companies and their associations (which have an obligation to answer within a set deadline).
- Creation of a mechanism for a third party to address evidence of high concern to authorities.

Treat the same issues with the same severity

Having different processes to restrict hazardous chemicals (Annex XIV, Art. 68.1 and 68.2 restriction) allows for decisions to be initiated by different actors, and for the decisions' speed and process to fit better the issues at stake. However, the difference in the processes cannot result in a situation where justifying the restriction of a similar situation – for example the use of the most hazardous chemicals – is made much harder under Art. 68.1 than the other processes. It is an undue barrier to a legitimate action launched by the Member States, or the Commission, and a waste of resources for the dossier submitter.

There should be the same burden of proof (presumption of unacceptable risk) across all processes to justify the regulation of carcinogens, mutagens and reprotoxic substances (CMRs), endocrine disruptors (EDCs), persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), very persistent and very mobile (vPvM) in consumer and professional uses across processes, as they can be tackled under Art. 68.1, 68.2 or Annex XIV. A non-rebuttable presumption of risk must apply to those substances when they could be used by consumers or professionals (no exposure assessment needed). A rebuttable presumption of risk applies to the same system in industrial uses.

There should also be a coherent approach to derogation and transition periods in terms of what can justify them, length, obligation to minimise and monitor emissions and scrutiny (see Demand #4 brief for full details):

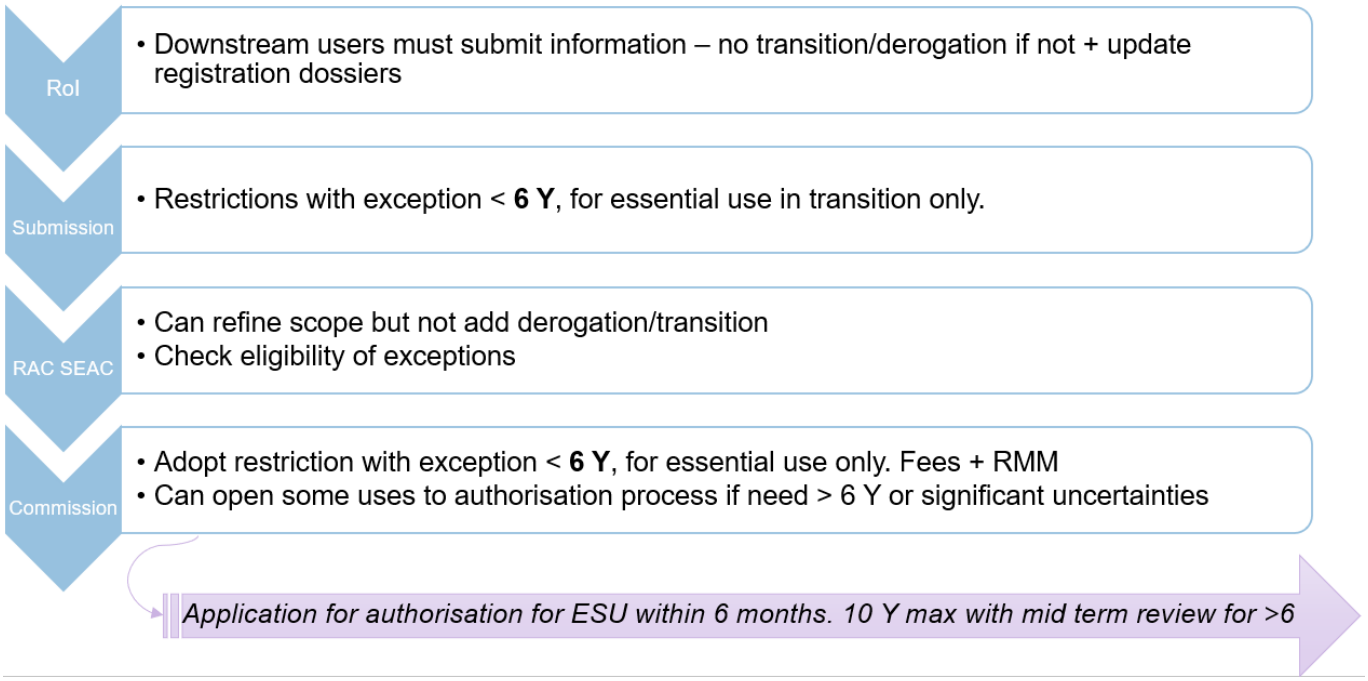
- **When the substances' properties are not the most harmful**: full discretion given to the dossier submitter, as today.

- **When the substances' properties are the most harmful**: the dossier submitter has the power to sort out essential and non-essential uses (on the basis of the new notifications from downstream users as well as their power to ask questions to relevant stakeholders). ECHA may consult with the Member States and the Commission in CARACAL when preparing a dossier. The dossier submitter must then:

    - apply the same principle applying to Art. 68.2 exceptions to the substance on its own, in mixtures and in products that could be used by professionals or consumers (see annex, and our paper "Demand #4: A coherent approach to acceptable use of the most harmful substances");

    - adopt a transition period of no longer than 10 years for other essential uses, and send the uses requiring more than 6 years to transition, or with significant remaining uncertainties, back to the authorisation process.

This is how the system could look:



Lighten the burden of proof for dossier submitters under Art. 68.1

- A more flexible **trigger** for regulation (unacceptable risk only rather than inadequate control), for a more effective process.
- Explicit **preference for broad restrictions** in the text (grouping, read across, cross-sectoral uses), with **enabling provisions for precautionary measures.**
- Decouple the restriction dossier and Annex I REACH, for which the dual role of restriction and registration did not work, by giving to the dossier submitter **more leeway on which risk assessment steps to follow, and requiring a less granular assessment overall.**
- **Re-focus the role of the Committees on support rather than censure**, and on the scrutiny of the proposed derogations. Clarify the difference between the role of the Committee for Socio-Economic Analysis (SEAC) and the role of the Commission, and the respective roles of the Committee for Risk Assessment (RAC) and SEAC.

Speeding up the final stage

Obligation for the Commission to publish its proposal and present it to CARACAL or the REACH Committee (depending on the procedure) within 5 months of the opinion, and to adopt the final decision within 12 months. Exceptionally, an extra 5 months may be used in the case of extreme complexity. The delay must be explained and justified at CARACAL.

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