ClientEarth

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Demand #3 for REACH reform

Expanded, fast-track restrictions

The Chemicals Strategy for Sustainability (CSS) commits to protect consumers, vulnerable groups and workers from the most harmful chemicals – the ones that cause cancers; gene mutations; that affect the reproductive, respiratory, immune, nervous or endocrine systems; are persistent and bioaccumulative or persistent and mobile; or toxic for a specific organ. And if the EU institutions and States have the tools they need to ban these chemicals from consumer and professional uses, then the level of protection will considerably increase.

But the existing tools are not fit for the job. The normal restriction process is too slow - between January 2011 and March 2022, an average of around 2.5 restrictions per year were adopted using the normal restriction process, falling short of the 11 restrictions per year predicted at the time of REACH's adoption.[1] The fast track restriction is opened only to carcinogens, mutagens and reprotoxic substances (CMRs) – just a small fraction of the most harmful substances we know. Even then, it has barely been used for substances in products – only two were adopted since REACH came into force.[2] The restriction of CMRs on their own and in mixtures available to the general public is the only one that has worked fairly well – it takes one year on average to complete them.[3]

Therefore, the fast-track restriction process must become a more central piece of the REACH risk management armada, by expanding immediately the ban of hazardous substances on their own and in mixtures available to the general public, by expanding the Art. 68.2 mandate to more hazard categories and to professional uses, and by ensuring that the mandate and the process guarantees that the Commission will indeed use this process to ban the most harmful chemicals from products.

[1] Impact Assessment submitted to the Regulatory scrutiny board, 11.
[2] 33 CMRs in textiles – entry 72 Annex XVII and 3 PAH in consumer articles, entry 50 Annex XVII.
[3] Entries 28-30 Annex XVII.

Directly expanding the ban of hazardous substances and mixtures available to the general public

Substances on their own and in mixtures are expected to lead to high human exposure and emissions to the environment, as recognised by the impact assessment submitted by the Commission to the Regulatory Scrutiny Board.[4] The Chemical Strategy also recognises that the simpler, generally faster approach which also provides the clearest signals for all actors to innovate is to ban these most harmful chemicals – with exception for essential uses.[5]

Entries 28-30 of REACH Annex XVII listing restrictions established a legal regime for substances and mixtures available for the general public, with a full ban and a few exceptions (fuels and matters covered by other regulations such as cosmetics).

The co-legislator could directly expand these entries – rather than allowing the Commission to do it a few years later - currently limited to substances submitted to a harmonised classification as known and presumed CMRs (category 1 A and 1 B) under Regulation CLP 1272/2008, to:

- Endocrine disruptors for health or the environment on the REACH Candidate List or classified as such under the revised Regulation CLP 1272/2008;
- Persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), very persistent and very mobile (vPvM) on REACH Candidate List or classified as such under the revised Regulation CLP 1272/2008;
- Specific target organ toxicity category 1 classified as such under the revised Regulation CLP 1272/2008;
- Respiratory sensitisers category 1 on the REACH Candidate List or classified as such under the revised Regulation CLP 1272/2008.

The Commission would have one year to list the relevant substances in the new appendices created for this purpose. In addition, for this expansion to become effective the legal mandate of Art. 68.2 needs to be expanded with regard to the new hazards.

Expanding the mandate to adopt fast-track restrictions

The mandate granted to the Commission by Art. 68.2 is currently limited to substances that meet the criteria for carcinogens, mutagens and reprotoxic categories 1 A and 1 B on their own, in mixtures or in articles that could be used by consumers. It needs to be extended to:

- **Substances** that meet the criteria under the revised CLP Regulation 1272/2008, or are on the REACH Candidate List for:
    - CMR category 2
    - Endocrine disruptors category 1 and 2

[4] Annex to the Impact Assessment, p. 488.
[5] COM(2020) 667, 9.

- PBT/vPvB and PMT/vPvM
- Specific target organ toxicity category 1 and 2
- Respiratory sensitisers category 1 and 2
- Substances affecting the immune and neurological systems

The Commission might not always include category 2 substances in the future restriction. But it is relevant to design the mandate broad enough to allow the Commission to adopt measures to address category 2 substances, which might be necessary precautionary measures, considering the high concern connected to the hazard categories involved and the vulnerability of consumers and professionals. The precautionary principle underpins the REACH Regulation as per its Art. 1.3, but as recognised in REACH review studies, has never been actively used in restrictions. To make it happen, the mandate of the EU institutions and States need to allow them to adopt precautionary measures (which includes adopting measures to address category 2 substances, and beyond).

The Commission has considered to rewrite Article 68.2 to refocus its scope on the substances that are submitted to a harmonised classification under the CLP Regulation, instead of the more inclusive terminology applying today to a substance that "meets the criteria for" the relevant hazard categories. Such re-writing would be an unacceptable step back, a narrowing of the Commission's mandate that will prevent its capacity to be responsive to scientific and practical knowledge.

- **Professional uses**

Professional users are frequently exposed to the most harmful chemicals during their private and professional life, during long periods of time and sometimes without proper protection or training.[6] They are therefore often more at risk than consumers, with intersectionality considerations further deepening the need for the expansion.

- **Groups of substances**

REACH must strengthen the mandate of the Commission by indicating an explicit preference for group approaches, and allowing the assessment techniques that make it possible (read-across, etc.).

Ensuring that the fast-track restriction will be used

A non-exhaustive list of reliable sources deemed acceptable to conclude the hazard assessment

Art. 68.2 does not limit the mandate of the Commission to the substances that have already been placed on a regulatory list (be it the REACH Candidate List or harmonised classifications under the CLP Regulation). The Commission has, however, exercised its mandate as if this limitation existed. The text should include a non-exhaustive list of sources the Commission may use to justify a restriction, including:

[6] See the Impact Assessment, 11.

- REACH Candidate List
- Self-classification by companies under the CLP Regulation as recorded in the C&L inventory hosted by ECHA
- Harmonised classification under the CLP Regulation
- Other restrictions under International law, EU law or law of other countries (a practice done for example by Safer Consumer Products Regulations in California, that refer to the REACH Candidate List).

Open the initiation to the Member States

The Commission and the Member States share, under REACH, the responsibility to initiate the elimination of the most harmful chemicals – they should share the power to initiate the process supposed to be the quickest and least resource intensive.

Creating a commitment for the Commission to use its mandate

As detailed in our Demand #1, REACH should make explicit the objective of its risk management process – the elimination of the most harmful substances, with a timebound commitment to eliminate exposure from consumer products and products used by professionals. This objective – and commitment – should be anchored in the fundamental right to a healthy environment, of which a precondition is the effective right to a non-toxic environment.

To implement this commitment, the Commission must be obliged to review the restriction roadmap, with specific commitments for fast-track restrictions. The roadmap must be submitted to an annual review after discussion in CARACAL.

Get better information on use to ease the process

It is harder to regulate without understanding the real uses of the most harmful substances. This is why additional improvements are needed:

- New obligation for **registrants** to update their registration dossier when the Commission or Member States register their intention to launch a restriction (Registration of Intention/RoI) or when a substance is placed on the Candidate List.
- New obligation for **downstream users** to notify information at the RoI stage or after candidate listing (information on use and exposure patterns, risk management measures, emissions or exposures as well as alternative and substitution efforts) – see brief for our Demand #2.
- New power for the Commission (or via ECHA) to ask questions to any relevant stakeholders (companies and their associations for example) on any topic relevant to the regulatory action planned.
- A failure to provide information should lead to the exclusion of the companies from any future derogation/ exception and in some context leads to fines.

Specification on rules for exceptions to ease the process

See the brief for our Demand #4 that covers what the system should look like for Art. 68.2.

REACH 2 is an opportunity to adopt a more coherent and legitimate approach to allowing the continued use of the most harmful chemicals, by relying on a set of common principles:

- get information on use early,
- continued use, production and sale are acceptable for essential use only,
- the longer the exception, the harder it is to obtain,
- exceptions are controlled, monitored/tracked, and
- exceptions are submitted to a fee.

Art. 68.2 restrictions may apply to substances on their own, in mixtures or in products. The rules applicable to exceptions must adapt to the difference in potential use and exposure patterns related to these uses.

Substances and mixtures

Substances and mixtures for supply to the general public: the restrictions of CMR in substances and mixtures are currently handled by entries 28-30 of Annex XVII. The only exceptions are the uses and properties already ruled by another legislation (medicinal and cosmetic products), fuels (essential uses) and artists paint (on the edge of professional and personal use).

The same regime should continue to apply, with adaptations, for the substances and mixtures that could be used by consumers and that have the properties newly added to Art. 68.2. The current exclusion for medicinal and cosmetic products however should be limited to health concerns, as environmental concerns are not covered by these regulations. A 1 year grace period could be considered.

Substances and mixtures for supply to professional users: entry 28-30 needs to be expanded to professional users. The adaptations listed above for consumer use apply. However, it is important to consider that professional uses might entail essential uses in need of a longer transition period. A provision could be added to allow the Commission to grant a transition period of maximum 3 years for essential uses.

Substances in products

Substances in products for supply to the general public: there should in principle be no exceptions to the ban of the most harmful substances in products. The scope however can be set in a way that recognises that the issue is already handled by another sectoral law – for example, if a restriction of CMRs in products is adopted, the scope should mention that toys are not covered because the law applicable to toys already tackles this issue. A 1 year grace period may be allowed.

Where the substance is indispensable to the existence of a product that is critical to health, safety or the functioning of society, an exception of no longer than 3 years may be considered if the information submitted after the Registration of Intention, candidate listing or obtained by ECHA (upon request by the Commission) after asking direct questions to relevant stakeholders is sufficiently precise and conclusive to establish that there is no emission throughout the entire lifecycle.

Substances in products for supply to professional users: exceptions may be allowed for a maximum of 3 years where the substance is indispensable to the existence of a product critical to health, safety or the functioning of society. Exceptions may be allowed for the concerns already handled by other EU sectoral laws

Safety relief valve – emergency authorisation: the Art. 129 "safeguard clause" is currently limited to granting Member States the power to adopt emergency restrictions of the use of hazardous chemicals. In order to soothe the concerns of incapacity to answer an emergency need for a hazardous chemical, a provision allowing the Commission to grant an exceptional and short term authorisation could be added – if special circumstances characterised by an unpredictable, unavoidable and external (due to context) threat to human life or wildlife may occur that is serious, certain and imminent. An obligation to monitor and review should apply.

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