ClientEarth

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Demand #4 for REACH reform

A coherent approach to continuous use of the most harmful substances

REACH 2 is supposed to create easier processes to phase out the most hazardous (groups of) substances, and if the new legal regime is successful, the transition towards safe and sustainable chemistry will happen much quicker, making the EU a world leader.

But the success of the new regime will be determined by how demands and needs for exceptional continuous use will be handled. Because chemical substances rarely have only one use, which means that banning them requires a lot of resources to decide on the acceptable exceptions. A balance needs to be struck between the need to incentivise substitution, by strictly screening which exceptions are legitimate, and the limited resources of public authorities to do so. Today, the approach to exceptions does not meet this need because it manages to be both too lenient and too resource intensive for public authorities. This situation is mainly due to the way the text was implemented, but the system built in REACH was conducive to these practices.

Therefore, a better balance must be enshrined in REACH, by creating a coherent approach to exceptional production, sale and uses of the most hazardous substances across all REACH processes, based on the common principles that they should be short, controlled and critical to society.

In this paper we explore why a change is needed, detail the principles on which the new approach must be built and explain what the application of these principles to each process (REACH authorisation, fast-track restriction and normal restriction processes) would look like.

Why is a change needed?

Exceptions to restrictions of the most hazardous substances are granted today across all REACH risk management processes – Annex XIV “authorisations”, as well as derogations or transition periods under the normal restriction process (Art. 68.1) and the fast-track process for consumer use (Art. 68.2).

They are today both too lenient and too resource intensive to handle. The reasons why are explored below.

Lack of access to critical information

When public authorities lack visibility and understanding of the "real life" of the substances – the use patterns, tonnages, conditions of use, emissions and exposure - it considerably increases the resources needed to regulate, and plays in favour of illegitimate requests for exceptions. Unfortunately, such a gap still exists in REACH. Information asymmetry between companies and public authorities is still a reality when it comes to where, why and how substances are used (and in what quantities). Because alternative providers rarely bring information to the table, to preserve commercial relations,[1] they also lack visibility on safer substances or techniques available. Finally, the overreliance on the data submitted by companies interested in continuous use also creates issues.[2]

Burden of proof

REACH authorisation

The authorisation process was supposed to ease the work for EU institutions and States by placing the burden of proving that an exception should be granted on the companies asking for it. However, this reversal of the burden was mostly ignored by the main actors, under the leadership of the Commission. This was sanctioned by the European Court of Justice, which rightly saw as illegal authorisations granted when the application did not manage to prove that the conditions were fulfilled,[3] or simply did not contain the minimum information required.[4] The leniency in turn increased the resources monopolised for authorisation, as applications that lack information to a critical point are not excluded upfront.[5]

REACH restriction

Member States and ECHA have struggled with the burden of proving that a restriction is necessary, which weighs especially heavy on the selection and design of exceptions.[6] This has led to excessive exceptions, for example the excessive transition time for cosmetics in the Commission's proposal for microplastic restriction[7] or the derogation of the main sources of emissions in the terphenyl restriction currently under consideration by ECHA.[8]

[1] See ClientEarth and ChemSec report "How to find and assess alternatives in the authorisation process" covering this topic.
[2] Ibidem.
[3] T-837/16, Kingdom of Sweden v European Commission, ECLI:EU:T:2019:144, appealed by the Commission (C-389/19).
[4] The case is not final, but the Advocate General was adamant - Case C-144/21, European Parliament v. Commission "Chemservice", ECLI:EU:C:2022:846.
[5] See as recent examples: the Gruppo Colle application and Ilario Ormezzano Sai Spa application for authorisation for the use of sodium dichromate as mordant in wool dyeing.
[6] For example, the Commission decided not to support France's proposal to restrict hazardous substances in baby diapers due to uncertainties related to the risk, despite the impossibility to rule out the risk (RAC opinion) and the particular vulnerability of the population targeted. See: Health and Environment Alliance | Restriction on harmful chemicals in single-use diapers: an opportunity to protect children's health that Europe is on the verge of missing (env-health.org)
[7] EU Commission proposal for a restriction of synthetic polymer microplastics - Comitology Register (europa.eu). See the reaction from the microplastics-free cosmetics industry: Statement 0Brands (rethinkplasticalliance.eu).
[8] Annex XV Report for terphenyl, hydrogenated - c0cb9178-9bc7-b4f3-1c25-0fda75b81fb1 (europa.eu).

Other issues specific to REACH authorisations

The way the REACH authorisation regime was built caused other issues. For example, some situations suffered from not targeting all the relevant actors at the table. This is the case when powerful buyers (for example, car producers) request from their suppliers the use of the restricted substance – either explicitly or as a consequence of the performance required. The open possibility to ask for renewal creates an incentive to prolong the derogation, and extra work for public authorities.[9] Finally, requests are treated individually, which means their additional impact is not addressed.

Making it work – principles common to all processes

1. Burden of proof – get better information on use, earlier

It is much harder to regulate without visibility on the real life of the most harmful substances. This is why there is a need for:

- A new obligation to notify information at the Candidate List and Registration of Intention stages (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.
- A new power for ECHA and the Member States (as dossier submitters) to ask questions to any relevant stakeholders (companies and their associations, for example) on any topic relevant to the regulatory action planned.
- Rules specifying that a failure to provide information leads to the exclusion of the companies from any future derogation or exception and in some contexts, leads to fines.

2. Continuous production, sale and use is acceptable for essential use only

Continuous production, sell and use of the most hazardous substances must become rare

The production, sale or use of the most hazardous substances must be treated as unacceptable by default. This is indispensable to the respect of people's right to a non-toxic environment, a precondition of the right to a healthy environment, which we propose to integrate to the core of REACH (see brief on our Demand #1) to strengthen the current situation where fundamental rights are only referred to in recitals. It is also necessary to the fulfilment of the Chemicals Strategy for Sustainability's promise to eliminate all non-essential uses of these substances, which we propose to integrate as a goal of the REACH risk management processes (see brief on our Demand #1). As a result, exceptions must be rare and legitimate.

[9] See for example the case of trichloroethylene: REACH authorisation and the substitution of hazardous chemicals: The case of trichloroethylene - ScienceDirect.

Only essential uses

The most hazardous substances may provide many functions, but it is only when they bring a critical service to society that their continuous production, sale and use can be seen as acceptable. The criteria defining essential use set by the Montreal Protocol are a great starting point:

- The use of the substance is necessary for health, safety or critical for the functioning of society, for example is necessary for sustaining basic conditions for human life and health,

  and

- Its function has no technical or chemical alternative acceptable from the standpoint of environment and health. For example, the use of microplastic in shampoo cannot be accepted because shampoo exists – and washes hair - without it.

A guidance could flesh out these criteria by specifying what “necessity”, “criticality” and “alternative” mean. Importantly, both the technical function of the substance and the service provided to society by the product or process relying on the substance must be taken into account. For example, a highly hazardous substance may be used for coating materials if it is required for the durability of an outside facing plane piece, but not to have shiny handles within the plane. For more details, see our brief on essential use.

The burden of proof should be on companies

Because continuous business in the most hazardous substances is unacceptable by default, the onus must be on the companies to prove that an exception is warranted. It means that:

- EU institutions and States have a clear mandate to reject a request for exceptions.
- Companies that desire an exception must provide complete, accurate and precise information to public authorities, in a timely way (see brief on our Demand #2):
  - Registration dossiers must be complete and updated.
  - At the beginning of the regulatory process (after entry on the Candidate List for authorisation, at the entry on the Registry of Intention for restrictions), downstream users are obliged to communicate detailed information to ECHA on the function, condition of use, exposure patterns, quantity used and alternatives.

If these obligations are not met, companies may not be granted or benefit from the exceptions.

Alternative assessment - acceptable costs and loss of performance

The analysis of the substitution efforts should focus on what is the earliest point at which the substitution can happen. This question better reflects the constant development of alternatives and the ability of regulatory and market drivers and incentives to accelerate the substitution process.

Availability: the availability of alternatives should not be focused on the specific companies' possibilities for substitution. If substitution has occurred already for some in similar applications, the user is under a higher burden of proof to justify the continuous use.

Technical availability: the focus should be on the preservation of the end use (function of the process or product) rather than the technical function of the chemical in the process or product. The former allows to

consider the absence of the need for the technical function, and the existence of a technical alternative when the latter encourages a chemical alternative with precisely the same performance only. A common understanding of what is an acceptable loss of performance (and acceptable evidence to prove it) must be set. On what the criteria for an acceptable loss of performance could be, see our brief on essential use.

Economic availability: take into account that alternatives might be more expensive but will most likely become less expensive if the original chemical is banned or restricted and as scale of alternatives increases or incentives are in place. The system must recognise that an increased cost is acceptable.

3. The longer the transition period, the harder they are to obtain

The entire system should be set so that every part pushes towards the quickest transition to a safe and sustainable solution. In practice it means that:

- Exceptions should never be for longer than 10 years, and should be submitted to a mid-term review when over 6 years.
- The shorter the transition, the less strict the scrutiny should be. The longer, the stricter. That should create incentive to ask for shorter transitions.
- A fee must be paid, growing over years, to incentivise transition and finance substitution activities.
- Exceptions should be avoided when the use pattern, because of direct contact or because of its presence in high volumes of material, justifies an assumption of emission, exposure or contamination across the life cycle, for example:
    - A very hazardous substance on its own, in a mixture or in a product that could be used by consumers must not be allowed for longer than a 1 year grace period. This is particularly important for fast moving goods, which have a high rate of change and/or high volumes. When they could be used by professionals, the transition must not be longer than 3 years.

4. Exceptions are controlled and submitted to fees

- The user must minimise emissions and exposure as much as possible considering best practices, which means applying a closed system when possible.
- It must monitor emissions and exposure, track presence and report them.
- Continued use of the most harmful chemicals is submitted to a growing fee.

5. Safety relief valve – emergency authorisation

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

Application of the principles for REACH's fast-track restriction (Art. 68.2)

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

Supply to the general public

The restrictions of carcinogenic, mutagenic and reprotoxic (CMR) chemicals in substances and mixtures is 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.

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

Supply to the general public

Exceptions must not be allowed in principle beyond the exclusion of the concerns already handled by other EU sectoral laws. A 1 year grace period may be allowed.

Where the substance is indispensable to the existence of a product itself 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, 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.

Supply to professional users

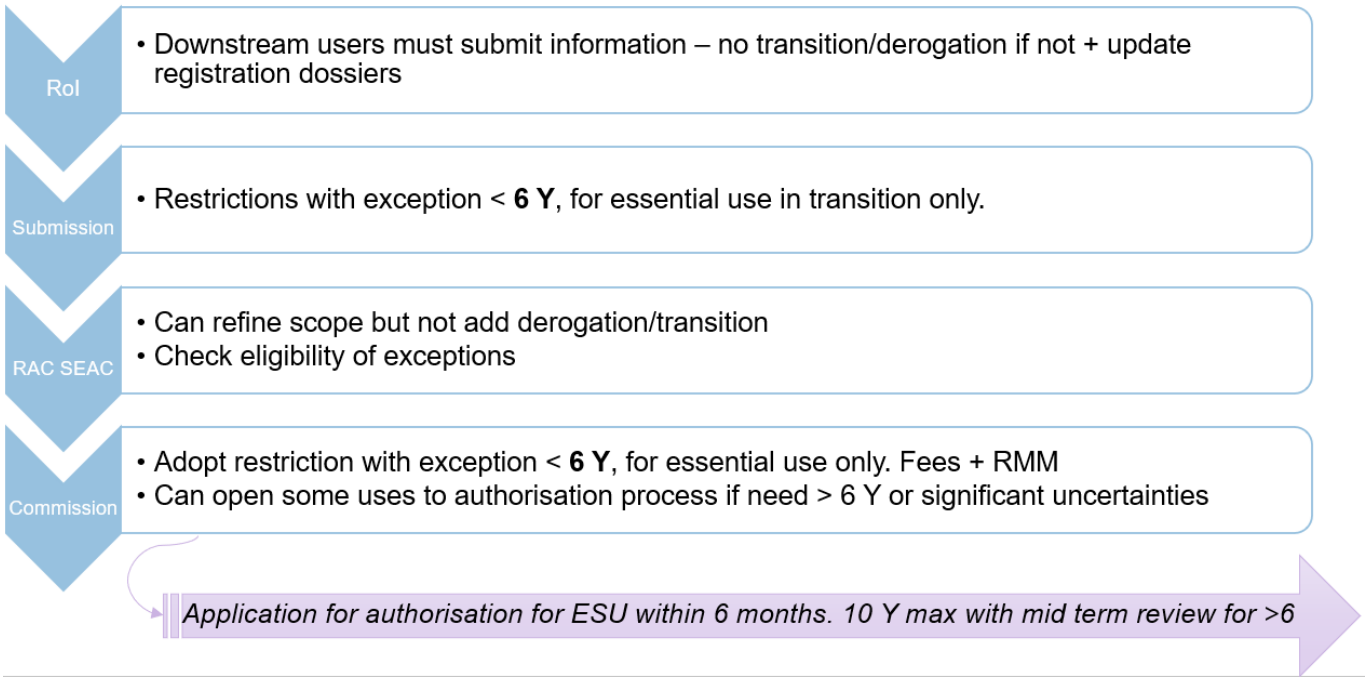
Exceptions may be allowed for a maximum of 3 years where the substance is indispensable to the existence of a product itself critical to health, safety or the functioning of society. Exceptions may be allowed for the concerns already handled by other EU sectoral laws

Application of the principles for REACH's normal restriction process (Art. 68.1)

The dossier submitter has the power to sort out essential and non-essential uses, on the basis of the new notifications from downstream users (see brief for our Demand #2) as well as their power to ask questions to relevant stakeholders (see brief for our Demand #3). 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 to a substance on its own, in mixtures and in products that could be used by professionals or consumers as the Art. 68.2 exceptions described above
- adopt a transition period no longer than 10 years for other essential uses, and send back to the authorisation process the uses requiring more than 6 years to transition, or with significant remaining uncertainties,.

This is how the system could look:



Application of the principles for REACH's Annex XIV restrictions (authorisations)

The whole system should be an **incentive to substitute as early as possible** by changing it so that:

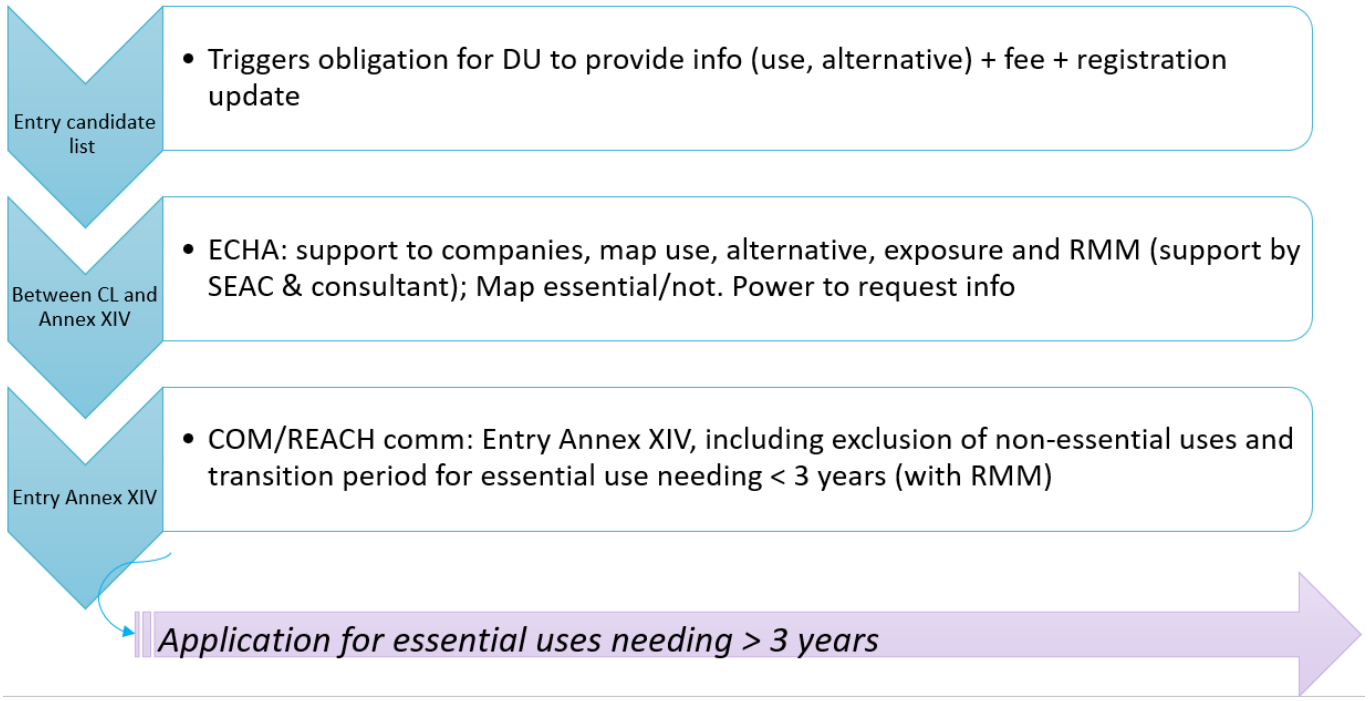
- Substitution efforts and discussions start from the Candidate List (which also allows public authorities to not be solely dependent on the applicant's data).
- Authorisations are for 10 years maximum and are non-renewable.
- The Commission can use the decision placing the substance of very high concern (SVHC) on Annex XIV to directly grant authorisations for essential use bridging towards an alternative, for no

longer than 3 years. The suppression of the need to ask for an authorisation should incentivise the request for shorter transitions.

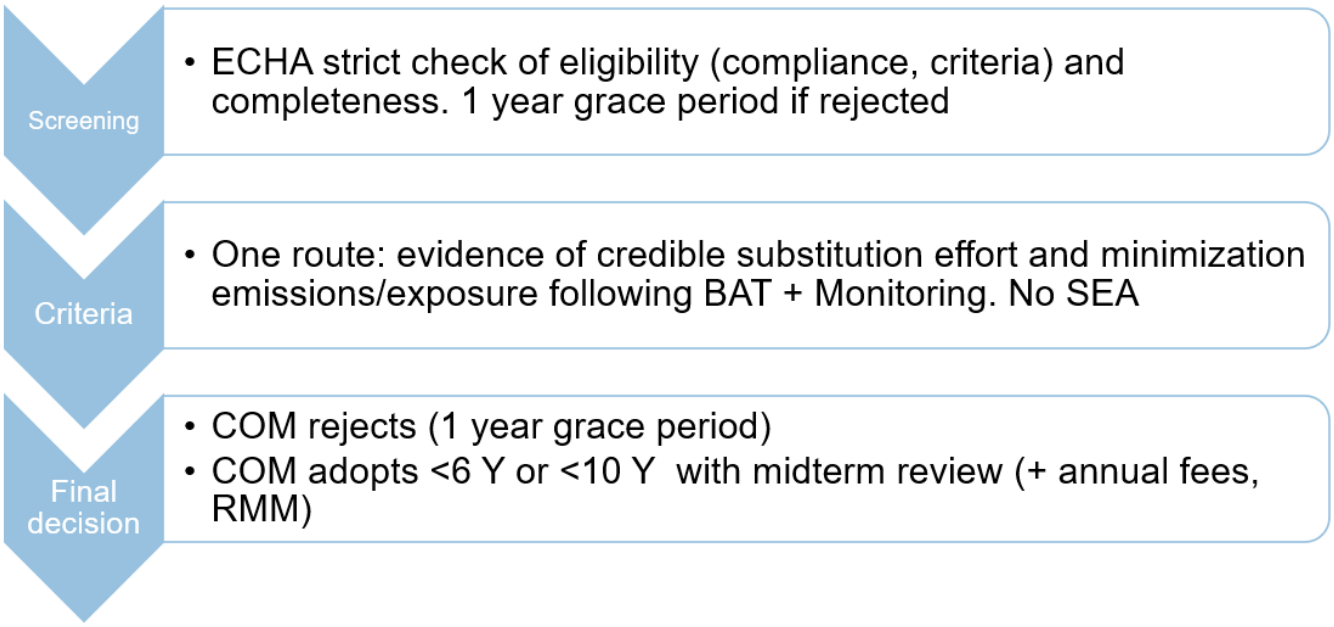
- Only critical uses should be allowed, which involves a change in the criteria for eligibility (only one route to apply – critical use with minimised exposure and emission and a credible substitution plan). To ensure that the criteria are met without too many resources spent on screening, three filters are created to limit the number of cases for which a full assessment is needed:
    1) The Commission excludes identified non-essential uses in the Annex XIV decision
    2) ECHA staff screen the eligibility of the use. Which includes matching the criteria, but also having sufficienty granular information in the application, as well as having complied with the obligation to send information upon entry into the Candidate List.
    3) SEAC members check the credibility of the substitution plan, in light of the information collected on the availability of alternatives.
- Fees attached to use should grow over time, to incentivise quicker substitution.
- Authorisations are submitted to risk management measures enabling the minimisation of, and an obligation to monitor, exposure and emissions (and report on the results).

Steps of the processes

Filter out non-essential use before applications are made



A smoother and stricter screening process from the application



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