ClientEarth

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Demand #3 for REACH reform

Boost the impact of the Authorisation title

The authorisation title organises a decision-making process in three steps.

First step: a signal to companies that substitution must happen for the substances placed on the "Candidate List". Second step: setting a date by which all uses must be eliminated, and a date before which requests to continue using the substance (authorisation) must be submitted. Third step: a screening of the requests, placing the burden of proving that continuous use is acceptable on the companies doing the demands. This, and the early signal sent by the Candidate List, was supposed to save public resources by having few authorisations, and making decisions easy to take.

But the goal has only partially been met. The Candidate List was successful as a signal to substitute, and this must be preserved and strengthened, by easing the identification of substances of very high concern (SVHCs) and ensuring that Annex XIV becomes an even stronger incentive to substitute.

However, the authorisation title failed to handle appropriately the application cases where substituting was indeed complex, or where the applicants refused to follow the frontrunners. This is mainly because this reversal of the burden was mostly ignored by the main actors, under the leadership of the Commission. Applications that lacked critical information were not excluded upfront[1] and were actually granted. This was sanctioned by the European Court of Justice.[2] This wrongful implementation of REACH resulted in a system that manages to be both too lenient and too resource intensive for public authorities. Therefore, changes are needed to strike a better balance, by ensuring that public resources are spent only on the cases presenting true difficulties rather than struggling to finish a decision process unable to manage unfit applications.

[1] 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.

[2] Which rightly saw as illegal authorisations granted when the application did not manage to prove that the conditions were fulfilled - T-837/16 , Kingdom of Sweden v European Commission, ECLI:EU:T:2019:144, appealed by the Commission: C-389/19) or simply did not contain the minimum information required - 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.

Ease the identification of SVHCs

Why?

Art. 57 lists several properties deemed to be of very high concern, and finishes with a safety net – the substances that are of very high concern because they are "of equivalent concern" as the ones listed, specifying that endocrine disruptors are such substances of equivalent concern to identify case-by-case. More properties need to be added to the explicit list, to save the burden of proving the equivalency,[3] and to reflect the new developments under the CLP Regulation.

How?

The substances should be added that meet the criteria for classification under Annex I to Regulation (EC) No 1272/2008 with the following properties: persistent, mobile and toxic (PMT), very persistent and very mobile (vPvM), chemicals with endocrine disrupting properties (EDC) category 1A or 1B, and substances meeting the criteria for classification as a respiratory sensitiser category 1.

In order to reflect the Chemical Strategy for Sustainability's (CSS) promise to start progressing on immunotoxics and neurotoxics, the equivalent concern clause should be re-written as follows:

(j) substances — such as those having immunotoxic or neurotoxic or ozone depleting properties or which do not fulfil the criteria of points (a) to (i) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (i) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

Expand the role of the Candidate List

Get visibility on market practices

Why?

The work of EU institutions and States has been made considerably harder by not having visibility on market practices, because of key information gaps regarding use patterns, tonnages, conditions of use, emission and exposure. It created barriers to moving substances in Annex XIV (the "authorisation list"), for fear of an avalanche of applications for unforeseen uses.

At the authorisation stage, this gap trapped authorities into an overreliance on the applicants' information. The hope in REACH 1 was to have alternative providers bring information during the process that would break this overreliance. But it happened rarely, because the adversarial nature of the REACH authorisation

[3] Which is a case-by-case approach and therefore more resource intensive as well as susceptible to challenge, as showed by the two cases brought by PlasticsEurope (C-119/21P and C-876/19P) against the identification of BPA as an EDC for health and the environment, or the case brought by Chemours for the identification of GenX (See T-636/19 appealed in C-293/22P) as a PMT.

process placed alternative providers in a sensitive situation vis-à-vis current or potential clients.[4] Registrations were also supposed to bring light on use, but they did not because of vague requirements and poor information flow from users to manufacturers, importers and sellers.

This can be solved by attaching information obligations for downstream users to the Candidate List.

How?

For more details see our Demand #2.

Obligation to update registration dossiers upon entry to the Candidate List and information obligation for downstream users: REACH 2 needs to obligate downstream users to report their use of an SVHC within 8 months of entry onto the Candidate List, with specific information requirements covering at least:

- Sector(s), with differentiation according to market structures of DU sectors;
- Function(s) of substances in products and preparations;
- Product category(s) and function, with sub-category(s) by application;
- Process category(s) and function, with sub-category(s) by application;
- Article category(s) and function;
- Societal function of end use (product, process or article);
- Intended transformation (if intended to transform);
- Information on production, import and export volumes - total volume per use, including product categories and total intermediate use;
- Substitution plans including efforts done plus planned and potential alternatives;
- Specific information on risk management measures in place and remaining exposure or emissions.

Failure to meet this obligation would exclude companies from the right to apply for authorisation. On this basis ECHA would be charged to map the uses and identify which might be critical without alternatives.

Right for ECHA to request information: any actor in the supply chain of a substance, mixture or article containing a SVHC as well as their competitors or association have the duty to answer questions on properties, use, function, exposure, potential alternatives and any other information necessary to fulfil the aim of the authorisation title

Create a financial incentive by obliging users of listed SVHCs to pay a fee growing over time. That fee could support their substitution activities.

Ensure transparency on the use of SVHCs to customers, consumers and third parties by clarifying the scope of Articles 33 and 66.

[4] For the full picture on why alternative providers do not contribute, but also on how their contributions were ignored when they did happen, see How to find and analyse alternatives in the Authorisation Process – ChemSec

Bring forward reflections on substitution

Why?

Because the authorisation process is adversarial, it is not prone to an ambitious and holistic alternative assessment by the companies. Their goal, as per the process, is to prove that there is no alternative. The situation is however rarely black or white, and bringing forward the assessment would help to have a more credible picture of the substitution opportunities – that gives an idea of the situation for specific companies, but more importantly at societal level as well. Creating a space for this discussion also matters because the authorisation process does not always allow to have all the relevant actors at the table. For example, the user might be a small or medium company providing a product or material upon the rigid specifications of a powerful customer (let's say the car industry). The actor submitted to authorisation has in this case very little leeway on what could be a lower acceptable performance. They also might not have the skills to develop an alternative.

It might be fruitful to create spaces for these discussions, with all relevant actors – including customers and alternative providers.

How?

Budget: the use of a SVHC must be submitted to a fee, that would fund ECHA's work post-entry in the Candidate List

Facilitation: ECHA could have a role, or another solution could be the creation of substitution centres and networks, inspired by the model of the Massachusetts Institute TURI. Substitution support centres could support authorities preparing restriction dossiers with the alternatives assessments as well as support companies in finding, assessing, and adopting alternatives, including convening whole sectors or users of candidate chemicals to expedite the substitution process. This would include bringing alternative providers more systematically to the table and making sure their views and data are taken into account.

An easier transfer to Annex XIV – more power to the Member State Committee (MSC)

Why?

The entries to Annex XIV have been fewer, and less important. This is partly because of the fear of the burden caused by many applications. The changes to the process aim at alleviating this concern, but in addition it is preferable to not leave the decision solely to the Commission.

How?

Currently, ECHA proposes substances for listing after a discussion at MSC. The final decision is then taken by the Commission, under the comitology process. We suggest that when a majority emerges at MSC on an entry, the Commission is under the obligation to add it in an accelerated pace. The Commission should also be obliged to update Annex XIV annually.

Increase the incentive created by Annex XIV

All the changes below have the same goal – fixing the current situation where the process is both too lenient and too burdensome. It aims at excluding quickly unacceptable uses, so that resource intensive full scrutiny is reserved for the cases that are truly in need of it, and at making the decision-making process easier.

Expand the role of Annex XIV decisions – exclude uses and give bridging authorisations

Today, Annex XIV decisions do the following:

- Enact the entry of (a) substance(s) of very high concern in the authorisation list;
- Set an application date - the deadline for companies to apply for authorisation;
- Set a sunset date, the deadline for all companies that have not applied to stop using the substances listed.

In the current system, it would be hard for these decisions to do more, as information gaps obscure visibility of market practices. But the new information obligations we recommend to attach to the Candidate List would solve this issue. Equipped with the knowledge of the uses and their conditions, the Commission – and the Member States, via comitology – could do much more with Annex XIV decisions, including all of the above and:

- Identify the non-essential uses excluded from the right to apply for authorisations;
- Grant a “fast track authorisation” for identified essential uses that need 3 years or less to bridge towards a safe alternative.

Such a system could save private and public resources, by reserving the long authorisation process for the cases that truly need this depth of scrutiny. It would also increase legal certainty, and therefore the strength of the signal to transition sent by the Candidate List.

Criteria for application – one route, focused applications

Refocus the applications

Today, applications have been opened to “upstream actors” (manufacturer, seller) applying for a wide range of diverse uses. This has led to applications lacking critical information and being extremely hard to process.

Applications should be open:

- To downstream users;
- To several downstream users with similar use and condition of use (joined downstream application);
- To upstream actors but with a scope covering specifically defined and homogeneous uses.

One route only

Today, REACH authorisation relies on two "routes" – two different reasons for which the continuous use of a substance of high concern may be considered acceptable:

- Proof of adequate control of the risk to human health or the environment (not opened to persistent, bioaccumulative and toxic/PBT, very persistent and very bioaccumulative/vPvB or non-threshold substances)
- Absence of adequate control but, 1) the benefits of the continuous use for society outweigh the risks and 2) there is no alternative.

In practice though, the adequate control route was the rare exception and the socio-economic route did not work well. Applicants – logically – were neither able nor keen to embrace a real societal point of view, and the socio-economic assessment turned into an analysis of the extra costs for them connected to the transition. The criteria of the socio-economic route contributed to the partial failure and controversy around the system, as we explained in our "Socio-economic assessment and REACH authorisation report".

In addition, these two routes do not fit the new focus of the process on essential use. Indeed, the societal benefits of the continuous use are supposed to be considered in the question of criticality, something that we propose to be handled by the Commission and the Member States when the substance is placed on Annex XIV. Moreover, all essential uses are supposed to minimise exposure and emissions – if possible by using closed systems, if not by applying the best available practices for minimising/controlling emissions and exposures.

We therefore propose to simplify the system by having only one route, with new criteria:

The applicant must prove that:	1. A **closed system** or the **best available risk reduction measures** are in place – evidenced by more than the Chemical Safety Report, which is revealed too often to be too imprecise; as well as monitoring and tracking of emissions and exposure to collect and notify data; 2. There are **not yet any technically or economically feasible** alternatives;[5] and 3. There is a credible and ambitious substitution strategy, thoroughly detailed in a **Substitution Plan.**
Socio-economic factors are taken into account differently	1. The criticality of a use for society is taken into account by the Commission and the Member States when excluding non-essential uses (because they are not critical or because other products and process with the same function but not using the SVHC are available) in the decision to place the substances on Annex XIV.

[5] The analysis of economic and technical feasibility will have to change. Economic feasibility should target the affordability of the effort by the companies, the current practice that considers any additional cost compared to SVHC use as infeasible must be abandoned. On the technical feasibility, changes will also have to happen, in line with the recommendations ChemSec and ClientEarth made in their 2018 report on "How to find and assess alternatives".

2. The affordability of the substitution is taken into consideration **as part of the analysis of the appropriate length of the transition period as detailed in the substitution plan.**
3. Rejected decisions – after preliminary investigation or full analysis – are granted a 1-year grace period to soften the effects.

In practice, it means that no socio-economic analysis is needed, saving public and private resources. The current overreliance on applicants' data will be solved by the possibility for the Risk Assessment Committee (RAC) and Socio-economic Assessment Committee (SEAC) to consider the application against the information on uses, alternatives and condition of uses received from all downstream users upon entries on the Candidate List.

Screening of applications – strengthen the filter at entry

According to the system we propose above, applying for authorisation is possible only when:

- The companies involved have complied with their obligation to update the registration and submit information to ECHA after entry onto the Candidate List
- The uses are not excluded from application by the Annex XIV decision.

ECHA staff should be in charge of checking the first and second requirement before sending the application to the committees. If the requirements are not met, the Commission must adopt within 3 months a decision to reject the application, granting a 1 year grace period.

- All the information required to apply is provided

The third requirement is harder to check without a full analysis of the application, but ECHA should have the power to identify a manifest gap at this stage. A company may have one month to complete the information. Failure to do so should lead to the same consequence described above.

A broader view of alternatives

The analysis of the substitution plan should focus on identifying 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 mainly on the specific companies' possibilities to substitute. 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 a need for the technical function, and the existence of a technical alternative while the latter encourages chemical alternatives 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 the criteria for what 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.

Refocus SEAC on substitution efforts

Today, SEAC's remit covers both the analysis of substitution plans, and the scrutiny of the socio-economic assessment done by the companies. The former has worked better than the latter, and should become the focus of SEAC (with an adaptation of the composition, in order to gather more experience in the analysis of substitution efforts). SEAC's could be renamed the "Substitution Efforts Analysis Committee".

Ease the rejections – grant a 1-year grace period

Today, the rejection of an application is politically sensitive because of its immediate impact – which could be softened if the Commission was mandated to grant a 1-year grace period.

Reinforce the incentive to substitute within the system

- Authorisations must be 10 years maximum and non-renewable.
- Fees must be imposed to users, that grow over time.
- Ensure transparency on use by making mandatory the notification of key information related to use under Art. 66 (user name, country, address, use name and detailed description of use, current status, name of authorisation holder, precise volume used, number of staff, substitution activities, as well as any information which collection is required by the authorisation).
- End unacceptable delays in the adoption of authorisations

Predictability and speed are key in creating an incentive to substitute. But there are shocking delays experienced today [6] from the adoption of the opinion by the Committees, to the final decision on authorisation. A 12 month deadline post-opinion of the Committees should be imposed.

Summary – added value of the changes

The current implementation of REACH authorisation unfortunately boosted its risks – such as the overfocus on the applicants – and reduced its advantages – such as what the reversal of the burden of proof can deliver. REACH 2.0 needs to turn things around.

Advantages of REACH authorisation	**Booster in REACH 2**
Incentive to substitute early	Candidate List entry triggers:

[6] ClientEarth evidenced analysis "ClientEarth shows that the Commission takes an unreasonable time to adopt chemical decisions | ClientEarth", 2018, still relevant today.

	- the payment of a (growing) fee by users - support for substitution offered to companies, including all relevant actors in the supply chain. Increased predictability & speed - Limited discretion of Commission on entry in Annex XIV (direct listing if MSC majority, annual update) - In the final decision: deadline to avoid the shocking delays of the last years, pre-set detailed criteria and consequences, particularly for transition period (which will also simplify the debate in SEAC) No renewal of authorisation, 10 years maximum
Unveil uses, alternatives, exposure and risk management measures	Better information - Strengthened REACH registration requirements on description of use - Candidate List triggers obligation to notify uses for upstream and downstream actors (tonnage, function, use and exposure patterns, alternatives and substitution plans) to increase predictability of regulatory need and workload - Alternative providers involved in cooperative stage - Less dependency on applicant's data by having ECHA commission a market analysis (by a consultant, funded by fees on SVHC use) to identify best practices and support authorities' assessment of uses, exposure and alternatives
Risks of REACH authorisation	**Mitigation in REACH 2**
Excessive focus on situation of the applicant rather than best practice	**Information used from other sources than the applicant**: during the analysis of application for authorisation, best practice, identified grateful to the information sent upon entry on the Candidate List and any market analysis done by ECHA, is used as a benchmark of what is acceptable/feasible Third parties (including alternative providers) involved in discussions after candidate listing Power to ECHA to ask questions to any stakeholder on alternatives and uses, plus a market survey
Too many resources expended by public authorities	Limited eligibility for authorisation by adding filters: - Exclusion of non-essential uses identified by ECHA in Annex XIV decision Limited number of cases submitted to full analysis: - Annex XIV decision lists non-essential uses to exclude them from application and fast track authorisation for essential use needing 3 years or less to substitute - Strict preliminary investigation before the full analysis of application for authorisation Simplified and improved decision-making criteria: - Better quality application: collective/upstream application allowed only if it covers homogenous uses - Only one route, no socio-economic assessment and simpler criteria - Rejection eased by granting a 1 year grace period. Transfer to DG ENV the sole responsibility, fitting the fact REACH's main objective is health and environmental protection
No level-playing field	Increased risks of non-compliance (control, sanction) Intermediate uses covered as well as import and export (via restrictions)

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