

REACH 2 risk management system

Doing much more with limited resources

The Chemicals Strategy requires considerable acceleration of the regulation of hazardous chemicals. If the reform gives to the EU institutions and States tools fit for the task, they will be able, despite their limited resources, to shift the legal status of the most harmful chemicals from legal to illegal.

But the pathways emerging in the impact assessment do not seem capable of delivering a system that can do what the current system cannot: match the number of substances currently on the market, and the rate at which substances are introduced onto the market. For example, expanding the scope of Article 68.2 and tweaking the authorisation system will not suffice. Attempting to legalise the mistakes of the past, which option 2 seems to do, is unacceptable.

The structural weaknesses or misuses of the text that led to the following problems must be acknowledged and addressed:

The easiest and lightest process, Article 68.2 restrictions, is the least used

This “fast track”, hazard-based restriction process targeting consumer uses of CMRs is only open to the Commission and has only been used twice.

The most used process, Article 68.1 restrictions, is the heaviest and hardest

This longer, specific risk-assessment process has an excessive burden of proof, especially for health concerns. It is often used for situations that were eligible for fast-track restrictions, and the process sometimes repeated for different issues created by the same substance or situation.

The middle ground, Annex XIV, is a powerful tool that was made burdensome and then deserted

This hazard-based restriction of all uses with the possibility to secure a scrutinised transition was created for critical situations requiring a blanket ban, such as high volumes and wide, dispersive uses. The way that the authorisation system was interpreted however made it a contentious and resource-intensive process.

Therefore, we suggest changes that allow each process to bring its specific added value to the system, while ensuring that they each contribute in their own way to a consistent approach capable of delivering the goal of the CSS: the significant reduction of the production, use and impact of hazardous chemicals.

1. Make all restriction processes less burdensome

Legitimate safeguards against arbitrary or discriminatory law must not become barriers to necessary action. But in the search for the right balance, chemical regulation erred on the side of the less law. REACH reform must bring back a better balance.

Empowered for the new tasks - A consistent mandate across all processes

The current legal bases do not provide the powers required for the tasks set out in the EU Chemicals Strategy. The following changes are needed:

- ✓ **Set an explicit common goal for all processes:** the significant reduction of the production, use and impact of hazardous chemicals and the full phase-out of the most harmful chemicals.
- ✓ **Cover sustainability hot spots:** to ensure a safety net for future actions under the Sustainable Product Initiative, Article 68.1 must explicitly cover sustainability hot spots in the production and use of chemicals, including the issues caused by chemicals impairing reuse and recyclability.
- ✓ **Introduce a legal basis mandating the creation of a global level playing field:** include an explicit power to regulate the import of products manufactured with process chemicals banned in the EU, and to ban the manufacture for export of chemicals banned for use in the EU.

Pre-regulation phases – Good regulation, yes. Jumping through hoops, no.

The impact assessment brought up several ideas for pre-regulation steps. Some are a necessary investment to save time down the line, but others risk causing unnecessary delays.

- ✓ **Maintain reasonable expectations for RMOAs:** RMOAs can be useful, but must be voluntary and must not lead to a displacement upstream of an extremely difficult, specific risk assessment which the CSS is planning to eliminate downstream – which CEFIC's proposals, for example, would bring about.
- ✓ **No compulsory pre-listing for 68.1 and 68.2 restrictions:** Article 68.2 can currently be used for non-listed substances which meet the criteria. This must remain the case, to allow quick reactions to new issues. Similarly, the candidate list cannot become a pre-step to Article 68.1, which would destroy its value as a process capable of capturing emerging risks.
- ✓ **Do not add steps to blanket bans:** CLH classification must not become a pre-step for the Candidate List, which is already a pre-step for Annex XIV. In addition, candidate listing is much quicker. It should be the preferred pathway for SVHCs with high volumes or a wide diversity of uses. In order to benefit from the regulatory consequences attached to harmonised classification, a bridge must however exist to automatically turn an SVHC entry into a CLH.

Simplify the requirements – The definition of sufficient information to act

The duty to state reasons includes the requirement to prove the need to act (existence of an issue) and to prove the relevance of the measure under consideration (proportionality). But it has led to burdensome processes because the level of information needed is unclear or excessive. Setting explicitly in law presumptions as to these matters can considerably lighten the burden for the EU institutions and States.

For all processes – Create presumptions about what actions are needed

- ✓ **Harmonised trigger for action:** under Article 68.2 and Annex XIV, the existence of a high concern triggers restrictions. There is every reason to apply a similar approach under Article 68.1. The trigger for action which is today “unacceptable risk” must change to “high concern”. Across all processes, the existence of a high concern must be assumed if the most harmful substances are involved (CMRs, EDCs, PBT, vPvBs – and PMT, vPvM), and demonstrated in the other cases.
- ✓ **Include a hierarchy of action:** explicitly set a preference for phase out over other actions. This is in line with the Chemicals Strategy’s toxic-free hierarchy, with the STOP principle¹ applied in health and safety law and with the Court’s finding recognising that a restriction on the placing on the market “is often the most effective measure” for achieving the primary REACH objective - health and environmental protection.²
- ✓ **Favour future proofing:** set a preference, as much as possible, for dynamic restrictions (making reference to the SVHC list or CLH to ensure automatic updates).
- ✓ **Grouping:** building very broad restrictions, such as for microplastics or PFAS, is hard work. The use of “read-across” and the grouping of substances to prevent nonsensical substitution or aggregated and cocktail effects must be explicitly allowed.
- ✓ **Strengthen the political willingness and capacity to adopt precautionary measures** by anchoring the right to do so in the text and the method for how to do so in the annexes (and later, guidance).

For the most harmful substances – Set a consistent regime

- ✓ **Consistent across all uses:** the power to adopt hazard-based bans on the most harmful chemicals, currently set out in Article 68.2 and Annex XIV, must be expanded. Expand targeted bans without pre-listing (68.2) to professional uses and expand the power to adopt hazard-based blanket bans with pre-listing (currently under Annex) to cover intermediate uses.
- ✓ **Consistent across processes:** Article 68.2 assumes that consumer and professional use of the most harmful substances is of high concern, and rightly so – either because of the potential for exposure or because of the high number of products, and hence mass of material flow, involved. Given that the power to act with a generic assessment for these situations exists under 68.2, the same situations obviously should be subject to the same regime when they are addressed under another process – which may happen, as a very broad restriction under 68.1 can cover many

¹ For substitution, technical measures, organisation and personal protective measures.

² General Court of the EU, Case T-226/18, *Global Silicones Council*, Para. 170.

different uses, including consumer and professional. It would be a waste of resources to carry out several processes in parallel, or to force Member States or ECHA to do a specific assessment. Automatic bans must be allowed without further justification. Similarly, the requirement to justify the ban on an industrial use must be lightened.

For other hazardous substances – Make a lighter assessment the norm

- ✓ **Coherent approach:** the same logic that justifies a generic assessment of the risk in case of consumer and professional use of the most harmful substances also justifies a lighter assessment than what exists today for other hazardous substances with similar uses.
- ✓ **Allow for a more qualitative, slimmed down assessment of risk and proportionality,** closer to the regime applied today for non-threshold and PBT substances (with the possibility to take adequate control into account in the derogations and transition periods).

2. Ensure the processes are used

All the existing risk management processes under REACH have a role to play as parts of the future system, and if they are properly designed and used together, then they will enable the EU institutions and States to deliver the goal of the Chemicals Strategy. But the impact assessment process has not so far provided visibility on how the system will work because each piece is being developed in parallel and in isolation – which is understandable but nonetheless damaging. We need to look at the big picture, considering what each different part brings to the whole and how best to use all of them.

Clarify the added value of each process

To avoid complex discussions on the proper pathway, the specific added value of each process must be clarified.

	Type of action	Added value
Article 68.2	Hazard-based targeted ban, with or without pre-listing	Promoting safe-by-design products, for some or all product categories, by restricting all the CMRs, EDCs, PBT, vPvBs that are and will be on the candidate list and/or CLH even with no knowledge of presence, use or impact Stopping an unacceptable use by acting upon knowledge of the presence, use or impact of a substance of concern in a product category
Annex XIV	Hazard-based blanket ban, with pre-listing	Full elimination of the most harmful chemicals
Article 68.1	Any action, with or without pre-listing	Catch all, safety net Especially good for emerging risks and very broad groups

Ensure the easiest and lightest processes are used

- ✓ **No need to wait –the legislator must address the low-hanging fruit.** The first papers on GRA state that nothing can be done before REACH 2 enters into force. But the legislator has the power to amend Annex XVII and to restrict the use of chemicals. The legislator should conserve the Commission's resources by directly adopting the bans already promised:
 - EDC, PBT and vPvB substances (PMT and vPvM should be covered as well) in substance and mixtures available to the general public, by reference to candidate list entries and then to CLH when in place (amendment of entries 28-30 Annex XVII).
 - CMRs in childcare articles.
- ✓ **Article 68.2 – increase accountability and political acceptability:** this process has been used only twice, in part because of hesitation about how to approach substances in consumer articles, and in part because of reluctance from some Member States. These barriers must be taken down:
 - Open the initiation of the process to Member States;
 - Clarify the processes for handling exceptions to the rules (see below);
 - Create accountability on the work plan, with an obligation for the Commission to adopt a report on actions done, delayed or abandoned, with reasons given.
- ✓ **Annex XIV – increase accountability on delivering full phase-out of the most harmful chemicals:** the way the authorisation chapter was applied made it burdensome and led to it being less used for the most relevant substances. Reactivating it as a critical tool requires:
 - Spending fewer resources on sorting out requests for continuous use (see below);
 - Creating accountability on the use of the candidate list: the Commission must report on the suspected SVHCs not yet listed and explain the reasons for the delay;
 - Creating accountability for entries in Annex XIV: the Commission should report on the volume of SVHC per use per year and explain why their full phase-out is delayed, and ECHA should continue to propose priorities for entries.

Ensure processes are initiated for the most pressing issues

- ✓ **Article 68.2 – beyond empowerment, a commitment to use:** include a provision committing to deliver consumer products free from the most harmful chemicals by 2030.
- ✓ **All – no crucial can fall through the cracks:** given that public authorities cannot know about all the issues, and that few Member States actively pursue restrictions, there is a risk that some issues that would benefit from EU action remain under the radar. Members of the public should have the right to bring substantiated concerns of exposure to or emissions of hazardous substances to the Member States or to ECHA, to trigger a restriction process. They must have access to an appropriate legal procedure to submit such concerns to their national competent authority, triggering an obligation to assess such concerns and to consider taking necessary operational steps to prevent further damaging emissions or exposure.

Ensure adequate resources to tackle the hardest cases

- ✓ **ECHA** – the new financial framework must guarantee resources for ECHA to fully contribute to the development of broad restrictions. The development of the other chapter will require resources; that must be taken into account.
- ✓ **States** – the restriction workplan must involve both the Commission and States to ensure a fair division of labour. Member States must also commit sufficient resources to the Committees, in particular to RAC.

3. Addressing the need for exceptions – Saving resources without sacrificing meaningful scrutiny

A better balance can be achieved by limiting the number of cases considered, by increasing the intensity of the scrutiny in proportion to the duration of the transition period considered, and by making the EU institutions and States no longer fully dependent on applicants when it comes to understanding the market practices.

Better visibility of market practices

- ✓ **Registration first – limit the calls for evidence by expanding the information requirements**
 - Calls for evidence are time-consuming, and direct research by public authorities are resource-intensive. Registration must become the tool it was supposed to be and deliver the information needed to regulate. The adoption of options 1 to 4 developed in CARACAL Doc. CA/12/2022 would improve the system.
 - Option 3, the creation of a new requirement for downstream users to report their use to ECHA, is essential, and could be organised as a tiered requirement – basic information on volumes and use upon registration, more detailed information including potential alternatives provided upon entry in the candidate list, in Annex VI CLP or in the register of intention.
- ✓ **Create a duty to respond to information requests from authorities**

A new legal basis must give ECHA and the Member States' competent authorities the power to ask questions to manufacturers, importers and users of substances (on their own, in mixtures and in articles) on their use (quantity, conditions of use, technical function); and to ask questions to alternative manufacturers and users.

- ✓ **ECHA must have the power and budget (via fees for use of substances of concern) to do market surveys**

Apply a consistent approach across processes

This approach would limit the type of uses eligible for transition period (essential use, respect of minimum criteria), ensure consistency across processes and guarantee phase-out by making transitions time limited. It should also create incentives for companies to apply for the minimum period manageable by subjecting short transition periods to a much lighter regime.

	Definition	Maximum duration	Process
Unacceptable uses	<p>Substantive criteria</p> <ul style="list-style-type: none"> -Substance or mixture for consumer or professional use -Products/process with a similar function exist without the substance of concern (non-essential) <p>Formal criteria</p> <ul style="list-style-type: none"> - Registration not updated - Exposure/emissions not monitored 	1-year grace period	<p>68.1 – dossier submitter</p> <p>68.2 – Commission</p> <p>Annex XIV – non-essential uses excluded from application by MSC decision Procedural requirement: data and completeness check by ECHA secretariat</p>
Use in transition	<p>Eligibility</p> <ul style="list-style-type: none"> - Critical use - Alternative exists, but not available or feasible immediately. Credible substitution plan must justify the period needed. - Emissions and exposure known and minimised 	<p>1-3 year max</p> <p>1-year grace period if rejected</p>	<p>68.1 – dossier submitter directly</p> <p>68.2 – Commission directly, optional opinion of MSC on criticality if restriction covers broad mix of uses</p> <p>Annex XIV- after opinion of MSC on criticality and strict eligibility check, accelerated process, decision by ECHA</p> <p>Reduced information requirements</p>
	<p>Eligibility</p> <ul style="list-style-type: none"> -Same as above, but credible substitution plan has verifiable justification that more than 3 years is needed to transition. 	<p>3-6 years max</p> <p>Rejection: 1 year grace period</p>	<p>68.1 and 68.2 – same as above</p> <p>Annex XIV- after strict eligibility check, normal process, decision by COM</p> <p>Increased information requirements</p>
Use in transformation	<p>Eligibility</p> <ul style="list-style-type: none"> -Critical use -No alternative -Emissions and exposure known, tracked and minimised. Fully controlled after mid-term. 	6-12 years max, with mid-term review	<p>68.1 and 68.2 – must send back to RAC/SEAC for deeper scrutiny, optional opinion of MSC on criticality if restriction covers broad mix of uses for 68.2</p> <p>Annex XIV – after opinion of MSC on criticality and strict eligibility check, normal process, decision by COM</p> <p>Highest information requirements, failure to prove full control of emission/exposure at mid-term leads to ending authorisation</p>

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