REACH 2 - Shift the trend

4 changes to make safe chemicals the norm

1. Full data to market – Get the information needed to regulate

REACH registration requires companies to provide information on hazard and exposure, and if it had achieved its goal then it would have provided public authorities with all the data needed to identify and regulate hazardous substances. But considerable resources are spent by the EU institutions and States on calls for evidence and data collection, because the data collected via REACH registration is too often incomplete, inaccurate, unfit or insufficient. REACH reform must therefore seize the opportunity to get the information needed to regulate by filling the main gaps.

Raise expectations – From some data to full data

“No data, no market” in practice became “some data will do”. REACH 2 could raise the expectation by requiring truly full data to be allowed to market. That involves:

- Requiring the development and communication of missing data missing for comparatively novel hazard classes, such as endocrine disruptors and PMTs.
- Requiring an annual update of volumes and setting specific triggers for all updates, including an obligation to withdraw registrations when the manufacture/import stops.
- Tightening enforcement to ensure compliance, as detailed below in section 4.
- Reducing dependency on industry data by:
  - Taking advantage of automation – Create a formal and efficient mechanism to automatically monitor the literature and send triggers to quickly initiate or revise assessments in light of the newest research.
  - Creating a formal and efficient mechanism for third parties to feed ECHA the studies that have not been taken into account in the evaluation process or which are missing from registration dossiers.

The Commission is exploring the idea of requiring information on the environmental footprint of chemicals. Although we welcome the idea, if it covers the footprint of a chemical’s whole life-cycle, we do not think that REACH is the appropriate framework to introduce this requirement.
Unveil the entire chemical universe – Expand the scope of the substances covered

Only a small part of the chemical universe is currently subject to registration, despite the threat of chemical pollution that comes from what remains uncovered. The worst gaps in knowledge must be filled - for polymers (a full screening is required) and low tonnage substances (information requirements must be added).

2. Accelerate restrictions – Doing significantly more with limited resources

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. The structural weaknesses and misapplications 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.
- The most used process, Article 68.1 restrictions, is the heaviest and hardest.
- The middle ground, Annex XIV, is a powerful tool that was made burdensome and then deserted.

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 their collective goal: the significant reduction of the production, use and impact of hazardous chemicals. Our fully developed proposals are available here.

Gearing up for group restrictions – Make all restriction processes less burdensome

The changes proposed by the Commission to Article 68.2 are necessary and will help phase out some uses of the most harmful chemicals. But Article 68.2, even when expanded to professional uses and new hazard classes, cannot deliver everything the Chemicals Strategy promised. It will also not solve what made the duty to state reasons – including reasons for the need to act (existence of an issue) and reasons as to the relevance of the measure under consideration (proportionality) – into burdensome processes. The culprit there is the unclear or excessive definition of the level of information needed to meet the duty.

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

- Set a common goal for all processes in line with the Chemicals Strategy: the significant reduction of the production, use and impact of hazardous chemicals and the full phase-out of the most harmful chemicals.
- Introduce a strong legal basis to ensure 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.
Simplify the requirements – The definition of sufficient information to act

✓ For all processes – set clear assumptions in REACH of what actions are needed, namely, those which can deliver the promise of the Strategy: systematic use of grouping and of dynamic restrictions (making reference to the SVHC list or CLH to ensure automatic updates); and prioritising phase-out rather than risk control. In addition, the trigger for all processes must become the existence of a high concern, and not an unacceptable risk, as under Article 68.1.

✓ For the most harmful substances – introduce a consistent regime across use and processes. All uses of the most harmful substances must be eligible for a hazard-based ban, which means that Annex XIV must be expanded to intermediate uses. And the level of information and the intensity of the assessment required to ban harmful substances must not vary across process: if a broad restriction under Article 68.1 covers consumer or professional uses, they must be submitted to the same regime as under Article 68.2. A lighter assessment must also apply to industrial uses.

✓ For other hazardous substances – make a lighter assessment the norm. The main provisions and annex must considerably lighten the level of assessment and information required, in particular for health concerns. The regime should resemble what is applied today for non-threshold and PBT substances. Consumer and professional use should be submitted to lighter requirements.

Delivering the promise of the Chemicals Strategy – 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. The following considers what each 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.

<table>
<thead>
<tr>
<th>Type of action</th>
<th>Added value</th>
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<tbody>
<tr>
<td><strong>Article 68.2</strong></td>
<td><strong>Promoting safe-by-design products</strong>, 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</td>
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<tr>
<td></td>
<td><strong>Stopping an unacceptable use</strong> by acting upon knowledge of the presence, use or impact of a substance of concern in a product category</td>
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</table>
Ensure the easiest and lightest processes are used

- **No need to wait – the legislator must address the low-hanging fruit.** The legislator should conserve the Commission’s resources by directly adopting the bans already promised. The following should be included in the impact assessment:
  - EDC, PBT and vPvB substances (PMT and vPvM should be covered as well) in substances 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.

- **Increase the political acceptability of fast-track restrictions (Article 68.2),** by opening initiative to the Member States.

- **Create accountability on the use of Article 68.2, the candidate list and Annex XIV,** via an obligation for the Commission to report on past decisions to use these processes (or not), delays and volume per use of known or suspected substances of very high concern not yet phased out.

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 and professional products free from the most harmful chemicals by 2030.

- **All – no crucial issue can fall through the cracks:** 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. 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 the necessary operational steps to prevent further damaging emissions or exposure.

Addressing the need for exceptions – Save 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 market practices.

Better visibility of market practices

- **Registration first – limit the calls for evidence by expanding the information requirements on use and exposure.**
Create a duty to respond to information requests by 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 about 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.

<table>
<thead>
<tr>
<th>Definition</th>
<th>Maximum duration</th>
<th>Process</th>
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<tbody>
<tr>
<td><strong>Unacceptable uses</strong></td>
<td></td>
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<tr>
<td><strong>Substantive criteria</strong></td>
<td>1-year grace period</td>
<td>68.1 – dossier submitter</td>
</tr>
<tr>
<td>- Substance or mixture for consumer or professional use</td>
<td></td>
<td></td>
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<tr>
<td>- Products/process with a similar function exist without the substance of concern</td>
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<td></td>
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<tr>
<td><strong>Formal criteria</strong></td>
<td></td>
<td>68.2 – Commission</td>
</tr>
<tr>
<td>- Registration not updated</td>
<td></td>
<td>Annex XIV – non-essential uses excluded from application by MSC decision</td>
</tr>
<tr>
<td>- Exposure/emissions not monitored</td>
<td></td>
<td>Procedural requirement: data and completeness check by ECHA secretariat</td>
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<tr>
<td><strong>Use in transition</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Eligibility</strong></td>
<td>1-3 year max</td>
<td>68.1 – dossier submitter directly</td>
</tr>
<tr>
<td>- Critical use</td>
<td>1-year grace period if rejected</td>
<td>68.2 – Commission directly, optional opinion of MSC on criticality if restriction covers broad mix of uses</td>
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<tr>
<td>- Alternative exists, but not immediately available or feasible. Credible substitution plan must justify the period needed</td>
<td></td>
<td>Annex XIV – after opinion of MSC on criticality and strict eligibility check, accelerated process, decision by ECHA</td>
</tr>
<tr>
<td>- Emissions and exposure known and minimised</td>
<td></td>
<td>Reduced information requirements</td>
</tr>
<tr>
<td><strong>Eligibility</strong></td>
<td>3-6 years max</td>
<td>68.1 and 68.2 – same as above</td>
</tr>
<tr>
<td>- Same as above, but credible substitution plan has verifiable justification that more than 3 years is needed to transition</td>
<td>Rejection: 1-year grace period</td>
<td>Annex XIV – after strict eligibility check, normal process, decision by COM</td>
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<tr>
<td></td>
<td></td>
<td>Increased information requirements</td>
</tr>
<tr>
<td><strong>Use in transformation</strong></td>
<td>6-12 years max, with</td>
<td>68.1 and 68.2 – must send back to RAC/SEAC for deeper scrutiny, optional opinion of MSC on criticality if</td>
</tr>
</tbody>
</table>
- No alternative

- Emissions and exposure known, tracked and minimised. Fully controlled after mid-term.

mid-term review

restriction covers broad mix of uses for 68.2

Annex XIV – after opinion of MSC on criticality and strict eligibility check, normal process, decision by COM

Highest information requirements, failure to prove full control of emission/exposure at mid-term leads to ending authorisation

### 3. Some already do better – Favour the frontrunners, not the incumbents

Many users or manufacturers invest substantially in the transition towards safe alternatives and often benefit when substances of concern are restricted. But this economic benefit of restriction is ignored in REACH processes. That is because they tend to treat the chemical industry – a vibrant Tour de France full of diverse cyclists – as a homogenous peloton all destined to arrive at the Arc de Triomphe simultaneously. REACH processes mistakenly take the part (vocal incumbents) for the whole and assume that regulation means delaying arrival at the finish line in the same way for everyone. The result of this fallacy is decisions that tend to favour incumbents and weaken the sector. A change of gears is needed, allowing those investing in the transition to capture the yellow jersey. Regulators need positive and negative incentives to push others to speed up.

**Award a premium to those leading the transition**

In REACH processes, the leaders are often side-lined, because they are discouraged by the process, concerned about endangering existing or potential commercial relations with incumbents or do not have the capacity to engage. See, for examples and full explanations, [this report](#). Changes must happen to:

- **Identify the leaders in the market**, via market surveys and direct engagement with alternative providers and users.

- **Engage alternative users and providers.** ECHA and the Member States’ competent authorities must have the power to ask questions to manufacturers and users of substances of concern as well as their competitors, and those companies must have a duty to answer. This model – applied in competition law – will give a more balanced view of the market practices.

- **Include the benefits of regulation for transition frontrunners in the proportionality analysis.**
Create incentives to turn away from substances of concern

- Support substitution efforts via a funded substitution network.
- Raise the cost of using substances of concern by introducing a fee.
- Expose continuous users of substances of concern by amending Articles 33 and 66 so that all the information listed in ECHA’s guidance as “voluntary to notify” becomes compulsory – and public.

4. The rules are for everyone – Strengthen accountability

The European Green Deal Communication calls on the Commission and Member States to “ensure that policies and legislation are enforced and delivered effectively”. But today, many actors can escape REACH rules because the accountability systems created by REACH are deficient. Discussions on REACH 2 and enforcement currently focus on “enforceability”, and the solution proposed is a more systematic involvement of the enforcement forum. The forum has been useful and will continue to be, but the issues behind the lack of enforcement will in no way be solved solely by broadening its role.

Therefore, we need to use REACH reform to address the issue of enforcement more holistically and bring into chemical law best practices from other areas of EU law. There is no reason the safeguards protecting people and the environment against toxic chemicals should be weaker than those that apply to our consumer choices. REACH needs to be changed in the following way to meet that promise. The proposals that follow are fully detailed here.

It takes a village – Multiply the enforcers

REACH has an exceptionally broad scope. Who is covered? Manufacturers, importers and users from any sectors. What is covered? All chemicals, and almost all uses. If we had enough enforcers, then REACH’s impact would be multiplied. But today we do not have enough enforcers for the job, because the work relies mostly on the Member States, who do not have equal resources to dedicate to this work; and partly on ECHA, which struggles with capacity. Therefore, we need to drastically increase the resources spent on enforcement, by ensuring that all Members States are involved, and that they are not alone on the job.

- Consistency across the Member States – add clear and common obligations on enforcement systems and activities.
- ECHA as enforcer – provide the necessary power to withdraw registration numbers.
- Public authorities cannot be everywhere – Give private parties the tools to help.
REACH 2 must include an explicit legal basis for ensuring critical transparency on, at least,

→ the name of the parent companies in addition to the name of the registrant, the name of the companies (and of the parent companies) behind only representatives, the narrow tonnage bands for volumes placed on the market, exposure scenarios, the brand and name of articles containing substances of concern as well as the companies covered by authorisations and derogations.

The public can directly contribute to enforcement by bringing substantiated concerns of non-compliance with risk management measures to the attention of enforcement authorities, which also requires proper access to justice.

Ignoring the law does not pay – Make non-compliance risky business

Violating the law should never bring more benefits than risks. Sanctions for violations must be genuinely dissuasive and applied in a consistent manner. But the reports published on this topic so far by the Commission show that the Member States do not take a strict enough approach. REACH reform must solve this issue by aligning with the best practices in EU law.

 ✓ Sanctions – harmonise and strengthen them in line with current best practice in EU law
 ✓ Transparency – make Name & Shine and Name & Shame another incentive to comply
 ✓ Compensation – introduce civil liability for violation of risk management measures protecting health
 ✓ Collective redress – expand the scope to REACH

Ease of monitoring – Create the tools needed to establish accountability

Enforcing the law requires knowledge, and if the enforcement system has the appropriate tools to get a picture of how the law is applied in practice, then free-riders can be targeted. But REACH currently fails to create accountability in part because it lacks the basic tools needed to know who must abide by the law and who does not. REACH reform is therefore an unmissable opportunity to fix this issue, with the following actions:

 ✓ Tighten the obligation to notify information under Articles 33 and 66, making the information whose notification is currently indicated as voluntary in ECHA’s guidance on those Articles compulsory.
 ✓ Create an obligation for manufacturers and importers to provide analytical reference standards upon request for researchers (non-commercial purpose) and public authorities.