

ChemSec's response to the European Commission's suggestions at CARACAL 54 (April 3, 2025) for revising REACH

Summary

It is crucial that simplification does not become an act of deregulation. The Commission should simplify REACH to ensure the highest protection of citizens and the environment by implementing the aims set out in the Chemical Strategy for Sustainability.

Key points:

1. Ensure an overall and explicit aim to phase out SVHCs in the legal text of REACH.
2. Ensure that REACH provides a harmonised approach to regulating substances on the EU single market (i.e. predictability and level playing field) by setting clear time limits for restrictions and authorisations.
3. Don't add new formal and time-consuming processes (such as RMOA).
4. Retain all the current regulatory tools to ensure REACH is equipped to phase out the worst substances and uses:
 - I. Improve the implementation of the Authorisation procedure and address wide dispersive uses as a priority. Only authorise essential uses.
 - II. Expand GRA to phase out all most harmful substances by restricting them in both consumer and professional uses. Only derogate essential uses.¹

ChemSec is puzzled, disappointed and extremely concerned about the direction indicated by the European Commission at CARACAL 54 (April 3, 2025) for revising REACH. If pursued, this direction would:

- Drastically weaken existing regulatory tools used to phase out the worst chemicals
- Increase the burden on Member States and reduce their right of initiative
- Reward the laggards and hamper innovation in safer products
- Reduce the protection of citizens and the environment.

This would be an act of pure deregulation, not simplification. Regulatory tools to address the most harmful substances on the market would be dismantled. The idea seems to be – contrary to all the evidence – that self-regulation by industry would be enough to deal with even the worst chemicals. The PFAS crisis is a painful, costly and clear example that self-regulation does not work. A primary objective of REACH is to provide a high level of

¹ European Commission (2024), [Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals](#) (C/2024/2894).

protection for health and the environment by ensuring that substances manufactured, used or placed on the market do not have adverse effects, with REACH provisions being underpinned by the precautionary principle².

The loosening of chemicals regulation at the EU level suggested by the Commission at CARACAL 54 would mean a loss of harmonisation on the single market, a loss of predictability and level playing field, not to mention an unacceptable lack of protection of citizens and the environment. Member States will be forced to act on a national level if the EU regulation is insufficient, which is both counterproductive to the EU competitiveness agenda and would make any circular economy efforts futile. At a stage where the EU needs strong preventative chemicals regulation more than ever, the suggestions from the Commission risk taking us 20 years back in time instead of ensuring regulation that is equipped for the problems that remain to be tackled. Specifically:

- The Commission intends to drastically diminish the use of the Authorisation procedure, which has the aim of phasing out SVHCs, and which also drives substitution beyond regulatory requirements. **This phase-out aim must therefore be explicit for all regulatory tools (including all restrictions), as the use of Authorisation would no longer be the most important tool to safeguard the protection of human health and the environment.**
- The Commission is implying that the hazard classes to be covered by GRA restrictions would be significantly reduced compared to its earlier commitment and assessment. Giving up GRA for the most harmful substances³ would reduce the huge benefits for health and the environment but also negatively impact the possibilities to achieve a competitive circular economy⁴. **To make up for the minimal use of the Authorisation procedure, and to simplify REACH, it is therefore paramount that the Commission expands the use of GRA to phase out all the most harmful substances.**

We would like to remind the Commission that REACH was originally introduced because the system of addressing chemicals one at a time, and with the burden of proof on the regulating authorities, was not protective enough, was too slow, did not drive substitution for wide dispersive uses, and do not apply the polluter pays principle. In short, it was not a modern solution. Later, acknowledging the legislation's weak implementation, an ambitious REACH revision was promised in the Chemical Strategy for Sustainability⁵ (CSS). This strategy remains the best guidance for the REACH revision. The strategy is underpinned by a wealth

² Article 1 of REACH.

³ Table 1 of the Communication from the Commission – [Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals](#) (OJ C, C/2024/2894, 26.04.2024, ELI:)

⁴ Letter from companies to Ursula von der Leyen and her Commissioners, [31 March 2025](#), regarding the REACH revision and circular economy.

⁵ Communication from the Commission, [Chemicals Strategy for Sustainability Towards a Toxic-Free Environment](#) COM/2020/667 final

of evidence⁶ demonstrating that this is the best long-term and sustainable way forward for the EU. This strategy was welcomed by both the Council and the European Parliament.

ChemSec has outlined how to modernise and simplify REACH⁷ in such a way that would provide a high level of protection for citizen and the environment while at the same time increasing the EU's competitiveness. Below we highlight the most important points in relation to the Commission's presentation at the CARACAL meeting.

1. Registration and Evaluation

Key points:

- Improve the information on hazards, uses and so on in substance registration dossiers and regular updates, incentivised by ECHA denying or revoking registration numbers, and by linking the information on uses with possibilities to apply for authorisation or derogations.
- Introduce a Mixture Assessment Factor that adequately represents reality.
- Introduce a stepwise registration of polymers.

The “No data – No market” principle is a core feature of the REACH regulation for both low- and high-volume chemicals. However, experience has shown that the **information provided in registration dossiers** today is often insufficient and not kept up to date. This information, or lack of it, forms the basis of further evaluation. At CARACAL 54, the Commission proposed to improve the availability of information by requiring data for additional important hazards. It was also proposed to strengthen enforcement by limiting the validity of a registration dossier to 10 years and enabling ECHA to revoke registration numbers when companies do not provide sufficient information. ChemSec welcomes this development. We also believe that stronger incentives are needed to achieve a sufficient level of data and keep it updated, especially when it comes to information on uses. This information requirement should be linked to the possibilities to apply for derogations or authorisations. If a use is not indicated in the registration, there should be no possibility to get a derogation from a restriction or an authorisation for that use.

The CSS clearly describes the growing scientific consensus that the effects of unintentional chemical mixtures must be integrated fully into chemical risk assessments via a **Mixture Assessment Factor, or MAF**. At CARACAL 54, the Commission acknowledged the need for

⁶ European Commission: Directorate-General for Environment, Milieu Ltd, Risk & Policy Analysts (RPA), RIVM, Ökopol, Bakker, J., Reihlen, A., Meura, L., Camboni, M., Goldenman, G., Lietzmann, J., [Study for the strategy for a non-toxic environment of the 7th Environment Action Programme](#) – Final report, Publications Office, 2017.

⁷ ChemSec [Position paper on REACH](#), 31 January 2025.

this improvement of REACH. It is important that MAF are not only introduced for high-volume chemicals. In addition, it is important that this factor reflects reality, so it must always be well documented that any chosen MAF is sufficient to take all potential mixture effects into account.

The CSS also includes a commitment from the Commission to extend the duty of **registration of polymers**. The experience of PFAS has clearly shown why this is necessary. ChemSec would welcome this and suggest a grouping and stepwise implementation.

2. Formalised risk management option analysis (RMOA)

Key points:

- Do not add a new and formalised RMOA. It is likely to:
 - Reduce Member States right and duty to initiate regulatory processes for SVHCs and most harmful substances
 - Delay regulatory action even further.
- Harmonisation in the single market is not supported by emission control legislation through the Industrial Emissions Directive and other “end-of -pipe” solutions, which cannot achieve the same levels of protection.

The Commission suggests adding a formalised **risk management option analysis (or RMOA)** to the process of regulating chemicals in REACH. This would add extra burdens to the regulatory process and demand additional time. Moreover, we already see industry asking to have a role in this process. Involving industry would risk reducing Member States’ right of initiative to regulate harmful substances. We urge the Commission to respect the roles and responsibilities of different stakeholders.

Delaying and reducing the use of REACH to regulate chemicals on the market could increase national initiatives to regulate chemicals and thereby create disturbance in the single market. Member States should have the full right to initiate regulatory processes without a pre-decision or prior discussion with industry. A very important perspective is that if the aim of the candidate listing is changed by introducing an RMOA as a first step in the authorisation scheme, the core aim of REACH – to phase out Substances of Very High Concern – would be completely lost. ChemSec sees no benefits to formalising this process. On the contrary, we urge the Commission to present proposals to speed up and simplify the process of implementing new restrictions, as it currently takes years to regulate harmful chemicals⁸.

⁸ EEB, [The Need For Speed](#), July 2022.

Formalising additional steps with the aim of limiting emission control to the Industrial Emissions Directive and other “end-of -pipe” solutions is problematic, as it does not achieve the same level of protection. For widely used chemicals in products, this approach cannot control emissions and exposure over the entire lifecycle, or when materials are recycled and used in new products.

3. Authorisation

Key points:

- Improve the implementation of the Authorisation procedure.
- Retain wide dispersive uses as a priority.
- Ensure that all Authorisations have clear time limits set by the regulatory authorities.

The Authorisation procedure is designed to be the driver for substitution, with the aim of phasing out Substances of Very High Concern, SVHCs, giving priority to wide dispersive uses. At CARACAL 54, the Commission suggested drastically reducing the use of the Authorisation procedure. Such a change would remove the substitution drive from the Candidate list by restricting the Authorisation procedure only to uses that are related to production, not those present in finished products, and would specifically exclude the possibility to address wide dispersive uses. With such a change, the aim of phasing out SVHC is completely lost. ChemSec instead suggests improving the implementation of the Authorisation procedure, with details provided in previous input⁹. This regulatory tool should keep the priority focus on substances that are widely used and therefore need horizontal phase-out to prevent harm to health and the environment.

The Commission also opens the door to introducing the use of “substitution planning”¹⁰ or “substitution pathways”. While it is commendable to support companies with innovation and substitution, it is crucial to keep these activities outside of the REACH regulation as it otherwise could lead to lack of level playing field, unfair competition and loss of predictability.

⁹ ChemSec, “[Simple is smart: How a revised REACH can be both simpler and more effective](#)”, January 2025.

¹⁰ ChemSec, “[Substitution Planning: Flexibility is not simplifying REACH](#)”, September 2024.

4. Restrictions

Key points:

- Extend the phase-out aim of REACH to restrictions (including GRA).
- Expand GRA to all most harmful substances.
- Use GRA for both consumer and professional uses.
- Provide a clear and ambitious timeline for the stepwise implementation of GRA for articles, with a set end date.
- Empower Member States with the right to initiate GRA restrictions.
- Ensure that all derogations from restrictions (including GRA) have clear time limits set by regulatory authorities.

In the Chemicals Strategy, the Commission promised an extension of the **Generic Risk Approach (GRA)** to all most harmful substances in mixtures and articles, including for professional uses. This generic approach makes sense both to increase the protection of citizens and the environment, pave the way for a circular economy¹¹ and to simplify procedures in REACH.

However, judging from the Commission's CARACAL 54 presentation, the GRA looks set to become extremely narrow as the COM considers diverging from the hazard classes previously announced, presumably to a very narrow scope. There is also no indication of timeline or the scope of article categories. With this approach, GRA will not conform to the promises made in the CSS, nor mitigate the loss of protection from reducing the Authorisation procedure. This decrease in ambition would also counteract circularity and open the door to regrettable substitution – namely, replacing substances with hazard classes in scope of GRA with equally harmful substances in hazard classes out of the GRA scope.

At CARACAL 54, the Commission also clarified its view that professional uses should not be covered by GRA, even though the need for addressing these uses was clearly acknowledged in the CSS. Many professional users lack the possibility to use required personal protection etc, especially self-employed and small companies. In addition, the products sold for professional uses are often used by non-professionals. The products also end up in the same waste streams and water, and would contaminate the resources that are intended to be cleaned up through GRA.

The existing main restriction procedure (Article 68.1) is extremely burdensome for Member States, does not apply the polluter pays principle, and requires a detailed risk assessment which in many cases suffers from lack of specific data on exposure and estimates of safe level

¹¹ See footnote 4.

of exposure (which many times is not scientifically possible to establish for most harmful substances). This has been time consuming and resource intensive, and in recent years REACH has in many cases been characterised as “paralysis by analysis” among regulators instead of being a system to ensure that the worst substances are efficiently phased out in the EU.

During CARACAL 54, the 68.1 procedure was barely mentioned by the Commission. As neither the Authorisation procedure nor the GRA would be equipped to address the wide dispersive uses of the worst chemicals, restrictions under 68.1 would be the only option for phasing out the main bulk of substances and uses. The burning question is therefore: Which Member States will have the resources to provide the dossiers required? Or will ECHA be given the resources to do them?

The Commission says it is open to introducing the use of “substitution planning”¹² or “substitution pathways”, also for restrictions. As described above, it is crucial to keep these activities outside of the REACH regulation as they otherwise could lead to a lack of level playing field, unfair competition and loss of predictability. ■

¹² See footnote 10.