EEB Comments on REACH Revision options presented at CARACAL 54

22 April 2025

INTRODUCTION

The Commission's proposals are too little, too late. For years, the EU is debating on how to achieve a stronger 'No Data, No Market' principle and better enforcement of REACH, as the chemical industry continues to ignore legal obligations to provide safety data — one of REACH's core failures.

While we welcome some proposals aligned with the Chemicals Strategy for Sustainability (CSS) — such as the long-overdue registration of polymers, where Commission studies have consistently shown the societal benefits far outweigh the costs — we have endured nearly two decades of inaction. This negligence has contributed to widespread harm from substances like microplastics and fluoropolymers, which could have been prevented.

We urge the Commission to tackle real-life exposure to chemical mixtures through the MAF and the extension of fast-track restrictions under the Generic Risk Approach (GRA) to better protect vulnerable groups from substances like endocrine disruptors and persistent chemicals. The Commission should address in particular persistent, bioaccumulating and mobile chemicals to stop irreversible and widespread pollution, to protect our environment, food and drinking water today and for future generations.

Many other critical commitments seem to have been abandoned — including the fast-track ban on hazardous chemicals in professional use and registration of low-volume substances — despite their proven benefits to health and the environment.

The current proposal lacks the ambition and tools needed to rein in harmful chemicals. Rather than streamlining the process, the Commission is adding bureaucratic hurdles, such as the RMOA, and narrowing the scope of authorisation — pushing all regulation into the slow and burdensome "normal" restriction route.

This is a step backwards — back to a pre-REACH era of delay, complexity, and continued risk to public health and the environment.

To enhance the efficiency and effectiveness of chemical risk management, we propose systematically assessing structurally similar substances as groups under REACH. The current one-by-one approach is too slow and has led to regrettable substitution, where one harmful chemical is replaced by another with similar hazardous properties. Group assessments will accelerate regulatory action, close data gaps, reduce animal testing and regulatory burden for authorities, and protect better health and the environment. We urge the Commission to integrate this approach across REACH.

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REGISTRATION

Title II of REACH

Registration is the pillar on which hazard identification and subsequent risk management measures are built under REACH, including restriction and phase-out of substances of very high concern. It is also the basis for informing all actors along the supply chain about hazards of the chemicals they use and on how to control them. However, today the high level of non-compliance of the registration dossiers is a major bottleneck in the implementation of REACH as it overloads the evaluation process and drains ECHA resources. It is the cause for delays in hazard identification and the implementation of risk management measures, leaving people and the environment exposed to potentially toxic chemicals for many years. A high level of protection of citizens and the environment can only be successfully achieved by requiring solid evidence at the early stage of substance registration, which means that the registration dossiers must contain all the information needed for hazard identification and risk management. At the same time, a zero-tolerance approach is needed for substances with non-compliant registration dossiers currently on the market, because their safety is not proven.

Therefore, we welcome the proposal to strengthen the no data no market principle, including setting a deadline for the **validity of registration dossiers** and the **option to revoke registration numbers**, given the persistent high level of non-compliance of the chemical industry with their obligations to provide adequate information and to update their registration dossiers — even when new hazards are identified by authorities or substances are regulated based on those hazards.

This widespread non-compliance is not only illegal — it's dangerous. It puts workers, citizens, and the environment at serious risk. The Commission proposals for a **validity period of the registration dossier** is of great importance, however, we consider a 10-year validity period exceedingly generous. Waiting a decade to take on board new scientific knowledge on chemical hazards is far too slow. We would rather see a validity period of 3 - 5 years to ensure up-to-date dossiers.

The Commission has made clear that this measure will not impose extra costs on companies, therefore we hope that the chemicals industry will also support this measure.

Remaining in the dark about the real risks of chemicals is bad for public health, bad for the environment, and ultimately bad for business. It's time the EU chemical industry respects the law and takes responsibility for the safety of its products.

To address the high level of non-compliance, we call on the Commission to strengthen the registration provisions by implementing a **rigorous verification process** at the time of registration to ensure that new dossiers are complete upon submission, by enabling ECHA

to effectively assess the quality and adequacy of the registered data at registration. Also, an **ad hoc completeness check** could be helpful in this respect.
Furthermore, we suggest to **couple renewal of the validity of the registration to compliance of the dossier**. It should be noted that revision of REACH will only be successful if the registration decisions require comprehensive and adequate safety data before allowing chemicals on the market.

Mixture Assessment Factor (MAF): We support the inclusion of MAF as the best approach to address real life exposure to chemical cocktails. The MAF should be sufficiently high to provide protection to the daily exposure to multiple chemicals and should not be limited to chemicals registered above 1000 tonnes per year. **MAF should apply to all chemicals subject to a chemical safety assessment**.

Information requirements

The REACH standard information requirements for registration dossiers should require all data needed for hazard identification and risk management, including for the new hazard classes introduced in the revised CLP regulation: Endocrine Disrupting Chemicals (EDCs), Persistent, Bioaccumulating and Toxic chemicals (PBT and vPvB) and Persistent, Mobile and Toxic chemicals (PMT and vPvM). Therefore, we welcome the Commissions initiative on updating the REACH Annexes. For details, we refer to the specific comments provided to the Commission in writing.

Low tonnage substances

We ask the Commission to extend the requirement for a chemical safety assessment to substances produced or imported in quantities between 1 and 10 tonnes per year and revise the information requirements for this tonnage level accordingly. Furthermore, a proposal for registration or notification of substances manufactured or imported in quantities below one tonne per year is necessary. Over 100 000 chemicals may be marketed in the EU today without having any information on their use and toxicity.

Polymers

We fully support the notification of all polymers and also a stepwise registration process for all polymers prioritising the potentially most hazardous polymers and those polymers produced in highest volumes as plastic building blocks, as people and the environment are universally exposed to these chemicals through micro and nano plastics.
Information on hazards of polymers will ensure actors along the supply chain can control risks, ensure information to recyclers for safe circular economy and ensure innovation towards safer chemicals. The lack of information on polymers is a main hurdle to regulate chemicals, adding burden on authorities and companies.

EVALUATION

The lack of information in the registration dossiers is a bottle neck in the identification and regulation of harmful chemicals. Therefore, streamlining and simplification of the evaluation process is needed to ensure faster generation of the information for hazard identification and risk management. We support the proposals presented at CARACAL regarding Dossier- and Substance evaluation, especially the ability to **revoke registration numbers in case of non-compliance with legal information requirements or non-compliance with evaluation decisions.**

However, regarding the Commission proposal to remove the fixed target for compliance checks in the current legal text, we suggest updating the targets to achieve compliance of all dossiers, in order to progress towards achieving the CSS goal of zero tolerance to non-compliance.

Also promoting the **use of group assessments** and read-across in the legal text on evaluation will increase the effectiveness of evaluation, prevent regrettable substitution and contribute to a reduction of animal testing.

We propose to keep the testing proposal requirement reserved for vertebrate testing, extending this requirement to all animals will complicate the process and lead to an increased burden for companies, ECHA and member state competent authorities, without improving protection of health and the environment.

Regarding the revision of the **decision-making process**, we suggest establishing deadlines for every step in the process, this means additional deadlines to be set in REACH articles 51.1 and 52.1.

Finally, introduction of fees is required for actions that create additional workload for ECHA, such as a fee covering the costs associated with non-compliant dossiers.
Streamlining and simplification of the evaluation process, will reduce the burden on authorities and accelerate the regulatory control of harmful chemicals.

AUTHORISATION

Regarding the simplification elements presented to CARACAL, we believe that only **the "Clarification of the main requirements for applications for authorisation" will reduce the burdens** of this process while maintaining its aim to assure that these substances of very high concern are progressively replaced.

Improving implementation through clarifications following the recommendations from the courts and the Ombudsman, like not allowing AfA that are not in conformity in the first place, would address the high burden on authorities that the process has caused. Better and earlier information on uses and alternatives will ease the implementation and the burden on authorities when deciding on applications to continue using substances of very high concern.

We strongly oppose the introduction of an additional upfront analysis and discussion of regulatory options to decide if and which substances should be subject to regulation. It already takes two decades to identify and regulate hazardous chemicals in the EU, and adding new steps will further delay addressing the increasing health and environmental impacts of hazardous chemicals. Additional processes are at odds with the expressed aim simplify REACH and reduce the burden on authorities and companies.

Instead of adding burdens to the existing processes we believe authorities should take stock of the work done by ECHA on grouping and assessing regulatory needs and prioritise chemicals identified already as requiring regulatory action.

We also oppose strongly the initiative to change the role of the candidate list to a tool to prioritise regulatory action in general, instead of being first step to authorisation only. This is against the aim of the authorisation chapter to phase-out the substances of very high concern and shift the burden of proof to industry and will lead to additional delays and regulation and overburdening of authorities.

The proposal to changing the prioritisation criteria is very concerning as it will reduce the scope of authorisation, both by limiting chemicals that would be prioritised and the uses that would be covered.

Looking at the bigger picture on options presented at CARACAL regarding regulating chemicals, if the scope of authorisation is reduced banning most hazardous substances would rely on Art 68.1 ordinary restriction process. This is, we would be going back 20 years to the pre-REACH system. Ironically, we have REACH because the restriction system was found inefficient and burdensome.

Considering the bottle neck at the Commission today, with a dozen files pending decisions, delayed on average 2 years- some for 4 years - and the limited resources of member states and ECHA, the proposal to rely only on ART 68.1 would basically stall the regulation of the most hazardous chemicals.

Therefore, we consider that the authorisation process should maintain its prioritisation criteria and include all uses of SVHC covered by authorisation process. To simplify authorisation, only essential uses should be authorized, the adequate control route should be eliminated, and decisions should be based on the availability of alternatives. A

mechanism to get better and earlier info on uses together with a correct implementation of the legal text would speed-up and reduce burdens.

RESTRICTION

As commented above, we strongly oppose the introduction of an upfront additional assessment process (RMOA) that would increase complexity, burdens on all actors, on authorities and delay phasing out the most harmful chemicals.

To honour the CSS commitment of improving the protection of people and the environment, in particular most vulnerable population, and to drive competitiveness as reflected in the COM's Competitiveness compass, restriction process needs to speed up, and the burden on authorities need to be reduced.

This should be done by extending the fast-track restriction process Art 68.2. to all the most hazardous chemical classes, including persistent substances (PBT/vPvB and PMT/vPvM) as originally planned by the Commission. Persistent chemicals pose the greatest threat, leading to long-term and widespread exposure via contaminated food and drinking water, affecting vulnerable groups and future generations. To prevent future PFAS-like scandals, it is crucial that PBT/vPvB AND PMT/vPvM substances are regulated with highest priority. Without this, we risk repeating the mistakes of the past, allowing hazardous chemicals to accumulate in the environment and cause irreversible and widespread harm.

We propose to establish a transparent workplan to phase-out MHS in articles and mixtures aimed for the general public by 2033.

We support the CSS commitment to extend this fast-track restriction route to professional uses, these are uses where the most vulnerable workers are exposed to hazardous chemicals due their lack of knowledge, training and control measures, such as hairdressers, self-employed painters, cleaning professionals, constructers, etc. Furthermore, we suggest expanding the right of initiative under Article 68(2) to the competent authorities of member states, in order to simplify and reduce the regulatory burden.

Additional measures to improve normal process Art 68.1 should include **grouping chemicals for restriction by defaul**t as we have seen how it has successfully worked (microplastics, tattoos, PFAS), reducing the burden on authorities; and **establishing clear phase-out timelines** to ensure predictability and a level playing field for companies,

Adding RMOA steps to regulatory processes will only add complexity and delaying protections. It is time to make use ECHA's work over the last years, assessing regulatory needs and making proposals for group restrictions, instead of increasing complexity and delaying action through new RMOA steps.

ENFORCEMENT

We agree that improving enforcement and compliance of EU companies with legal obligations should be a priority of the REACH revision.
It is unacceptable that there are still no consequences for the high level of non-compliance with registration obligations (80% on-compliant evaluated dossiers).
It is unacceptable that registration dossiers and SDS are not updated with SVHC identification and classification and labelling,
The revision should include previous commitments for increasing compliance, such as:

- √ Empowering ECHA to revoke registration numbers, also supported by IND stakeholders in the past.
- √ Make registrants accountable for costs inherent to non-compliant dossiers.
- √ Implementing a dossier expiration date.

We agree that enforcement of compliance of imported goods is important, but this shouldn't give "carte blanche" to European companies.

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