April 2025

HEAL comments on CARACAL 54 proposals for the targeted revision of REACH

Contents

INTRODUCTION

HEAL supports the revision of REACH in line with the commitments made under the EU Chemicals Strategy for Sustainability (CSS)[1], to significantly increase the protection of human health and the environment from harmful chemicals, paying particular attention to vulnerable population groups. We also welcome the attention to simplify the implementation of the legislation, provided that it doesn't result in a weakening of the ambition to avoid harm to the planet and to current and future generations.

The reform should be driven by REACH's founding principles; namely implementing the 'no data, no market' principle, putting the burden of proof regarding the safe use of chemicals on the registrants, and ensuring a high level of protection of human health and the environment against harmful substances.

The manufacture, use and trade of chemicals is globally linked to unintentional chemical exposures and is subsequently contributing to the burden of disease and environmental pollution in Europe, leading to substantial health, societal and remediation costs. For example, exposure to endocrine disrupting chemical in the EU are associated with various diseases and dysfunctions including IQ loss, endometriosis, obesity, diabetes or male infertility, causing estimated median annual costs of

[1] European Commission. 2020. Chemicals Strategy for Sustainability Towards a Toxic-Free Environment.

€163 billion in the EU.[2] Additionally, remediation costs for PFAS (per- and polyfluoroalkyl substances) have been estimated to range between €95 billion (in case PFAS emissions cease immediately and only legacy PFAS are remediated) and €2 trillion (in case emissions continue and emerging PFAS are also remediated) over the next 20 years.[3] An ambitious REACH revision is needed to minimise future disease costs by endocrine disruptors and to prevent persistent environmental pollution and remediation costs analogously to PFAS in the future.
Simultaneously, it is essential that the REACH revision doesn't miss on the opportunity to take up the latest scientific evidence and to align REACH with recent changes in related EU regulatory files, especially with the adoption of four new hazard classes in the CLP regulation.[4]
An updated and consolidated REACH can contribute to increasing European autonomy in the chemicals sector by promoting innovation and the circular economy through the smart use of chemicals and clean material cycles, which don't contain harmful chemicals or substances that hamper recycling.

We have not yet received a proposal from the Commission for the REACH revision with legal text for the presented points, making it difficult to provide detailed suggestions without the full picture. Therefore, our comments are based on the presentations given by the Commission and the comments made at the CARACAL meeting on 3 April 2025.

SUMMARY OF HEAL KEY COMMENTS

We thank the Commission for the chance to comment on the presented ideas and view a number of the proposals as a promising start, which need to be strengthened to achieve a health-focused REACH revision. To **deliver on the goals outlined in the CSS with simple and effective measures and finally provide more confidence in the effectiveness of REACH to better protect people health,** it is crucial that the following items presented on 3rd April are maintained and substantially improved:

- Mixture allocation factor (MAF) for chemical risk assessment: the consideration of scientific evidence about the **combined exposure to chemical mixtures** in risk assessment (e.g. simply through applying a Mixture Allocation Factor (MAF)) is essential to start tackling effectively the risks posed by chemicals mixtures and should not be limited to the substances produced at the highest tonnage (i.e. above 1000 tons per year);
- **Extension of the existing generic risk management approach** (GRA) currently applied to CMRs only. In line with the commitments of the CSS and to be coherent with the updated CLP regulation, GRA needs to be extended to further hazard classes of the most harmful

[2] Trasande, L., Zoeller, R. T., Hass, U., Kortenkamp, A., Grandjean, P., Myers, J. P., DiGangi, J., Hunt, P M., Sathyanarayana, S., Bellanger, M., Hasuer, R., Legler J., Skakkebaek, N. E. & Heindel, J. J. 2016. Burden of disease and costs of exposure to endocrine disrupting chemicals in the E uropean Union: an updated analysis. Andrology, 4(4), 565-572.
[3] The forever pollution project. 2025. https://foreverpollution.eu/lobbying/the-bill/
[4] European Commission. 2023. Commission Delegated Regulation (EU) 2023/707.

chemicals (incl. especially endocrine disruptors and persistent, bioaccumulative or mobile substances). This is crucial to avoiding unacceptable risks for the public and the environment and to allow for the fast-track restriction of substances with most hazardous properties;

- **Obligation to notify polymers** and **register prioritised polymer groups** (polymers requiring registration, PRR). Due to the exemption from registration, there is currently no centralised public database on the identity of polymers that are manufactured and placed on the EU market and no structured information on volumes, uses or toxicological effects of these chemicals. It is high time to start addressing this data gap to enable scrutiny and research of the hazards and risks of polymeric chemicals.

At the same time, we have **strong concerns** about other elements which have been presented, that will further **prolong the procedures for risk management of harmful chemicals and introduce undue bureaucratic burden on authorities**. Therefore, we ask the Commission to reconsider those initiatives which would:

- **weaken the authorisation process,** in particular by:
    - removing the prioritisation criterium of "widespread use" for the phase-out of Substances of Very High Concerns (SVHC) (Article 58(3));
    - allowing for more flexibility to exclude certain uses from authorisation and therefore not achieving a phase-out of the affected SVHC;
    - introducing transitional periods after an application for authorization is refused and thus keeping a phased-out substance on the market for longer;
- **introduce mandatory new bureaucratic burden on authorities** (e.g. obligatory Regulatory Management Options Analysis (RMOA) before risk management);

These changes would compromise the chances to implement the much-needed modernisation of REACH with regards to improving the quality of registration dossiers and facilitating the work of the authorities, the effectiveness of the authorisation process and supply chain communication, i.e. topics in need of updated and improved implementation, as also outlined in the last reviews of the regulation.[5,6]

DETAILED COMMENTS

Registration

- Integration of a mixture allocation factor (MAF) into chemical risk assessment

[5] European Commission. 2018. Commission General Report on the operation of REACH and review of certain elements: Conclusions and Actions.

[6] Umweltbundesamt. 2018. REACH Weiterentwicklung Vergleich des Review-Berichts der EU Kommission mit verschiedenen Studien und Berichten im Kontext der REACH-Überprüfung.

Humans and wildlife are simultaneously and continuously exposed to many chemicals.[7] These complex chemical mixtures can affect the health of organisms, even when the individual mixture components are only present in low concentrations, which would not lead to toxic effects in individual exposures.[8] Despite a decade-old acknowledgement of a regulatory gap in the consideration of combined effects of unintentional chemical mixtures[9], the risk assessment of industrial chemicals under REACH is currently still based on single chemicals without an integration of unintended mixture effects.

HEAL therefore welcomes the introduction of a Mixture Allocation Factor (MAF) into the chemical risk assessment of all registered substances, as a simple and practical policy measure to finally better tackle the risks posed by chemicals mixtures.[10,11,12]

As research has specifically shown that also chemicals that are present in very low concentrations, can contribute to mixture effects in a mostly additive manner,[13,14,15] we strongly urge the Commission to make the use of a MAF mandatory for the risk assessment of all registered substances under REACH. Especially considering vulnerable population groups, such as pregnant woman, infants or the elderly, we believe a MAF that is only applied for those substances produced at the highest tonnage (i.e. above 1000 tons per year) is not protective enough.

- Notification of all polymers, identification of polymers requiring registration (PRR) and registration of PRR

HEAL supports a notification obligation for all polymers, to be able to map the polymer universe in the EU and subsequently define polymers requiring registration (PRR). These PRR should then be registered, their safe use demonstrated, and potential risk management measures communicated. Polymers are a specific group of chemicals, consisting of (long) chains of repeated chemical monomer units, that is currently exempt from registration requirements under REACH. Polymers can be very diverse in structure, containing different elements, functional groups or side-chains and being of variable length. This diversity in structure leads to large differences in the properties of

[7] European Commission. 2012. Communication from the Commission to the Council. The combination effects of chemicals – chemical mixtures.

[8] Kortenkamp, A., & Faust, M. 2018. Regulate to reduce chemical mixture risk. Science, 361(6399), 224-226.

[9] European Commission. 2012. Communication from the Commission to the Council. The combination effects of chemicals – chemical mixtures.

[10] Bopp, S. K., Kienzler, A., Richarz, A. N., van der Linden, S. C., Paini, A., Parissis, N., & Worth, A. P. 2019. Regulatory assessment and risk management of chemical mixtures: challenges and ways forward. Critical Reviews in Toxicology, 49(2), 174-189.

[11] Drakvik, E., Altenburger, R., Aoki, Y., Backhaus, T., Bahadori, T., Barouki, R., ... & Bergman, Å. 2020. Statement on advancing the assessment of chemical mixtures and their risks for human health and the environment. Environment international, 134, 105267.

[12] Hassold, E., Galert, W., & Schulze, J. 2021. Options for an environmental risk assessment of intentional and unintentional chemical mixtures under REACH: the status and ways forward. Environmental Sciences Europe, 33(1), 131.

[13] European Commission. 2012. Communication from the Commission to the Council. The combination effects of chemicals – chemical mixtures.

[14] SCHER, SCCS, SCENIHR. 2012. Opinion on the Toxicity and Assessment of Chemical Mixtures.

[15] Martin, O. V., Martin, S., & Kortenkamp, A. 2013. Dispelling urban myths about default uncertainty factors in chemical risk assessment–sufficient protection against mixture effects?. Environmental health, 12, 1-22.

polymers: some can be water-soluble while others do not dissolve in water; some can be very persistent while others are easily broken down; some can cross biological membranes and enter cells while other may not be able to do so. Due to the exemption from registration, there is currently no centralised public database on the identity of polymers that are manufactured and placed on the EU market and no structured information on volumes, uses or toxicological effects of these chemicals. Nevertheless, scientific research shows that polymers can have chemical and physical effects on human health and the environment.[16,17,18] Furthermore, it was reported that certain polymers can be prone to transformation and degradation over time, leading to the formation of mobile products that can be more bioavailable and hazardous then the parent polymer.[19,20] Polymers that have been associated with problematic properties and would benefit from notification and registration obligations include for example PFAS polymers, such as side-chain fluorinated polymers, which are known to release their perfluorinated side chains as non-polymeric PFS moieties over time.[21]

- Update of the registration process in line with the learnings from 20 years of REACH

The past reviews of REACH and analysis of data available on registered substances have indicated issues with the quality of registration dossiers, for example non-sufficient information on the substance identity, on (eco)toxicological effects and uses, and high rates of non-compliance hampering efficient risk management and requiring many resources from the authorities for any REACH and CLP processes. [22,23,24,25]

Therefore, HEAL welcomes a much-needed update of the registration process, to provide a clear motivation for registrants to bring dossiers into compliance and keeping them up to date, minimising delays in risk management caused by data-gaps. The update of the registration process

[16] Almroth, B. C., Groh, K., Walker, T. R., Bergmann, M., Allen, S., Nerin, C., Scheringer, M., Fantke, P., Muncke, J., Green, D., Syberg, K., Diamond, M., Bour, A., Lohmann, R., Schaeffer, A., Collins, T. J., Allen, D., Soto, A. M. & Sundelin, B. 2021. Statement on the registration of polymers under REACH-The main goal of the process should be to ensure a high level or protection of human health and the environment.

[17] Rodrigues, M. O., Abrantes, N., Gonçalves, F. J. M., Nogueira, H., Marques, J. C., Gonçalves, A. M. M., 2019. Impacts of plastic products used in daily life on the environment and human health: What is known? Environmental Toxicology and Pharmacology 72, 103239.

[18] Julinová, M., Vaňharová, L., & Jurča, M. 2018. Water-soluble polymeric xenobiotics–Polyvinyl alcohol and polyvinylpyrrolidon–And potential solutions to environmental issues: A brief review. Journal of environmental management, 228, 213-222.

[19] Arp, H. P. H., & Knutsen, H. 2019. Could we spare a moment of the spotlight for persistent, water-soluble polymers?.

[20] Liu, X., Xiong, Y., Gou, X., Zhao, L., Wang, S., Wei, Y., ... & Chen, D. 2025. Environmental impacts of polymeric flame retardant breakdown. Nature Sustainability, 1-14.

[21] Lohmann, R., & Letcher, R. J. 2023. The universe of fluorinated polymers and polymeric substances and potential environmental impacts and concerns. Current opinion in green and sustainable chemistry, 41, 100795.

[22] European Commission. 2013. General Report on REACH.

[23] European Commission. 2018. Commission General Report on the operation of REACH and review of certain elements: Conclusions and Actions.

[24] German Environment Agency. 2015. REACH Compliance: Data Availibility of REACH Registration Part 1: Screening of chemicals > 1000 tpa.

[25] German Environment Agency . 2018. REACH Compliance: Data availability in REACH registrations Part 2: Evaluation of data waiving and adaptations for chemicals ≥ 1000 tpa.

should include the presented measures of time-limited validity of registration, ad-hoc completeness checks by ECHA and a revocation of registration numbers as a consequence for non-compliance. We believe that these measures can be implemented without undue bureaucratic demands on registrants, as explained by the Commission in the April CARACAL meeting. Compliance with the decade-old provisions of REACH is a matter of course for us.

Evaluation

- Improvements of the evaluation processes

HEAL agrees with the presented initiatives to improve the dossier and substance evaluation processes. Specifically, we welcome the option to explicitly refer to potential hazard (alongside potential risk) as a possible justification to select (groups of) substances for substance evaluation. Likewise, we support the simplification for the already applied practise of selecting (groups of) substances for substance evaluation based on structurally similar substances, constituents, transformation or degradation products. Allowing ECHA to conduct substance evaluations will provide support for member states and can further accelerate the progress of this process in our opinion.

Risk management: Authorisation and Restriction

- Extension of generic risk management approach (GRA)

The generic risk approach is a risk-based decision-making tool and a preventive measure for avoiding unacceptable risks for the public and the environment. It currently allows for the fast-track restriction of substances with certain hazardous properties (namely carcinogens, mutagens and substances that are toxic to reproduction; CMRs) for consumer uses.
In line with the commitments of the CSS and to be coherent with the updated CLP regulation, HEAL believes that extending the GRA to further hazard classes is a simple and effective measure to regulate the most harmful chemicals in a predicable way. We call on the Commission to extend the GRA to include all the categories of endocrine disruptors (known, presumed and suspected) as well as persistent, bioaccumulative or mobile chemicals into its scope.
Like CMRs, endocrine disruptors are known to have the potential to affect future generations and to act at extremely low levels.[26,27] Transient effects of endocrine disruptors at critical development periods, which rely heavily on hormone signalling (e.g. certain time points during gestation, mini-puberty, puberty or menopause), can also lead to delayed effects later in life.[28] There is growing evidence from across scientific disciplines that endocrine disruptors contribute to the onset of

[26] Gore, A. C., Chappell, V. A., Fenton, S. E., Flaws, J. A., Nadal, A., Prins, G. S., ... & Zoeller, R. T. 2015. EDC-2: the endocrine society's second scientific statement on endocrine-disrupting chemicals. Endocrine reviews, 36(6), E1-E150.
[27] Endocrine Society. 2023. Endocrine-disrupting chemicals in the European Union: https://www.endocrine.org/-/media/endocrine/files/advocacy/society-letters/endocrine-disrupting-chemicals-in-the-european-union-jan-2023.pdf
[28] Svingen, T., Andersson, A. M., Angelova, J., Axelstad, M., Bakker, J., Baumann, L., ... & van Duursen, M. 2024. Enhanced identification of endocrine disruptors through integration of science-based regulatory practices and innovative methodologies: The MERLON Project. Open Research Europe, 4, 68.

numerous diseases including neurodevelopmental problems, infertility and other reproductive disorders, and hormone-sensitive cancers like breast and prostate cancers.[29]
As endocrine disruption has only recently been added as a hazard class under CLP and no standard information requirements under REACH are in place yet to detect endocrine disrupting properties, the information available to identity and classify chemicals as endocrine disruptors is currently very limited[30] and will likely stay limited in the near- to medium-term future. Therefore, we expect many chemicals to be initially classified as"suspected endocrine disruptors", based on the strength of the limited available evidence.[31] To be able to nevertheless protect citizens from these chemicals efficiently and without delays, we strongly recommend extending the GRA not only to "known and presumed" but also to "suspected endocrine disruptors".
Persistent chemicals pose a well-known risk for humans and wildlife, as by definition, they do not or only very slowly degrade. This means that sooner or later they are occurring ubiquitously around the globe and can even be detected in pristine environments. Substances that are both persistent and bioaccumulative have been recognized as substances of very high concern since the beginning of REACH, as they accumulate in living organisms and often magnify in food chains, which can lead to extremely high exposures to (top) predators, including humans. Therefore, we consider it high time to extend the GRA also to PBT and vPvB substances, to ensure their rapid restriction also in widely used articles such as textiles.
Likewise, we urge the Commission to include persistent and mobile substances in the GRA, as effects and impacts of PMT/vPvM substances are often similar to PBT/vPvB.[32] PMT/vPvM substances can for example accumulate in drinking water cycles, leading to exposures that can be very difficult to assess and that are neither possible to avoid by consumers nor easy to clean-up once they have occurred. Restricting PMT/vPvM chemicals in a simple and automated manner via the GRA would therefore in our opinion be the best policy option to protect human health and the environment.

- Improvements for regular restrictions

Apart from GRA, regular restrictions under REACH (Article 68(1)) have also shown to be beneficial economically, generating at least four times more benefits to society than what they cost, while also mitigating the risks of harmful chemicals for at least seven million EU consumers and workers.[33] However, this risk management process has been proven to be too slow, with a median time of over five and a half years passing between the publication of a restriction intention and the entry into force of the restriction.[34]

[29] Ho, V., Pelland-St-Pierre, L., Gravel, S., Bouchard, M. F., Verner, M. A., & Labrèche, F. 2022. Endocrine disruptors: challenges and future directions in epidemiologic research. Environmental research, 204, 111969.
[30] Homer. M. L., Christiansen, S., Axelstad Petersen, M., Holbech, H., Ebsen Morthorst, J., Lund Kinnberg, K. 2024. Prioritisation of Endocrine Disruptors for Regulation. CeHoS-5.3.
[31] European Commission. 2023. Commission Delegated Regulation (EU) 2023/707.
[32] Hale, S. E., Arp, H. P. H., Schliebner, I., & Neumann, M. 2020. Persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances pose an equivalent level of concern to persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances under REACH. Environmental Sciences Europe, 32, 1-15.
[33] European Chemicals Agency. 2021. Costs and benefits of REACH restrictions proposed between 2016-2020.
[34] European Environmental Bureau. 2022. The Need for Speed.

Therefore, HEAL sees a need for further improvements to the regular restriction process, for example by further encouraging group-based restrictions and clarifying the necessary provisions. We ask the Commission to clarify which improvements are foreseen for regular restrictions, as we noticed that no ideas were put forward in the CARACAL meeting.

- A strong and effective authorisation process to phase-out substances of very high concern

Authorisation is the key risk management process to phase-out harmful substances under REACH. The authorisation process is currently under scrutiny due to the long decision-making times and the high administrative burdens it places on regulators.[35,36] Nevertheless, data analysis has shown that placing substance of very high concern on the authorisation list led to a decrease of their use. ECHA has estimated that in 2021 the combined volume of substances subject to authorisation placed on the EU market was 45 % less than it was in 2010.[37]
HEAL is in favour of an improvement of the implementation of the authorisation process for example by rejecting or deprioritizing incomplete applications for authorisation, as also proposed by the European ombudsman in her 2024 report.[38] We do not support any initiatives that will weaken the authorisation process or its phase-out goal and keep substances of very high concern on the market for longer. This includes several ideas presented at the April CARACAL meeting, such as the consideration to remove "widespread use" as a prioritisation criterium for SVHCs, an increased flexibility to exclude uses from authorisation, which would reduce the effectivity of a system that aims at the phase-out of chemicals, or transitional periods after an application for authorization is refused.

- Obligatory Regulatory Management Options Analysis (RMOA) before risk management

Regulatory Management Options Analysis (RMOA) or Assessments of Regulatory Needs (ARN) are voluntary assessments often conducted by authorities to decide on further risk management steps for (groups of) substances. Their scope and processes are currently not defined in REACH.
HEAL does not support the introduction of an additional mandatory step in risk management, including a mandatory RMOA or ARN, due to concerns about adding further delays to the risk management procedures and a lack of clarity on the benefits of this obligation. We are aware that RMOA and ARN are already conducted before the initiation of restrictions and SVHC identifications and have been for the last decade.[39,40] Additionally, we would like to note that harmonized classifications are currently also regularly initiated as a follow-up to dossier and substance evaluation and we do not think that an additional RMOA or ARN would add any benefit if this is the case. We would also like to point out that ECHA sees ARNs as iterative processes that can be

[35] European Commission. 2020. Chemicals Strategy for Sustainability Towards a Toxic-Free Environment.
[36] European Ombudsman. 2024. Recommendation on the risk management of dangerous chemical substances by the European Commission (case OI/2/2023/MIK).
[37] European Chemicals Agency. 2022. Changes of market volumes of chemicals subject to authorisation in 2010-21.
[38] European Ombudsman. 2024. Recommendation on the risk management of dangerous chemical substances by the European Commission (case OI/2/2023/MIK).
[39] European Chemicals Agency. 2020. Grouping speeds up regulatory action. Integrated Regulatory Strategy Annual Report.
[40] European Chemicals Agency. 2024. Integrated Regulatory Strategy – Past successes and future outlook.

adjusted when new data becomes available.[41] We therefore call on the Commission to clarify if it envisions RMOA and ARN as having a time-limited validity and under which circumstances obligatory RMOA and ARN would need to be updated or repeated in case new data becomes available.

- Implementation of the Essential Use concept

The essential use concept, as introduced in the CSS, aims "to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health."[42]. Delivering on the CSS commitments to the concept, the Commission has published a Communication in 2024, detailing guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals[43]. Within this Communication, the phase-out aim for the most harmful substances in non-essential uses, in particular in consumer products, is again reiterated. In its main part and in the annexes, the Communication provides definitions and guidance on terms and principles of the essential use concept and how to apply the assessment, including a flow chart. HEAL supports the implementation of the essential use concept to determine which harmful chemicals can be eligible for applications for authorisation and derogations from restrictions, i.e. non-essential uses would not be able to apply for authorisation or be considered for an exemption from a restriction. We believe that in this way the concept would contribute to the simplification of chemical risk management under REACH, by facilitating decision-making and increasing regulatory efficiency. We urge the Commission to keep the application of the concept as simple and predicable as possible, by applying it as outlined in their 2024 Communication [44], thus providing clarity and predictability to registrants, authorities and other stakeholders.

[41] European Chemicals Agency. 2023. Speeding up the identification of chemicals of concern. Integrated Regulatory Strategy Annual Report.
[42] European Commission. 2020. Chemicals Strategy for Sustainability Towards a Toxic-Free Environment.
[43] European Commission. 2024. Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals.
[44] European Commission. 2024. Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals.

The Health and Environment Alliance (HEAL) is the leading not-for-profit organisation addressing how the environment affects human health in the European Union (EU) and beyond. HEAL works to shape laws and policies that promote planetary and human health and protect those most affected by pollution and raise awareness on the benefits of environmental action for health.

HEAL's over 70 member organisations include international, European, national and local groups of health professionals, not-for-profit health insurers, patients, citizens, women, youth, and environmental experts representing over 200 million people across the 53 countries of the WHO European Region.

As an alliance, HEAL brings independent and expert evidence from the health community to EU and global decision-making processes to inspire disease prevention and to promote a toxic-free, low-carbon, fair and healthy future.

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