AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Response

Reform of REACH Authorisation and Restriction

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Executive summary

As the European Commission considers the reform of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) authorisation and restriction processes, it must pursue targeted, incremental improvements rather than a complete overhaul, such as removing the authorisation system and REACH Annex XIV. Instead, reforms should include, among other measures: streamlining the authorisation and restriction provisions; retaining authorisation as a potential risk management option where appropriate; better prioritising substances for further regulation; allowing industry to apply for derogations of general applicability; and using a harmonised and holistic set of criteria to assess derogations from regulatory risk-management measures. Above all, the principles of risk assessment and science-based decision-making must guide any revisions to REACH.

Introduction

On 6 July 2022, the Commission presented its latest document on the reform of the REACH authorisation and restriction processes for discussion at the meeting of the Competent Authorities for REACH and Classification, Labelling and Packaging of Substances and Mixtures Regulation (CARACAL) 45. The document offers the most detailed overview so far of the Commission's thinking on the future of authorisation and restriction processes, including how they align with key concepts under the Chemicals Strategy for Sustainability, such as the extension of generic risk assessment (GRA) and the essential use concept (EUC).

Given the significance of these proposals, as the Commission moves to complete its impact assessment and draft its legislative proposal for the revision of the REACH regulation, it should reflect upon stakeholders' input. The following sections highlight several considerations that are particularly important moving forward.

1. A hybrid approach for authorisation and restriction reform, based on options

In its paper, the Commission focuses on three policy options for reforming authorisation and restriction processes under REACH:

- streamline the authorisation and restriction provisions;
- merge authorisation and restriction provisions into one system; or
- abandon the authorisation provisions but keep the Candidate List.

As stated in the American Chamber of Commerce to the EU's (AmCham EU) previous positions and in keeping with the findings of the 2018 REACH review, the Commission should pursue improvements to REACH that are targeted and incremental, avoiding the severe uncertainty that would stem from an unjustified overhaul of EU chemicals legislation.

Completely removing the authorisation system and REACH Annex XIV would result in major and unjustified changes to the way REACH works. Annex XIV currently exempts certain uses and applications, including intermediate uses, which are safely managed and contained on manufacturing sites. These exemptions are fully justified and should be maintained.

At the same time, the Commission's concerns about alleviating burdens related to current authorisation provisions, both for industry and the authorities, are understandable. Consequently, a solution for reforming authorisation and restriction should be based on option 1 ─retaining authorisation as a potential risk management option where appropriate ─ and also integrate tweaks and simplifications from other options, as detailed below.

2. Future role of the Candidate List

The Commission notes that for all three options, identification and prioritisation of substances for further regulation would take place through the public activities coordination tool (PACT) and the Candidate List. There is significant value in pursuing better prioritisation, and the Commission should take this approach to reform. In particular, the Candidate List could be removed from the Authorisation Chapter since inclusion in Annex XIV is not the most appropriate risk-management option for all substances of very high concern (SVHCs), particularly when they are used primarily as intermediates.

Once new substances are included on the Candidate List, the European Chemicals Agency (ECHA) could be tasked with screening to determine the most appropriate regulatory pathway to address potential risks when not completed earlier in the process eg through PACT. This would allow for a more comprehensive assessment of the interface between risk-management measures under REACH and other legislation, such as occupational safety and health regulations. Avoiding prioritisation of SVHCs for Annex XIV listing by default would save resources for both industry and the authorities, particularly in cases where authorisation would carry limited benefits and other risk-management options would be preferable.

3. Derogations of general applicability

While it is preferable to retain authorisation in Annex XIV, there is merit in the proposal to introduce the possibility for industry to apply for derogations of general applicability. Whereas the Commission's paper links this proposal to option 2 (merger of Annex XIV into Annex XVII), such a change could be introduced while retaining authorisation and restriction as separate chapters in REACH. Specifically, industry could be allowed to request derogations of general applicability both for substances listed in Annex XIV and Annex XVII. This would reduce the burden on industry and the authorities – avoiding the need for multiple assessments of individual applications – while retaining a more flexible regulatory toolbox. However, it should still be possible to include derogations upfront during the restriction process itself, where the Annex XV submitter or the Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) deem appropriate based on the evidence available.

4. Generic risk management approach

The Commission's paper highlights the extension of GRA as a key feature across policy options. As noted in previous AmCham EU positions, an excessive reliance on automatic restrictions based on hazard classification under GRA would be disproportionate and carry a heavy risk of causing unintended consequences for key product groups and value chains. The principles of risk assessment and science-based decision-making – which are absent under GRA – must remain at the core of EU chemicals legislation.

Against this backdrop, the Commission's commitment to prioritisation in the context of a work plan aimed at implementing GRA is laudable, particularly when it comes to 'types/categories of articles […] based on considerations of exposure potential throughout the lifecycle' and 'products for professional users […] based on considerations of similar exposure patterns to consumers'. In regard to implementing restrictions based on GRA, the Commission should focus on substances carrying the most critical hazards (eg SVHCs) used in consumer mixtures with high potential for exposure. In line with the input provided above, the Candidate List should also be used as a tool to prioritise and assess various risk-management options before moving ahead with a GRA restriction.

5. EUC

Section 3 of the CARACAL paper focuses on policy options for introducing the EUC, including two flowcharts with procedural scenarios for EUC assessments.

The rationale for reforming REACH is partially driven by a willingness to speed up regulation and alleviate burdens on authorities and stakeholders. If not implemented proportionately, concepts like EUC that appear simple in principle may result in extremely burdensome regulatory procedures in practice. For example, industry may need to prepare — and authorities would need to assess — significant numbers of EUC derogation requests for substances in uses that may not pose an actual risk but may nevertheless be restricted under GRA.

Instead, EUC should be used as a complementary tool for decision-making, through a harmonised and holistic set of criteria used as a reference when assessing derogations from regulatory risk management measures. As a general rule, EUC should complement and not replace risk assessment and socio-economic analysis activities under key REACH processes.

Legal certainty would be fundamental in setting EUC criteria, particularly if the concept is formally integrated into REACH regulatory processes. EUC criteria should therefore be introduced through legislation and be complementary to socio-economic analysis (option C1 in the Commission paper). While guidance may offer additional support for stakeholders, criteria based exclusively on guidance would significantly undermine the predictability of the legislative framework. The Commission should provide EUC criteria through legislation rather than guidance. In the case of O5A (Once an article, always an article), ECHA guidance indicated that an article was the product that was delivered/sold/shipped into or within the EU. This guidance was later challenged by France and overturned by the European Court of Justice, causing great disruption and urgency to comply with the legal definition, particularly in how it impacted Article 33's safe use communication requirements.

When it comes to the process for EUC assessments, the paper correctly notes that 'some elements, in particular criticality for the functioning of society and necessity for health and safety, go beyond merely scientific facts, hence decisions on them will need to be taken by appropriate legitimate bodies'. There is merit in the proposal put forward by the European Chemical Industry Council (Cefic) around setting up an 'Essential Use Committee' under the auspices of the Commission.[1] Neither of the two scenarios included in the CARACAL 45 paper introduces a new body specifically tasked with essential use assessments. However, the second scenario offers a better opportunity to integrate broader policy considerations in EUC decision-making by giving the Commission and the REACH Committee an upfront role in screening essentiality, with the possibility to request more detailed

[1] https://cefic.org/app/uploads/2021/05/2021-05-How-to-introduce-the-%E2%80%98Essential-Uses-Concept-under-REACH-Concept-paper.pdf

assessments from ECHA committees in complex cases. Still, this would be a major addition to the REACH Committee's current responsibilities and requires further exploration of the committee's ways of working, particularly in securing the right level of expertise, transparency and access for stakeholders. At a minimum, agendas and committee documents must consistently be published well in advance of meetings, and access to meetings must be granted to impacted stakeholders.

6. Assessment of alternatives

Assessment of alternatives will inevitably be a key element in the implementation of EUC, regardless of which scenario is selected. As noted in the CARACAL paper, assessment of alternatives can often be complex. Information on alternatives should be requested at an early stage to allow for appropriate consideration during EUC assessments. This could be done, for example, through calls for evidence for SVHCs included on the Candidate List. Key to ensuring informed decision-making is an appropriate ECHA Working Group to deal with alternatives and provide expertise in difficult cases. The emphasis on strengthening substitution plans and cooperation between stakeholders would also be welcome, as drop-in alternatives will rarely be available for essential uses, and substitution will require significant research and development, testing, investments and time.

The end users often have a better understanding of the status of alternatives as well as valuable insight on the performance and industrial requirements. Additionally, certain industries such as aerospace and medical have other parallel regulatory requirements that must be met while substituting.

7. Minimal exposure

Whereas the CARACAL paper notes that derogation requests under GRA should generally be limited to essential uses, it also states that the Commission is assessing the need for excluding uses that feature minimal exposure throughout the lifecycle. Determining minimal exposure levels requires realistic testing requirements. This is especially crucial for products with long lifespans. The Commission must be able to exercise additional discretion in this area, as not all substances and uses subject to GRA will be the same, and additional flexibility will be warranted in cases where safe use can reasonably continue under minimal exposure patterns.

Conclusion

The additional perspectives the Commission shared at CARACAL 45 are an important step forward in securing a revision of REACH that is targeted and incremental. Appropriate reforms will lead to a regulatory system that is more efficient and less burdensome for industry and the authorities alike.