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Our position

Comments on the CARACAL paper on REACH authorisation & restriction

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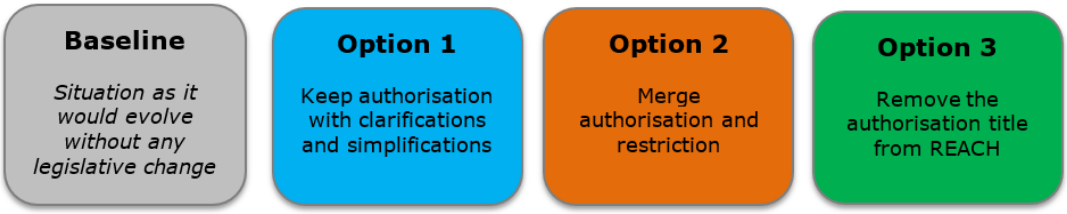
The European Commission presented the paper 'Discussion on potential options for amendments of the REACH Regulation in order to reform REACH authorisation and restriction processes' at the meeting of the competent authorities on REACH and CLP (CARACAL) on 27 January 2022. The Chemicals Strategy for Sustainability's (CSS) aims to improve the existing framework for EU chemicals policy and adapt it to help achieve sustainability and competitiveness ambitions. The following document comments on how the Commission can pursue improvements that are targeted and incremental, avoiding the severe uncertainty that would stem from an unjustified overhaul of EU chemicals legislation.

Policy options around authorisation and restriction

The Commission's paper on authorisation and restriction covers a range of policy options, which were already identified in the Inception Impact Assessment for the REACH revision. Some of these options (particularly options 2 and 3) would result in major changes to the way REACH works today:



In response to the Commission's proposals, the following key points must be stressed:

- On several occasions, the Commission's paper notes that proposals on the extension of the Generic Approach to Risk Management (GRA) and essential use criteria (EUC) should not be discussed at this stage and should be addressed separately. However, the reform of authorisation and restriction cannot be adequately discussed without taking into account parallel work on GRA and EUC, as both elements carry the potential to radically impact the framework for risk management under REACH.

- The rationale to reform authorisation and restriction is partially driven by a willingness to alleviate unjustified burdens on authorities and stakeholders. None of the proposed options above would achieve this. The solution is likely to be a hybrid option, but the key is to ensure this option is indeed less burdensome, more efficient and ensures transparency, predictability and legal certainty. While some proposals (such as a merger of restriction and authorisation based on GRA and EUC) may appear simple in principle, in practice these could result in extremely burdensome regulatory procedures. As an example, industry would need to prepare (and authorities would need to assess) significant numbers of EUC derogation requests for uses that may not pose an actual risk but may nevertheless be restricted automatically based on hazard classification under GRA. Furthermore, derogations based on EUC only could be extremely burdensome for industry and would need to take into account political or ethical considerations that might not reflect the actual risk. When possible, derogations should be granted on the basis of clear criteria, similar to those set for authorisation. The EUC might not be relevant for all substances

and all restrictions and should be used only when necessary (ie, broad restrictions covering nearly all uses and large group of substances, particularly large exposure etc.).

- There is an increasing number of broad restrictions, covering large groups of substances and close to all uses. The scope of those restrictions is often subject to interpretation and covers some uses which are not necessarily relevant to the substance. Justifications are often provided by industry on why a certain use or substance should be derogated from the scope of a restriction, *de facto* shifting the burden of proof from authorities to the industry. The merging of Authorisation and Restriction should allow for derogations to be proposed early in the process - in the Annex XV dossier, for instance. Member States are increasingly reliant on calls for evidence which would provide them the necessary information to grant derogations. As such, calls for evidence could be harmonised and made mandatory when drafting an Annex XV dossier.

- The paper notes that 'the Candidate List could remain as a tool to prioritise substances for regulatory action, in particular for restrictions but could also contribute to prioritisation for other regulatory action, e.g., under Occupational Safety and Health legislation (OSH), Industrial Emissions Directive 2010/75/EU (IED)'. The Candidate List should indeed be removed from the Authorisation Chapter of REACH and instead be used as a step to review potential risk management options within or beyond REACH. In this sense, it may then be necessary to rename it (eg 'SVHC list'). Inclusion in Annex XIV is not necessarily the most appropriate risk management option for all substances of very high concern (SVHCs), particularly in cases where uses are primarily industrial (including intermediate uses). In this respect, professional and industrial uses should be regulated under the relevant legislation and not duplicated under REACH in the context of the GRA. Once new substances are included in the Candidate List, ECHA could be tasked to conduct a screening to determine the most appropriate regulatory pathway to address potential risks (where this has not already been done earlier in the process eg through the Public Activities Coordination Tool [PACT]). This would also allow for a more comprehensive assessment of the interface between risk management measures under REACH and other legislation, such as occupational safety health..

  Another proposal in the paper is to introduce an 'annual fee' for manufacturing or using SVHCs in the Candidate List. We would caution against this, as continued production and use of certain SVHCs may be due to the fact that they are deemed essential in certain applications. Fees will likely not help to incentivise substitution activity in industry sectors. Unnecessarily penalising manufacturers and downstream users in essential sectors would undermine the competitiveness of EU actors on the global stage and potentially result in premature obsolesce of substances and formulations required for essential uses, many of which may be low volume and therefore already a risk for obsolescence by formulators.

- Criteria for listing substances as SVHCs are likely to evolve based on the outcomes of the separate CLP revision currently being prepared by the Commission. The Commission should consult AmCham EU's comments to the CLP public consultation for further input on the proposed new hazard classes The notion of equivalent level of concern is also likely to change significantly, in a scenario where new CLP hazard classes are introduced covering substances currently addressed under equivalent levels of concern(eg ED, PMT). The need to maintain a separate ELoC category of SVHCs may disappear altogether in such a scenario, as it would become redundant and simply undermine regulatory predictability and investment efforts by industry. The Commission also proposes to create a 'dynamic link' between CLP and REACH. This may trigger very long lists that become difficult to manage in terms of regulatory resources. There should be some form of prioritisation mechanism before initiating regulatory action for specific substances.

- The paper proposes to create additional notification requirements for manufacturers and downstream users of SVHCs (including annual updates on 'uses, tonnages and exposure/ emission patterns, waste management, possible alternatives for substances on the list'). Many of these information requirements are already present in registration dossiers, REACH article 33 and the SCIP database. The Commission should clarify the scope of the proposed new requirements and assess whether these would bring additional benefits or simply lead to increased burdens. If implemented, additional notifications could be voluntary instead of mandatory. Any information on alternatives, in particular when provided by third parties other than the manufacturer or downstream user, should be carefully assessed before being accepted and made available by ECHA. Otherwise, they are often inaccurate and fail to take into account aspects such as performance and competitiveness, and in the case of certain industries such as aerospace and defence, safety certification requirements. Making regulatory decisions on the assumption that alternatives exist - where this assumption is based on incorrect or incomplete information - risks leading to undesirable policy outcomes. Furthermore, any notification requirements for downstream users should not replace opportunities (eg, calls for evidence and consultations) for various stakeholders to provide information on the next steps of the regulatory process, ensuring all stakeholders' right to be heard at each step of the process. This could be achieved through an enhanced 'registry of intentions' that sets out what restrictions are being considered and why so that industry can start to collect and generate the necessary information to a reasonable timescale (for example, to justify that a use can be considered to be 'essential' and/or to be able to demonstrate 'safe use').

- In general, the end user industries usually are not looking for a direct alternative to an SVHC substance but often the formulation it is present within. For example, if an SVHC is contained in a sealant that aerospace and defence industries use, the alternatives we are looking to develop and test are sealants, not substances. Requirements for alternatives will be based on the overall requirements for the sealant and not the SVHC substance properties in isolation. If that sealant is used in various parts and components in an aerospace product it may not be possible to just replace it with a single new sealant. Industries may have to introduce multiple new sealants to meet requirements of parts and components subject to differences in operating environment, even within the same product.

- Option 1 (Keep the authorisation process, with clarifications and simplifications) should not be discounted, but should be limited to industrial uses. However, some of the proposals within this option raise concern. Removing the Member State Committee (MSC)opinion on draft recommendations to Annex XIV, or removing the consideration of the Agency's workload when determining prioritisation currently in article 58(3),is not suitable. The MSC opinion provides a balance in prioritisation decisions. It will continue to be important to collect comprehensive information though a consultation process and not just rely on information from parties as part of any Candidate List notification scheme. The effect of Annex XIV listing of a substance is further reaching and not just limited to EU based DUs and end users of the substances. With regard to suggestions in the paper that 'information requirements and submission fees for authorisation holders could gradually increase with every subsequent review report', review reports already require an increased level of information. Increasing fees would be an extra charge and would not have any positive influence on expediting the identification of alternatives and substitution. It is important to stress that industries apply for authorisation as a last resort and only when there is no other alternative. Authorisation is regarded as a business risk in case of obsolescence or authorisation refusal; it is expensive and does not provide long term certainty. Finally, a deadline for the Commission to amend Annex XIV would also reduce uncertainty. However, the case of substances that are recommended by ECHA, but not included

in Annex XIV, is not addressed. The future of those substances should also be clarified as soon as possible in order to give visibility to industry and reduce business uncertainties. This could be done, for example, by using the Candidate List as a step to determine the most appropriate risk management path for substances.

- As regards options 2 and 3 (merging authorisation with restriction or removing authorisation altogether), authorisation currently exempts certain uses and applications, including intermediate uses which are safely managed and contained on manufacturing sites. Intermediate exemptions should be maintained across other risk management options, should authorisation be merged with restriction or removed altogether (based on the current definition as interpreted by the Court of Justice of the European Union). Similarly, the paper proposes to remove exemptions under article 58(2) (ie where any risks are properly controlled on the basis of existing EU legislation). It would not be beneficial to remove such exemptions if uses are proven to be safe based on existing regulatory standards. In this regard, the Commission's proposal to simplify the process to exempt and derogate 'cases where the risk is likely to be more controlled (e.g., extension of the exemption to uses under strictly controlled conditions; use of closed systems)' is more appropriate. As regards to option 3, without EUC being defined, it is concerning that there would be no possibility for derogations, except for derogations for essential use.

ECHA committees

The paper includes a number of proposals related to the future role of ECHA committees. There are areas where improvements can be made (eg, more resources and specialised committee members to ensure committees are equipped to thoroughly review the scientific and technical details of specific proposals), but the answer is to strengthen the role of ECHA committees, rather than remove them from regulatory processes. The latter option can only result in weaker, less thorough decision-making. For example, the Commission proposes to remove Member State Committee opinions from the authorisation process. Equally, the Commission indicates that RAC and SEAC may not be included in the restriction process under the planned GRA extension. These proposals are extremely concerning, particularly when it comes to the EU's ability to assess derogations based on essentiality or safe use under GRA. The paper indicates that, in such cases, the burden of proof for justifying and assessing derogations and review periods (including potentially complex joint derogation requests by industry) would be with the Commission. The Commission should include a role for RAC and SEAC in delivering expert opinions as part of this critical process and derogations should be assessed by ECHA committees during the restriction adoption process (as opposed to after adoption). This would help avoid unintended consequences and allow for regulatory decisions that are based on a comprehensive understanding of how potential restrictions are likely to impact EU industry, technology and overall competitiveness.

The paper highlights the need to strengthen the role of the ECHA enforcement forum in risk management decisions. AmCham EU fully supports this, as enforceability is a key area for action listed in the CSS and must be accounted for in any decision-making process under REACH.

Reform of restriction

The requirement under REACH article 68(1) to initiate restrictions where there are unacceptable risks that need to be addressed on a community-wide basis, is highly valued. These unacceptable risks should be well documented in Annex XV dossiers and thoroughly reviewed by ECHA's committees. The extension of GRA proposed in the CSS can weaken this principle by simply assuming that a risk is present based on hazard classification and shortcutting scientific and socio-economic assessments by RAC and SEAC. Of particular concern, the CARACAL paper also hints that, under Option 2, GRA could be extended beyond what the CSS originally envisaged to also include 'any restrictions for uses of SVHC (including industrial uses)'. In the absence of safeguards for uses that are proven to be safe, this would be to the detriment of EU competitiveness, innovation and would significantly undermine EU industry. On this point, the Commission does recognise that, within GRA, 'if there are indications that certain use in articles can be considered "safe" during the life cycle of the articles, this could in principle be taken into account in risk management measures, in particular for articles'. A 'concept of safe use' must be introduced as a safeguard, should the Commission proceed with the extension of GRA as announced in the CSS

AmCham EU looks forward to contribute to the development of science-based and coherent EU chemicals policies through a constructive and collaborative approach.