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SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

AmCham EU response to the Inception Impact Assessment on the revisions of REACH and CLP

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €3 trillion in 2020, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

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Chemicals legislation – revision of REACH Regulation to help achieve a toxic-free environment

AmCham EU welcomes the opportunity to provide feedback on the upcoming REACH revision. Below, we offer specific comments on the key policy options identified in the Commission's IIA. For more detailed feedback, please consult our position paper on the Chemicals Strategy for Sustainability, attached to this submission.

Registration: Quality dossiers are essential to evaluate potential risks and take appropriate regulatory decisions. Requests made by authorities should nevertheless be proportionate and avoid unnecessary burdens. Including information on environmental footprint in registration dossiers could create opportunities to better account for the lifecycle sustainability of substances in regulatory risk management. More thinking is necessary, however, on the conditions for submitting such information and how this would be used in subsequent evaluation processes. Another example is the need to put in place a specific registration scheme for polymers requiring registration. The particularities of polymer chemistry make the current registration system for non-polymer substances inadequate for polymers. Finally, the proposal to revoke registration numbers for non-compliant dossiers could be a powerful tool but should be proportional and include clear conditions, legal rights and due process. Business confidentiality should be taken into account when it comes to disseminating such information.

Mixture Assessment Factor (MAF): Combined exposure is a complex matter and cannot be addressed via a 'simple' solution. The CSS proposes to introduce a Mixture Assessment Factor (MAF) in REACH Annex 1. While a MAF applied to all substances has the allure of simplicity, it would not be proportionate to use the same value to thresholds for human health and the environment. In addition, the proposal would lack specificity considering for the vast range of chemistries on the EU market that to a great extent do not co-occur. An appropriate and pragmatic approach is required which would be both proportionate and flexible. It is important to gather sufficient evidence to identify real-life cases to target in a legislative approach.

Restriction: We take note of the proposal to extend the use of generic risk management, but caution against moving further towards hazard-based regulatory instruments where risk management measures are automatically triggered by hazard classification. REACH restrictions must include a rigorous assessment pointing to unacceptable risks before banning substances and should be based on harmonised analytical test methods. Restrictions on large groups of substances will be more difficult to enforce than restrictions on single substances. Restrictions purely based on hazard can hinder investment certainty and disincentivise material innovations.

Essential uses: REACH Restriction and Authorisation already create opportunities to address the criticality of a use, its importance for society, as well as the availability of alternatives. Essential use criteria should be designed to support, rather than pre-empt regulatory decisions. For example, SEAC could use them as a reference for its opinions under existing REACH processes.

Authorisation: A number of cases have shown that Authorisation is not the best risk management option for all SVHCs (e.g. substances with significant intermediate uses or that are already covered by targeted restrictions). The current review periods recommended by RAC and SEAC are often not proportionate to the ease and cost-effectiveness of substitution. ECHA should review its guidance on how to justify longer review periods. The CSS

proposes to expand the list of substances that qualify for SVHC listing. We support this for endocrine disrupting chemicals but ask for a more cautious approach on PMT/vPvM substances. Due to the lack of a bioaccumulation concern, substances demonstrating mobility should be managed using existing REACH processes rather than through new SVHC criteria.

Enforcement: Enhanced enforcement policies will be critical to address imports, which account for the vast majority of non-compliance issues under EU chemicals legislation. Enforceability of EU measures should be assessed as early as possible in the regulatory process, ideally at the RMOA stage. Member States should allocate sufficient resources to strengthening enforcement of controls on imported goods. The ECHA Enforcement Forum can play an important role here.

Revision of EU legislation on hazard classification, labelling and packaging of chemicals

AmCham EU welcomes the opportunity to provide feedback on the upcoming CLP revision. Below, we offer specific comments on key policy options identified in the Commission's IIA. For more detailed feedback, please consult our position paper on the Chemicals Strategy for Sustainability, attached to this submission.

Endocrine disruptors (EDs): We supports a horizontal mechanism to identify EDs based on the WHO definition. However, CLP is designed to classify adverse effects, whereas EDs have an endocrine mode of action that is causally linked to an adverse effect. We are concerned about the potential for duplication with existing legislation. All substances identified under REACH as EDs are classified under CLP or could be classified in existing hazard categories. Alternative measures could be introduced under CLP without creating new hazard classes, such as supplementary EUH statements or an ED flag under existing hazard classes. Horizontal ED identification would be best achieved through SVHC listing. We ask the Commission not to limit policy options in its upcoming impact assessment only to the CLP regulation.

Hazard classes for environmental concerns: Existing CLP hazard classes for chronic hazards to the aquatic environment as well as human health hazard already overlap to some extent with PBT/PMT criteria. The Commission should clarify the additional benefits of hazard classes for PBT/PMT substances. Although the persistence (P) of a chemical in the environment may lead to a certain level of potential exposure when emitted to the environment, persistence alone is in our view not a sufficient indicator to inform on present or future risks to human health and the environment. P substances are often durable, contributing to high performance applications. An overly narrow regulatory focus on P under CLP will undermine innovation in conflict with commitments to promote durability, including in the context of the Sustainable Products Initiative.

Avoid international divergence: International regulatory divergence creates obstacles to economic growth and global trade. The EU should avoid unilateral deviations between EU legislation and UN GHS. The impacts of deviations from GHS caused by the proposals for new hazard classes should be fully assessed.

Labels: Regarding multi-lingual fold out labels, the impact assessment should address the practicality and cost of such a proposal, which could represent a practical solution for hazard communication on small packaging.

CLH dossiers: With respect to the mandate for the Commission or ECHA to initiate CLH dossiers, the Commission should take into account bottlenecks related to the expert resources needed to conduct a robust weight of evidence assessment of these proposals. Opportunities for stakeholder input should be ensured throughout the CLH process.

Classification of mixtures/MOCS: Classification for mixtures and UVCBs using the concept of MOCS will lead to the identification of hazards based on constituents. This would hamper the REACH concept that hazard and risk information should be at a substance level and substantially increase animal testing and costs of data generation. The classification of the MOCS should be entirely based on REACH dossiers. When there is existing information on MOCS, there should not be a requirement to generate further data on constituents.

Harmonised environmental and safety values: DNEL and PNEC derivation should stay in the REACH. CLP is about hazard communication and is framed under the UN GHS. Any consideration on DNEL/PNEC harmonisation in CLP would introduce unnecessary complexity.

Impacts on companies: Impacts on companies and in particular SMEs must be fully assessed. The statement that "EU companies will benefit from earlier adoption" assumes the companies will survive initial negative impacts on competiveness, which may or may not be the case. Recognition should be given to safe and sustainable chemicals which are currently available on the EU market, understanding that further improvement is possible. The danger of overclassification with the addition of new hazard classes should also be part of the impact assessment.