Downstream Users of Chemicals Co-ordination group

Discussion on potential options for amendments of the REACH Regulation in order to reform REACH authorisation and restriction processes CA/03/2022

DUCC comments

DUCC wishes to support a future regulatory framework that is protective of human health, addresses sustainability concerns, focuses resources on what matters, and is workable and enforceable.

In this context DUCC wishes to comment on the working document on the reform of REACH authorisation and restriction processes. Crucial points for downstream users, for a future regulatory process that will not result in an unworkable number of requests for derogations, are the importance of a **i) workable derogation procedure and ii) a holistic approach that considers all the changes being considered in both horizontal and vertical (sectoral) regulations.**

A future regulatory framework that acts through a blanket approach and does not focus resources on what matters would result, in our view, in unintended and/or unexpected consequences, such as the disappearance of useful products from the EU market without strong justification that this was absolutely necessary for the protection of human health or the environment. A prioritization process targeting SVHC substances in the candidate list could instead lead to a more targeted approach. Ideally the Candidate List should contain substances with reference to uses that need to be regulated with a priority, whereas the use of the same substance in other applications that can be demonstrated to be safe, should be derogated and continue to be allowed. We acknowledge that the burden of proof for safety should be with industry. This would address the main downside of the current Authorization process, i.e. having to spend many resources on applications that are not of high concern.

The revision of the Restriction and Authorisation processes should also be seen in the context of the full set of regulatory changes that are currently being discussed under REACH (Generic Approach to Risk Management, Essential Use Concept, Mixture Assessment Factor etc). DUCC thus wishes to raise the following two points on the GRA:

- The 'hazard-based GRA', as foreseen by the CSS, targets particular classification classes of CLP (currently CMRs Cat 1, but in the future many others currently undefined such as EDC). This is much wider than targeting certain uses of substances, substances as a whole (all uses) or even groups of substances. The default application of a hazard-based GRA to a certain hazard class could affect hundreds of substances at once, likely much more than grouping them in 'families', many of which are being used in applications with a history of safe use and these uses are not posing a concern. Hence the application of the 'hazard-based GRA' should be done as a last recourse, and a simple, workable derogation mechanism needs to be put in place to reach the objective of a quicker and more efficient regulation of substances.

- The GRA has been originally put in Restriction (Art 68(2)), The GRA has been originally put in Restriction (Art 68(2)), however it is in spirit a regulatory action which is closer to Authorization. Indeed, the REACH Authorization process starts with the identification of Substances of High Concern (SVHCs) simply based on hazard and ultimately results through Annex XIV of REACH phasing them out in Europe. A hazard-based GRA is not different: it is a ban of use without any consideration of risk. Indeed, a risk assessment is not made at any stage. The consequence is that a substance could be banned even if it safe for use. The GRA should be renamed as GHA (Generic Hazard management Approach) to clarify the legislator's intention and be opened to allow for safety-based derogations.

In order for the over EU regulatory framework to be both effective and future-proof, we strongly suggest that an holistic approach should be adopted in order to evaluate all possible side-, collateral and edge effects of any regulatory changes on other horizontal and vertical/sectoral regulations, given their current and growing inter-connectivity. At the moment there is a large number of documents, questionnaires, consultations, events, coupled together with multiple separate discussions of single aspects of the CSS. The lack of consideration of their interrelationship makes it extremely challenging for industry stakeholders to provide input within the tight deadlines set. DUCC also wishes to raise its concern of whether the input is being considered given the tight deadlines scheduled on the one hand, and on the other hand for regulators to ensure a workable, enforceable and future-proof EU regulatory framework.

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About DUCC

DUCC is a joint platform of **11 European associations** whose member companies use chemicals to **formulate mixtures** (as finished or intermediary products) for professional and industrial users, as well as for consumers.

DUCC focuses on the downstream users' needs, rights, duties and specificities under **REACH** and **CLP**.

DUCC's membership represents several important industry sectors, ranging from cosmetics and detergents to aerosols, paints, inks, toners, pressroom chemicals, adhesives and sealants, construction chemicals, fragrances, disinfectants, lubricants, crop protection, and chemical distributors industries. Altogether, their membership comprises more than **9.000 companies** across the respective sectors in Europe, **the vast majority being SMEs**. The calculated turnover of these companies is more than 215 billion euros in Europe.

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