International Association for Soaps, Detergents and Maintenance Products

REVISION OF EU LEGISLATION ON REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS

A.I.S.E. input to consultation on Inception Impact Assessment

31 May 2021

A.I.S.E. appreciates the acknowledgment of the REACH Regulation as one of the cornerstones of EU chemicals legislation, along with CLP, and thanks the European Commission for the opportunity to provide the following comments on the roadmap for its revision.

Process for revision of REACH

The 2018 report on the second review of REACH[1] concluded that the regulation is achieving its aims and objectives, and that, whilst some actions were identified to further improve its implementation, there was no need to change its enacting terms. The proposed revision of REACH should respect this conclusion and be limited to targeted amendments that will deliver those improvements.

A.I.S.E. recognises the political commitments made in the Chemicals Strategy for Sustainability to protect human health and the environment, but recalls that ensuring competitiveness for EU industry is also a key objective of the CSS. Ambitious policy goals need to be supported by **robust legislation**, providing predictability to drive investment and foster innovation, and a sound process to enable the transition. Businesses and authorities need realistic transition periods to implement changes, and core elements of legislation such as definitions, scope and criteria need to be agreed during the ordinary legislative procedure, not left open to be completed or amended through additional provisions such as implementing acts or through guidance. The Commission is urged **not to rush decision-making processes** for REACH (or any other legislation) in order to meet unrealistic deadlines set in the Strategy, but to ensure that these are conducted properly in line with the principles of Better Regulation[2].

The **impact** of all changes must also be robustly assessed, in conjunction with all relevant stakeholders. According to the Commission's Cumulative Cost Assessment study (2016) the overall cost of chemicals legislation to the detergents and maintenance products industry is approximately €670 million, corresponding to 33.4% of profits[3]. The sector is disproportionately impacted by administrative burden (representing 28% of total costs), so A.I.S.E. welcomes measures that will reduce such burden.

A proportionate, science-based regulatory framework

EU chemicals regulation must remain based on **sound science** reflecting both hazard and exposure (i.e. **safe use**). Revision of registration requirements to fill data gaps, especially for new hazard classes and criteria, could however conflict with the objective to **reduce testing on animals**. Now more than ever it is vital to secure regulatory acceptance of alternative methods

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN
[2] Commission Communication on Better Regulation published 29 April 2021
[3] A.I.S.E. factsheet on the Cumulative Cost Assessment for the EU Chemical Industry, October 2016

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and to make safety decisions on ingredients using state-of-the-art methodologies that avoid new animal testing. A.I.S.E. participates in and fully supports the project by the European Partnership on Alternative Approaches to Animal Testing on New Methodology Approaches.

The revision must also support and foster **innovation** by maintaining/extending exemptions on product- and process-orientated research and avoiding disproportionate regulatory burden on polymers, on low-volume substances or on the many millions of formulated mixtures on the EU market. Registration of polymers should be limited to those genuinely posing a risk to human health or to the environment in use (Polymers of Low Concern according to internationally recognised/used criteria should be exempted), and a structured procedure must be established for grouping of those polymers in order to reduce the number of registrations. The impact on (former) downstream users of registering polymers must also be properly assessed and mitigated.

In line with the principle that chemicals regulation should reflect scientific evidence on the **risk** posed, measures to address **combination effects** of chemicals should use, promote and extend existing scientific research into actual co-exposures and interactions in practice and the adverse effects that result, to enable a more targeted, evidence-based approach that avoids duplication of existing requirements, e.g. for worker protection. The precautionary application of (a) generic Mixture Assessment Factor(s) is a blunt instrument that could render unusable many chemicals valuable to meet Green Deal objectives and discourage/disincentivize further scientific research.

Reform of evaluation, authorisation and restriction

A.I.S.E. welcomes the objective to make regulatory processes more workable, efficient and predictable. A **Risk Management Options Analysis** should be obligatory in all regulatory decision-making to enable a holistic assessment, and **input from downstream users** should be explicitly incorporated in this, as it should be also in dossier and substance evaluation processes, since these actors have valuable data to contribute and are/will be affected by decision-making processes at all levels.

Whilst reform and simplification of the authorisation process will be welcome, A.I.S.E. calls for greater clarity on the suggested option for **national authorisation** of smaller applications, specifically its compatibility with the EU Single Market and potential impact on enforcement.

A.I.S.E. urges caution in extension of the (hazard-based) **generic risk management approach** to newly-defined hazards, which may lack robust scientific data as mentioned above. This approach should be applied in a targeted rather than blanket way, to substances and/or uses where adequate control of risk has not been demonstrated. The consequences for society of unduly broad implication could be severe, including a shortage of products on the market to tackle public health crises or a need for emergency measures to address this. Derogations are proposed for '**essential use**', however A.I.S.E. believes that all regulatory decisions require case-by-case assessment with proper analysis of the specific context. Rather than pre-defined criteria for 'essentiality', the concept could be developed as additional guidelines to support/facilitate existing regulatory processes under REACH, but not to replace them for direct use in regulatory decision-making.

A proposed extension of generic risk management to **professional users** is considered disproportionate and could impact negatively on the supply of efficacious products to professional markets. Professional users are subject to EU and national legislation on occupational safety and health, and a number of activities are undertaken by A.I.S.E. to support such users: e.g. dedicated

consideration of professional workers in the use map package (Sector-Specific Worker Exposure Descriptions, SWEDs), and collaboration with EFCI, the sector organisation of the professional cleaning sector, to facilitate use and understanding of Safe Use of Mixtures Information documents (SUMIs).

Simplifying/improving supply chain communication

A.I.S.E. fully supports the Commission's goal to improve information for downstream users and workers in safety data sheets, and has been a committed participant in activities of the Exchange Network on Exposure Scenarios (ENES) since its creation in 2011. A.I.S.E. continues to develop and promote its Use Map Package for upstream suppliers and SUMIs for downstream users of cleaning products, and welcomes the inclusion of measures to simplify and improve this communication in the revision of REACH. The potential to implement harmonised electronic formats for communication should be explored in cooperation with all relevant stakeholders in the supply chain.

Harmonised enforcement

Last but by no means least, A.I.S.E. fully supports **consistent enforcement** to protect the European Single Market and welcomes new measures to reinforce harmonised interpretation and control, particularly with respect to preventing imports of non-compliant products from outside the EU that could pose risks to consumers and the environment, as well as negatively affecting competitiveness for EU businesses – particularly SMEs - that invest heavily in compliance.

A.I.S.E. and its members are committed to successful implementation of REACH and other chemicals legislation and remain at the disposal of the Commission for further dialogue on all aspects.