A·I·S·E
International Association for Soaps, Detergents and Maintenance Products

CARACAL-44 (REACH OPEN SESSION & REACH/CLP JOINT SESSION)

A.I.S.E. comments

25 April 2022

A.I.S.E. thanks the Commission for the opportunity to provide written comments on the following REACH topics discussed in the 44th CARACAL meeting (23-24 March 2022).

AP4.1 Update on the revision of REACH

- <u>Evaluation</u> (feedback from ad hoc CARACAL meeting 16 March 2022)

The REACH Regulation clearly frames Substance Evaluation (SEv) as a process to evaluate whether a "*given substance constitutes a **risk to human health or the environment***". The principle that SEv is about risk is repeated throughout the REACH legal text (e.g. Article 44(2), Recitals 20, 66).

This was further confirmed by many ECHA Board of Appeal cases (starting from 2014) and detailed in the *three-prong test* (see BoA cases p. 59 of Digest of Decisions of the Board of Appeal of the European Chemicals Agency). Three criteria must be met by ECHA in order to request additional information under the SEv process:

- it must be able to show that there is a **potential environmental or health risk** – and that such a risk should be one that "**occurs in reality and not only theoretically**";
- it must prove that the **potential risk needs to be clarified**; and
- it must show that the information requested has a **realistic possibility of leading to improved risk management measures**.

The proposed approach for a *hazard-based* SEv rather than *risk-based* is completely inconsistent with the expectations under substance evaluations, which are based on evaluating the risk with the intention to provide the appropriate level of protection for human and the environment.

Moving the SEV assessment from today's *use/exposure/risk* toward *hazard* will:

- lead to unnecessary generation of data that will not improve risk management measures and will address theoretical risks that do not occur in real life.
- increase use of test animals, contrary to the principles of proportionality and animal welfare (Article 13(2)).
- divert human resources from ECHA, MS Competent Authorities, registrants and Contract Research Organizations to work on substances where the new data will have no impact on the current environmental or human health risk, as opposed to focusing on substances where the risk management measures may need to be improved to reduce the risk for human health and the environment.

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- <u>Update from the CARACAL Sub-Group Polymers</u>

Please refer to written comments from A.I.S.E. submitted separately to both CARACAL and to the CASG-Polymers on 25 April 2022.

- <u>Environmental footprint</u> (CA/18/2022)

A.I.S.E. believes firstly that it would be more appropriate for the document to refer to 'environmental impact' rather than 'environmental footprint', as the latter creates a misleading direct link to the official 'Environmental Footprint' method for products and organisations (PEF and OEF). Impacts on biodiversity or natural resources are currently not covered by PEF and OEF.

A.I.S.E. feels that in general, from CA/18/2022 it remains unclear what type of data would be requested from registrants, following which method and for which purpose (for example, a complete set of life-cycle data to be used for a life-cycle assessment). There is no clear picture of which product categories would be covered, and how/whether downstream uses would be reflected.

REACH is one of only few pieces of legislation that set minimum requirements on information for substances, for valid reasons (e.g. number of chemicals, versatile use of individual substances, multi-facetted environmental release scenarios etc.) Due to the complexity of REACH, related regulatory processes and value chains it is not clear on what basis any 'environmental impact' framework for chemicals should be derived. Many questions arise but remain unanswered, e.g. (indicative only and not exhaustive):

- How will/could this be linked to the REACH registration dossier in IUCLID and the Chemical Safety Report (CSR), especially given the diversity of the environmental impact across suppliers (due to production process, energy efficiency, location etc.) and its variability in time, necessitating frequent updates with administrative burden?
- How would customers/downstream users derive the necessary level of specificity to integrate environmental impact information into their own life-cycle assessments or PEF calculations?
- Is it intended to consider the existing process categories (PROCs) and environmental release categories (ERCs), and if so, how?
- What should be considered as the general (harmonised) reference database?
- How will Substances of Very High Concern be considered?
- How will confidential business information be addressed?
- How are tonnage bands (overall and for individual registrants) intended to be considered, also in light of manufacturer and importer status? In this context it appears unfeasible/unrealistic to consider also downstream uses.

Overall A.I.S.E. considers it too early to incorporate such information requirements into REACH. Downstream users need robust, high-quality data on substances to assess the sustainability of their products, materials and services, and the REACH registration dossier is not considered the right tool to capture these data.

- Implementation of the Generic Approach to Risk Management (CA/19/2022)

Please refer to separate written comments from A.I.S.E. submitted on 6 April 2022.

- Communication in the supply chain (CA/22/2022)

A.I.S.E. supports removing the possibility to provide a safety data sheet on paper only and making electronic provision obligatory, provided that this encompasses all forms of electronic communication (including PDF attachments sent by e-mail, XML files etc.) and does not mandate any specific format for transmission. This would bring the legal requirements into line with normal business practices in the 2020s.

As a long-standing participant in and supporter of the activities of the Exchange Network on Exposure Scenarios (ENES) through DUCC, A.I.S.E. supports giving a task to ECHA to develop – in cooperation with all relevant stakeholders - a common framework for a standard format for communication of information in the supply chain. Industry remains committed to facilitating improved flow of information through the value chain and sees an important official and neutral role for the Agency in coordinating between all of the involved actors.

AP10.3 Test Methods Regulation revision / IP4 Policy options to address animal testing in REACH

As a founder member of the European Partnership for Alternative Approaches to Animal Testing, A.I.S.E. supports all efforts to increase the uptake and use of non-animal test methods and to minimise any residual need for animal testing. In this context A.I.S.E. is generally supportive of the problem statements and suggested policy options in the document from Cruelty Free Europe.

Joint REACH/CLP session AP1 Information requirements

As an association representing downstream users (formulators), A.I.S.E. does not have a position on the detailed policy options for the revision of Standard Information Requirements for critical hazards. As a founder member of the European Partnership for Alternative Approaches to Animal Testing however, A.I.S.E. expresses its firm support for maximising the use of New Approach Methodologies (NAMs) to exploit the latest scientific advances in hazard and risk assessment and to avoid unnecessary animal testing.

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