A·I·S·E

International Association for Soaps, Detergents and Maintenance Products

CARACAL-43 (REACH REVISION)

A.I.S.E. comments 24 February 2022

A.I.S.E. thanks the Commission for the opportunity to provide written comments on some of the topics discussed in the 43rd CARACAL meeting on 27 January 2022.

AP3.1 Reform of authorisation and restriction processes (CA/03/2022)

A.I.S.E. does not have a clear preference for any of the options 1, 2 or 3 identified in CA/03/2022, but would like to make the following remarks on some aspects discussed in the document.

- **Future role of Candidate List**

  CA/03/2022 indicates that "*A dynamic link could be established with CLP, i.e., the hazard properties of substances on the Candidate List would be automatically updated in case the substance classification as CMR, ED, PBT, vPvB, PMT or vPvM is established or revised (same could be applied to the further step when, in case Option 1 is maintained, the substance is already included into Annex XIV).*"

  It is important that any such dynamic link is limited to updating of substances already included in the Candidate List, and is not applied to enable addition of new substances automatically to the Candidate List upon classification. The latter would render obsolete the process in Article 59, and would add large numbers of substances to the Candidate List all at once, triggering obligations for economic actors including downstream users and end users (existing obligations including communication through the supply chain, notification to the SCIP database etc.). The impact would be even greater in the event of potential new obligations mentioned in the document, e.g. annual notification requirements, fees etc.

  Such automatic inclusion would be neither workable nor proportionate to the benefit, since for many substances there can be valid reasons *not* to include these in the Candidate List (e.g. intermediates, already subject to adequate risk management etc.). A.I.S.E. supports focusing on what really matters, and in this context recognises the role of the Candidate List as a tool to support prioritisation of substances for regulatory action through a call for evidence.

  A.I.S.E. also emphasises – since it is not explicit in the document - that the aforementioned updating of the Candidate List must be based on harmonised classifications in Annex VI to CLP, and for legal certainty preferably as from the application date (but as a minimum, not before entry into force of the respective ATP to CLP).

- **Restriction under Article 68(2)**

  Article 68(2) of REACH refers to "*a substance on its own, in a mixture* ***or in an article*** *which meets the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, and could be used by consumers…*" (emphasis added). In entries 28-30 of Annex XVII however, the restriction is applied only to substances as such (or components of substances) and mixtures. All articles are excluded

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from the generic restriction by default, and restrictions are applied to articles only on a case-by-case basis where a specific risk is identified.

In CA/03/2022, section 3.2.6.2 may however imply a shift to inclusion by default, albeit with prioritisation:
"As regards restrictions for uses in articles, priority should be given to those for which exposure for consumers, professional users, vulnerable population groups or the environment, can be expected (e.g., textiles). 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."

Whilst such a prioritisation is welcome and necessary, this still represents a reversal of the current approach which is likely to be unworkable for the millions of articles on the market in Europe when the generic approach is extended to a much wider range of hazard classes. The current approach should be maintained, to apply restrictions for articles only on the basis of an identified risk, which could be elucidated by a consultation and report by ECHA as mentioned earlier in 3.2.6.2.
Furthermore in light of the expansion of scope in terms of hazards, this approach should be extended also to mixtures, with the need to apply Article 68(2) being assessed on a case-by-case basis for different hazards or different categories of consumer products depending on their use and exposure. (For example, for threshold effects it might be possible to determine a level at which uses will always be safe.)

For all options 1-3, the document states that "*COM (**might** ask ECHA to run consultation and prepare report) - COM makes proposal for Comitology*". This consultation and report step should be made systematic - not an option or exception - to avoid generic bans being applied to many substances without consideration of other parameters, such as assessment of potential benefits to deliver other objectives of the Green Deal. The consultation and report would enable more detailed information to be gathered from industry, including data on exposure and volume which are important to evaluate the effectiveness and impact of a restriction – again focusing attention on what matters, and avoiding wasted time and effort on uses of low concern.

Furthermore it is very important to have a workable and effective derogation procedure. In the Chemicals Strategy for Sustainability it is clearly stated that industry should have the possibility to obtain derogation from restriction (and authorisation) on the basis of essential use. However in CA/03/2022 the possibility for industry to request derogation is foreseen only in Option 2 and not in Option 1.
The generic approach under Article 68(2) will drastically increase bans on substances without the possibility for industry or other stakeholders to comment (unlike Article 68(1)). In any reform option adopted it is of critical importance that industry be permitted to request derogations (either generally applicable or specific to individual applicants); this rightly places the burden of proof onto industry, but is also in the interests of authorities if it will enable continued use of substances that would provide benefits for the objectives of the Green Deal.

Finally, and related to the above, if authorisation is merged with generic restrictions as per Option 2, this would result in the loss of industry's current ability to comment before substances are added to Annex XIV. No equivalent possibility is provided in this proposal.

It is therefore proposed that authorisation be absorbed instead into restriction under Article 68(1), where the possibility to give input at an early stage still remains, and that the possibility for industry to request derogations be added as for Article 68(2). But if it is decided to merge authorisation with Article 68(2), the possibility for stakeholders to comment should be added to the process at an early stage, as currently the case for authorisation.

AP3.2 Information requirements on endocrine disruptors (CA/07/2022)

A.I.S.E. has responded to the request from Ricardo to help fill remaining data gaps for the impact assessment, by sharing information on testing costs provided by members. A.I.S.E. also associates itself with written comments from DUCC following the 6th CASG-EDs meeting on 24 January, to which A.I.S.E. contributed as a member of DUCC.

AP3.3 Increased hazard information requirements (CA/09/2022)

As an association representing downstream users (formulators), A.I.S.E. has no position or detailed comments to make on the policy options for revision of Standard Information Requirements or on the questions posed in CA/09/2022. A.I.S.E. however expresses its firm support for the statement "*it is necessary to maximise the use of New Approach Methodologies (NAMs) to exploit the latest scientific advances in hazard and risk assessment and to avoid unnecessary animal testing*", and would welcome the adoption in the short term of a mechanism to ensure recognition of available NAMs.

AP3.4 Information requirements on uses and exposure (CA/12/2022)

A.I.S.E. will react separately on this agenda item and engage with the study consultant as required.

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