

CARACAL 44: A.I.S.E. COMMENTS ON CA/19/2022

Options to implement the extension of the generic approach to risk management in REACH

6 April 2022

A.I.S.E. supports the objectives of the Chemicals Strategy for Sustainability (CSS) and wishes to be an active partner to the Commission in achieving its successful implementation. The far-reaching extension of the generic approach to risk management (GRA) foreseen in the CSS however has the potential to impact hugely on the availability of safe and effective cleaning products for consumers and professional users. A.I.S.E. would like to share the following comments in response to relevant questions in section 2.2 of document CA/19/2022.

1. Do you support the overall approach sketched out for the implementation of the generic approach to risk management or do you think that there are key elements not taken into account? In particular, do you agree with the gradual implementation of restrictions under Article 68(2) according to a work plan?

A.I.S.E. agrees that the empowerment for the Commission to introduce new restrictions under Article 68(2) should be accompanied by a work plan for gradual implementation, which identifies where such restrictions may be appropriate (i.e. where risks are not demonstrated to be adequately controlled) and would be effective to improve protection of human health and the environment – i.e. focusing on what matters most. Implementing the GRA at once for all hazard classes and scenarios foreseen in the CSS would create an unmanageable workload, for both economic operators and authorities, and would be disproportionate to the objective to protect human health or the environment.

A.I.S.E. supports differentiation within implementation scenarios, for example hazard classes should be prioritised (as mentioned above) and addressed in a stepwise manner, with the GRA being applied only to hazard category 1, consistent with the current scope of Article 68(2).

One key element considered important for inclusion by A.I.S.E. is a workable procedure to apply for derogations based on the principle of **safe use**: i.e. where it can be demonstrated unequivocally – by a company, sector, authority or any other stakeholder – that exposure is minimised such that there is no concern justifying a ban.

2. What is your view on the possibility to differentiate between different types of articles? What should be the criteria for such differentiation?

The vast majority of products placed on the market by A.I.S.E. members are mixtures, however articles may still be of some relevance in the context of packaging or delivery systems for cleaning products. A.I.S.E. believes that restriction proposals for articles should be decided on a case-by-case basis, as is currently the case for CMRs, and based on consideration of the potential for exposure to or emission of the substance.

It does not make sense to restrict the mere presence of a substance in an article if it is contained in a solid matrix from which it cannot be released, or is even transformed (reacted/polymerised) such that it no longer exists in the article as the substance *per se*. Such exclusion is foreseen in existing product-specific legislation, such as the Toy Safety Directive for example.

3. What is your view on the possibility to differentiate between types of professional uses? What should be the criteria for such differentiation?

A.I.S.E. does not support any extension of the GRA to professional uses. The importance of professional cleaning and hygiene has been sharply highlighted during the recent pandemic, and having access to a full ‘toolbox’ of efficacious products is critical in this sector. Professional cleaning contractors are subject to a comprehensive set of rules established under Occupational Safety and Health (OSH) legislation (both at EU level and nationally) and are expected to be properly trained and skilled. A.I.S.E. is among a number of formulating sectors that provide support materials¹ to assist in this, including Safe Use of Mixtures Information documents (SUMIs)².

Any perceived shortfall in skills for certain groups of professional workers should preferably be addressed through **improved implementation and enforcement of OSH legislation** (coupled where relevant with national professional/business tax registration systems etc.) and the provision of well-structured, certified **sector-specific training programmes**. This is in the interests of the clients of professional service providers, as well as those providers themselves; the purpose and value of professional contractors will be negated if they do not possess skills and tools (including chemical products) exceeding those available to consumers.

The hierarchy of control measures in OSH legislation applies equally to professional workers, with substitution always the first choice wherever possible. If a chemical cannot be substituted without detriment on functionality, a generic ban would result in negative impacts on work performance and employment. If an unacceptable risk is still perceived after application of other OSH measures, **other tools** available in the existing legal framework can be used, e.g. specific restrictions established according to Article 68(1) of REACH.

4. Which elements should be taken into account in defining the terms ‘consumer use’ and ‘professional use’ in REACH for the purposes of the implementation of GRA?

To A.I.S.E. it is clear that ‘consumer use’ applies to any product which is available to the general public, for use outside the context of paid work. This would also apply to products which are in principle intended for professional use, but their supply is not restricted/controlled such that they are only available to professionals.

‘Professional use’ by contrast relates to use in the pursuit of an occupation or any paid work, but not in an industrial facility/setting.

As explained above A.I.S.E. does not support implementation of the GRA for professional users, however existing sources of data could be used to identify *specific* cases among professional users where targeted regulatory action may be justified, such as a restriction under Article 68(1)

¹ See <https://www.aise.eu/our-industry/professional-cleaning-hygiene.aspx>;

² <https://www.aise.eu/our-activities/regulatory-context/reach/safe-use-information-for-end-users.aspx>

of REACH. These sources include national, EU or international databases of statistics on occupational disease³, and data from Poison Centres on poisoning cases in occupational settings.

5. Do you have other suggestions to structure GRA restrictions, limit or extend their scope, and on the implementation scenarios?

A.I.S.E. recommends the inclusion of a practical and effective procedure to apply for **derogations**, as mentioned in the answer to question 1. The level of supporting evidence required to support a derogation application should be case-specific and proportionate to the level of concern.

A further element not mentioned in CA/19/2022 is the possibility to differentiate between subsets of types of **mixtures** as well as articles, beyond the broad use type (consumer/professional). This differentiation could be based on generic exposure/emission considerations for the type of product (mixture) – e.g. as provided by available sector use map packages⁴ - as well as available data, such as from human biomonitoring programmes. This would again help to target action where it really matters and avoid disproportionate impacts. For example (purely indicative and not exhaustive):

- Restriction of PBT/vPvB substances **only** in mixtures with wide dispersive uses
- No need for restriction of mixtures containing **respiratory sensitisers** where there is no risk or evidence of exposure via the inhalation route in the product lifecycle. For instance, allergy to enzymes among consumers of enzyme-containing laundry and cleaning products has not been reported since the late 1960's, and clinical evidence has shown that enzyme-specific sensitisation among the general population is very rare (0.126% for the period 1977 –2010)⁵, demonstrating that sensitisation due to exposure to enzymes in laundry and cleaning products is not an issue justifying the loss of their substantial sustainability benefits.

Finally, as noted in the response to question 3, A.I.S.E. suggests to focus on improving competence and safety among specific identified groups of professional workers through targeted training/certification programmes and related enforcement, rather than attempting to apply GRA restrictions to professional uses, which could have unintended consequences both for those workers and for society at large.

³ Examples: Berufsgenossenschaften established under [DGUV](#) in Germany; [European Occupational Diseases Statistics](#) (experimental); [International Labour Organization](#)

⁴ <https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library>

⁵ Sarlo, K., Kirchner, D.B., Troyano, E., Smith, L.A., Carr, G.J., Rodriguez, C., 2010. Assessing the risk of type 1 allergy to enzymes present in laundry and cleaning products: evidence from the clinical data. *Toxicology* 271, 87-93.