Action 4: Avoid overly-simplistic assessment – use targeted restrictions instead

The Issue?

Current rules cause practical issues

For some, simplification means broad bans on chemicals based only on hazard properties. While this may seem easy and quick, it overlooks critical factors – if a substance is classified for certain hazards under CLP Regulation, this will automatically trigger a ban in other legislation, like REACH, without proper risk and socio-economic assessment nor assessment of alternatives.

Under current rules, overly-simplistic assessment creates practical issues, especially when the substance is also used in fields not regulated by REACH. One example is the recent discussion amongst authorities on dinitrogen oxide (N_2O) (at CARACAL-53). Due to the harmonised classification of dinitrogen oxide (N_2O) as Reprotox 1 B, the substance – whether on its own or when present in a mixture – cannot be supplied to the general public. In practical terms, whipped cream cans containing N_2O supplied to consumers would be prohibited despite the substance being approved as a food additive under the Food Additives Regulation. Last December 2024, authorities were discussing derogations in REACH to allow continued use in such applications. This situation shows the unintended consequences of automatic triggers resulting in attempts to retroactively fix the issues via derogations, the so-called "policy by derogation".

Banning substances based only on hazard can have serious business implications

One proposal to enable faster regulatory action for the REACH revision is to extend Article 68(2), so called generic approach to risk management (GRA), to further hazard classes.[1] Such an approach would have serious business implications. According to an assessment made by independent economic research consultancy, Ricardo Energy & Environment, the business impact of such an extension showed that as many as 12,000 substances could be impacted (see p. 106). The consultants concluded that the most likely impacted portfolio would be 28 % of the industry's estimated annual turnover. The companies consulted for the study indicated that only around one third of this most likely affected portfolio could potentially be substituted or reformulated. Even when substitution, reformulation, and derogations are considered, the EU chemical industry could face a net market loss of around 12 % of its product portfolio by 2040.

Unclear and broad scope is difficult to enforce, if at all

Automatic triggers not only inflate the scope of restrictions, but also make their scope a moving target. For instance, the ongoing restriction proposal on skin sensitisers in textiles can potentially include in the future an ever-growing list covering more than 1,000 substances due to the automatic link between certain hazard classifications of any substance and the restriction – without a risk nor socio-economic assessment in between. The lack of clarify on which substances are or would be in the scope of a

[1] According to the latest information from the European Commission (CARACAL-48), extension of the GRA entails an extension of existing empowerment to the European Commission in Article 68(2) to new hazard classes: ED Cat 1, STOT RE Cat 1, PBT/vPvB, Respiratory Sensitisers, potentially PMT/vPvM for consumer and professional use. At CARACAL-53, the European Commission stressed that professional use will not be part of GRA extension, although that was the initial intention.

European Chemical Industry Council - Cefic aisbl
Rue Belliard 40 b.15 B-1040 Brussels Belgium
Tel. +32.2.436.93.00 mail@cefic.be www.cefic.org
EU Transparency Register n° 64879142323-90

restriction creates uncertainty for businesses and for enforcement authorities. Businesses need this certainty for product compliance, while enforcement authorities need to know exactly which substances (in which products) do they need to inspect. Specifically in the case of the ongoing skin sensitisers restriction proposal for textiles, even the ECHA Enforcement Forum advised that the "enforcement of this restriction could be challenging" due to high number of substances under the scope, problems involving sampling, sample preparation and analytical methods.[2]

The Solution

Do not add automatic triggers based on hazards – use targeted restrictions instead

Overly-simplistic assessments and any extension of the generic approach to risk management (GRA) under Article 68(2) should be avoided, as it overlooks the complexity of substances and their applications. Managing safe use of chemicals requires a good understanding of their use, applications and of potential exposure. This should remain at the core of risk management under REACH.

Regular restrictions based on Article 68(1) provide for a more evidence and risk-based approach. They include a full-fledged risk and socio-economic assessment that can equally address the most severe hazards (SVHC) in a more targeted approach, hence addressing regulatory and societal needs.

When restrictions are targeted, well-designed with upfront considerations (see factsheets on Actions 2 and 3) with a science-based and clearly-defined scope, their implementation and enforcement – including checks of imports at the borders – become more manageable and workable.

[2] Compiled RAC and SEAC opinions: Registry of restriction intentions until outcome – ECHA

Annexes

Background

- Overly simplistic assessment means any automatic trigger between certain hazard classification and regulatory measures, including the extension of Article 68(2) to additional hazard classes.
- Under the current rules in REACH, Entries 28, 29 and 30 of Annex XVII to Regulation (EC) No 1907/2006 prohibit the placing on the market and use, for supply to the general public, of substances that are classified as carcinogenic, mutagenic or reproductive toxicant (CMR), categories 1A or 1B, and listed in Appendices 1 to 6 to that Annex and of mixtures containing such substances above specified concentrations.
- An example of consequences of harmonised classification of N_2O on other legislation, including REACH, are nicely explained in document (CA/40/2024) prepared by the European Commission for CARACAL discussion 18-19 December 2024.