15th of April 2025

REACH REVISION: Position paper Cosmetics Europe

Cosmetics Europe is the cosmetics and personal care association. Through its network of active corporate and association members, Cosmetics Europe represents at least 80% of the European cosmetics industry in value, including more than 9,000 SMEs. Our sector provides approximately 3 million direct and indirect jobs across the continent. Cosmetics are an integral part of the lives and identity of European citizens, used by people of all ages to take care of their personal hygiene and to improve their well-being – from soap to skincare, toothpaste, perfume, hair dyes, sunscreens, and makeup.

Cosmetics Europe is pleased to provide its comments on the upcoming revision of REACH. In line with the mission letter to Commissioner Jessika Roswall and the recently published Competitiveness Compass, this revision should ensure that the principles of Proportionality and Better Regulation are respected, including through wide consultations, impact assessments, a review by the independent Regulatory Scrutiny Board and a new SME and competitiveness check.

The implementation of the REACH regulation over the past 18 years has demonstrated its effectiveness while also revealing some limitations, such as delays in revisions and enforcement.

Cosmetics Europe supports the revision of REACH, provided that it takes into account the valuable lessons learned over the past years, is based on robust scientific principles, is proportionate and aligned with the principle of Better Regulation.

1. Impact assessment

REACH regulation revision was paused after a 2022 public consultation and initial impact assessment. Now, with the revision restarting and a target adoption date of late 2025, the old impact assessment needs to be revisited. This refresh will account for the Commission's new focus on competitiveness and simplification, as well as changes in the regulatory and political environment since 2022.

Ask (1): Cosmetics Europe asks for the reassessment and interpretation of the conclusions of the previous impact assessment for the revision of REACH regulation in light of the new priorities of competitiveness and simplification.

2. Generic Risk Management Approach (GRA) under REACH

Under the current GRA regime in REACH, CMR category 1 substances with a harmonized classification are banned in consumer products. We understand that the classification of a substance with one of the new hazard classes can signal the need for swift and effective risk management. However, a CLP classification – regardless of the type of hazard – does not automatically mean that all uses of the substance pose an unacceptable risk. In order to ensure better predictability, and preserve industry competitiveness and innovation capacity, it must be assured that safe uses of the substance can be maintained. An efficient and effective system of restrictions, when necessary, including fast, quasi-automatic steps is a better option than a

simple extension of GRA that risks unjustified and disproportionate bans of safe uses which can lead to regrettable substitution. The concept of such system is described in section 3 (see hereafter).

Ask (2): Cosmetics Europe is opposed to the extension of GRA.

3. Grouping of substances

Cosmetics Europe acknowledges that grouping of substance can in principle be used to make regulatory processes more efficient, however, grouping is not a 'one off exercise' that is only done at the beginning of the process, when identifying substances of interest. Grouping must be a 'stepwise' approach that is repeated according to the regulatory question at hand (e.g., identification of substances of possible interest → chemical classification → restrictions). As an example: substances may be grouped according to their chemical similarities as a first step. In a second step, depending on the regulatory actions foreseen the relevant endpoints have to be assessed for each substance and grouping is only done on the basis of scientifically valid read-across approaches. Indeed, experience has shown that two "chemically similar" substances can have significantly different hazard properties.

Ask (3): Cosmetics Europe asks for efficient and effective grouping of substances when used as a streamlining tool to ensure sufficient time and predictability for industry to work on the different suggested regulatory actions listed for the substances.

4. Streamlining the Authorisation and Restriction Processes

Cosmetics Europe recognizes the pressing need to streamline the restriction process and reduce the number of authorisation dossiers under REACH. We support the objective of shortening delays and reducing the administrative burden, while allowing robust scientific decisions and enhancing the efficiency and predictability of risk management for harmful substances.

Experience under sector specific legislations show that targeted restrictions of specific "substance/use combinations" do not have to become a resource-intensive, slow system. A key aspect is that gathering of data and preparation of safety dossiers is the responsibility of industry. The role of ECHA and Members States experts should be one of peer reviewing this information rather that generating/ compiling it. Such system can also include quasi-automatic fast track elements where, in a full reversal of burden of proof, failure of industry to unambiguously demonstrate safety will lead inevitably to a ban of certain substance/use combinations.

To achieve this, Cosmetics Europe strongly advocates that:

The REACH revision should amend Article 68(2) and the respective entries in Annex XVII to include a safety-based derogation system that is based on 'demonstrated safe use'. Indeed, a GRA mechanism that does not consider safe uses goes beyond the legitimate safety objective of REACH and leads to disproportionate bans of safe uses of chemicals and possibly to regrettable substitutions while impeding innovation and competitiveness of the EU market. Such an

approach cannot be put in place in a product-specific or company-specific manner, but it is based on aggregated information collected across industry, thus representing all sectors' uses of interest in a single sector dossier. This allows to reduce the burden on the evaluating scientific bodies and on the competent authorities which receive a smaller number of dossiers.

In addition, by better prioritising substances the approach will also result in clear timetables/roadmap allowing high degree of predictability and legal certainty for all stakeholders.

The concept of the approach is described hereafter:

Starting point: Chemical universe defined by REACH registration.

Step 1: Filter REACH chemical universe for substances of possible concern using as criteria the outcomes of ARN, CORAP, SVHC, CLH etc.

→ Outcome: List of substance of potential concern.

Step 2: Screening and First Prioritisation: For resulting substances, ECHA/ Member States uses data from the REACH registration dossiers (uses, tonnages) to screen and prioritise substance for follow-up.

- **Fast track**: Substances in consumer use with a CLH classification as CMR 1 are automatically considered as priority for potential follow-up and added to that list.

→ Outcome: List of prioritised substances published and updated annually.

Step 3: On prioritised substances, Industry provides detailed information (beyond REACH information) on sector specific uses, exposures, tonnages. Information should be collected/aggregated at sector level rather than submitted on individual company/use level.

- **Fast track: Substances in consumer use with a CLH classification as CMR 1, the information to be provided includes an analysis of suitable alternatives (AoA).** Failure of industry to submit information would automatically lead to a ban in the following steps (reversal of burden of proof).

→ Outcome: Detailed information available to ECHA and Member States on specific substance/use combinations on the prioritised substances including information on availability of suitable alternatives for substance/use combinations of CMR 1.

Step 4: Second Prioritisation: Based on that information, ECHA/ Member States identifies **which specific substance/use combinations require regulatory risk management, including potentially restrictions.**

- **Fast track**: Substances in consumer use with a CLH classification as CMR 1 are automatically considered as requiring regulatory follow-up. For substance/use combination without submitted AoA or where suitable alternatives exist, a ban is recommended as regulatory risk management.

→ Outcome: List of substance/use combination requiring regulatory risk management including identification of uses, that will automatically be banned.

Step 5: Determine the most appropriate regulatory risk management tool for each identified substance/use combination, taking into consideration socio economic impacts. **Specific timelines are being set to allow workability, predictability and forward planning**. Note that for some substance/use combination the regulatory risk management tool may be in sector specific legislation (e.g. BPR, PPP, CPR) or OSH or IED rather than REACH.

- **Fast track:** Substances in consumer use with a CLH classification as CMR 1 – where the AoA showed that:
  i. there are suitable alternatives for a particular use → ban of that substance/use combination;
  ii. there are no suitable alternatives for a particular use → **safety evaluation** of this substance/use combination. There is a reversal of burden of proof. No need for authorities to demonstrate an unacceptable risk. Rather industry needs to submit a safety dossier (sector aggregated) on substance/ use combinations of interest for peer-review by ECHA (RAC, SCCS, BPC, etc.).
    - If safety is confirmed or unsafe exposure can be excluded a continued use is allowed under a **substitution plan** until availability of suitable alternatives.
    - If not safe the substance/ use combination is banned unless there is an overriding benefit (last resort use of authorisation process).

→ Outcome: Annual publication of a **Regulatory Roadmap** leading to comprehensive regulatory risk management that prioritises substances of concern, allows targeted restrictions based on substance/use combinations, fast tracks the ban of substances of most concern without automatic bans of safe uses.

Throughout all steps above, it is important to note that identification of individual substances (e.g.: CAS or EC number) especially in the case of grouping approaches should be available. This is necessary to allow companies and in particular SMEs to prepare for restrictions. It also minimises the risk of misunderstandings and uncertainties and increases the effectiveness and efficiency of enforcement. The current restriction of PFAS shows the risks of insufficiently defined broad restrictions of a group of substances. Very broad restrictions that group a wide range of substances without distinction causes a high degree of uncertainty and burden.

Ask (4): Cosmetics Europe asks for amending Art 68 (2) and respective entries of Annex XVII to introduce an efficient and effective system of restrictions, including automatic fast track processes accompanied by exceptional safety-based derogation mechanisms. Furthermore, restrictions should always provide a clear list of substances in scope.

5. Non-Animal Methods (NAMs)

The current REACH legislative framework requires animal tests only as a last resort.

The upcoming REACH revision is a unique opportunity to prioritize use of Non-Animal Methods (NAMs) in replacing animal tests, recognize the rapidly evolving state of the science on NAMs, and drive the regulatory acceptance and uptake of NAMs and NAMs data for hazard identification and risk assessment/ management of chemical substances. This can be achieved by use of

NAMs, particularly through application of Annex XI. Furthermore, strengthening a risk-based approach drawing on use-specific exposure data and in combination with NAMs would ensure an equal or higher level of safety, while avoiding animal testing.

It is crucial that REACH facilitates scientific progress and regulatory acceptance of NAMs to ensure animal testing is, indeed, mandated by ECHA only as a true and demonstrable last resort.

Ask (5): Cosmetics Europe asks to:

- **Enforce animal testing strictly as a last resort, ensuring that "last resort" truly means only when there are no other possibilities.**
- **Implement a scrutiny process when animal testing is deemed necessary by ECHA. This process should involve a committee of NAMs experts and/or public consultation.**

6. Consistency among chemical legislations

Ensuring efficient enforcement of the regulations is a key aspect for the revision of the REACH regulation. To achieve this, firstly there is a need for coherence between REACH and other horizontal pieces of legislation. REACH should be strengthened in terms of setting the horizontal definitions and concepts used in other horizontal chemicals legislation to avoid overlaps and contradictions. Secondly, these concepts should then be translated and adapted into sector legislation taking into account their specificities.

Ask (6): Cosmetics Europe asks for the revision of REACH to consider the current sectoral regulations already in place, to encourage the enforcement of the chemical regulations and ensure a level playing field.