

(English version)

**Question for written answer E-000762/26
to the Commission**

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(24 February 2026)

Subject: Ensuring risk assessment as the basis for proportionate regulation of cosmetic products

The classification of chemicals based on their properties and hazard profile is the responsibility of the European Chemicals Agency (ECHA) and is based on the opinions of the Committee for Risk Assessment (RAC). The role of the legislator is to take regulatory decisions, including restrictions or bans on the use of substances, based on the actual risks arising from specific uses and exposure levels in particular sectors, including the cosmetics sector.

Currently, however, neither ECHA nor the RAC systematically provide risk assessments for specific uses or information enabling a full exposure assessment, which creates a significant gap between hazard classification and proportionate regulation.

The Commission is therefore asked to answer the following questions:

1. How does the Commission intend to ensure that the legislator has access to use-specific risk assessments, so that regulatory decisions are not based solely on hazard classification?
2. Does the Commission plan to ensure that RAC opinions systematically cover exposure levels that do not give rise to concern for all relevant exposure routes: oral, dermal and inhalation?
3. How does the Commission intend to prevent situations whereby regulatory restrictions lead to disproportionate socioeconomic impacts in the absence of demonstrated risks to human health or the environment?

Supporter ⁽¹⁾

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**Answer given by Executive Vice-President Séjourné on behalf of the European Commission
(16 April 2026)**

1. According to the regulation on classification, labelling and packaging (CLP) of chemicals ⁽¹⁾, the Risk Assessment Committee (RAC) identifies the hazardous properties of substances. The Commission decides whether it is appropriate to subject a given substance to the harmonised classification as suggested by RAC. The decision is purely hazard based.

Regulatory decisions on the supply or the use of that substance are taken in accordance with the relevant sectoral legislation. Decisions to ban certain hazardous ingredients under the Cosmetic Products Regulation (CPR) ⁽²⁾ are based on their harmonised classifications. Derogation decisions are based on scientific opinions from the Scientific Committee on Consumer Safety ⁽³⁾ and cosmetic-specific criteria. The Commission proposed to simplify this system in the Chemicals Simplification Omnibus (Omnibus VI) ⁽⁴⁾ to provide more legal clarity for businesses.

2. In accordance with the CLP Regulation, for hazards linked to systemic toxicity ⁽⁵⁾, data obtained from the exposure of test animals via one route is deemed to cover all routes of exposure, unless the scientific evidence demonstrates that some routes are irrelevant. This is a general scientific compromise between scientific comprehensiveness and effort to reduce animal testing, embedded in the European and international rules.

3. Socioeconomic impacts of regulatory restrictions are not considered in the CPR. However, Omnibus VI proposes criteria for the assessment of the absence of suitable alternatives to a carcinogenic, mutagenic or toxic for reproduction Category c substance. This includes the technical feasibility of a potential alternative substance and its economic viability. The co-legislators are examining this proposal.

¹ This question is supported by a Member other than the authors: Andrey Novakov (PPE).

⁽¹⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R1272>.

⁽²⁾ <https://eur-lex.europa.eu/eli/reg/2009/1223/oj/eng>.

⁽³⁾ https://health.ec.europa.eu/scientific-committees/scientific-committee-consumer-safety-sccs_en.

⁽⁴⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52025PC0531>.

⁽⁵⁾ Toxicity possibly observed in other parts of the body than the point of entry of the substance.