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Joint Cosmetics Europe, EFEO, EFfCI, IFEAT, IFRA, NATRUE, SMEunited Questions and Answers Document on the Commission's Omnibus VI on Chemicals

Focus: Article 15 of the Cosmetic Products Regulation (CPR)

Safeguarding high standards of consumer safety while bringing clarity for industry and authorities

Ever since the publication of the European Commission's Omnibus VI on Chemicals, which includes targeted adjustments to the Cosmetic Products Regulation (CPR), a number of questions have emerged regarding its implications, in particular on the use of substances classified as CMR (Carcinogenic, Mutagenic, or Reprotoxic) under Article 15.

The Commission's Omnibus VI reaffirms that consumer safety remains the cornerstone of the CPR while introducing targeted improvements to make the regulation more operational and effective. These adjustments preserve the strict science-based approach and ensure that **any use of CMR-classified ingredients in cosmetics continues to require a positive safety assessment from the Scientific Committee on Consumer Safety (SCCS)**.

This Q&A aims to clarify the following points:

- The **scope and intent** of the Omnibus proposal in the context of Article 15 of the CPR.
- The continued **central role of the SCCS (Scientific Committee on Consumer Safety)** in safeguarding public health, with a **positive SCCS safety assessment remaining a non-negotiable precondition** for any use of CMR-classified ingredients in cosmetics.
- How the updated provisions respond to over a decade of experience with the **derogation process**, which in practice has proven **unworkable**, with **no derogations ever granted** despite evidence of safe use.
- Why were these adjustments **both necessary and urgent**, rather than waiting for the full revision of the CPR.

Far from weakening consumer protection, we believe that the Commission's Omnibus VI strengthens the CPR's science-based, risk-oriented framework. It provides clarity for authorities, predictability for industry, and confidence for consumers, ensuring the regulation remains both protective and workable, especially for substances proven safe in cosmetic use but automatically banned under hazard-based classifications that do not reflect actual exposure scenarios.

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Question 1. What has changed in the application of Article 15 derogations?

Short answer:

The Commission Omnibus VI proposal introduces clarifications that make Article 15 functional without compromising on consumer safety.

Long answer:

The Commission Omnibus VI proposal brings several **critical clarifications** to how Article 15 derogations are to be applied:

- **Clearer guidance on the "no suitable alternatives" criterion.** For more details, please refer to question 8.
- **Removal of the food safety criterion**, which was unfit for topical applications and blocked scientifically justified derogations. For more details, please refer to question 7.
- **Recognition of exposure route relevance**, ensuring decisions are based on actual cosmetic use. For more details, please refer to question 6.
- **Better alignment of timelines and procedures**, helping both authorities and industry navigate the process. For more details, please refer to question 10.

These changes make Article 15 **functional**, without reducing the high standard of consumer safety.

Question 2. Does the Commission's Omnibus under the Cosmetic Products Regulation continue to maintain the highest standards of consumer safety for substances classified as CMRs?

Short answer:

Yes. The Omnibus proposal fully maintains the strict consumer safety standards of the Cosmetic Products Regulation (CPR). The SCCS continues to play a central role, ensuring that any use of a CMR-classified ingredient in cosmetics – in certain, justified cases – is subject to a rigorous safety evaluation and only permitted when proven safe under realistic exposure conditions.

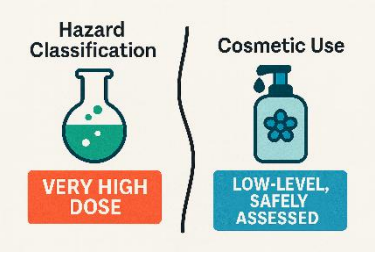
Long answer:

The derogation procedure under Article 15.2 remains intact, with different levels of evidence required depending on whether the substance is classified as CMR2 or CMR1:

- **For CMR2: A positive SCCS opinion is required,** confirming the ingredient is safe for use in cosmetics.
- **For CMR1**:
    - **A positive SCCS opinion,** based on known exposure levels and aggregate exposure across uses (not just cosmetics).
    - **Demonstration of no suitable alternatives**, with clear expectations on how this should be substantiated.

The Commission Omnibus proposal does not weaken these requirements. Rather, it clarifies and improves the derogation process, introducing clearer timelines and transition periods that bring greater regulatory predictability for both industry and authorities.

CMRs are not allowed without restrictions. The use must be based on defined use levels and specific product applications, and there must be no unacceptable risk under realistic consumer exposure scenarios. We believe that the Commission Omnibus proposal does not lower the bar but clarifies how scientifically sound derogations can be granted when appropriate, particularly when hazard classifications are based on exposure routes not relevant to cosmetics.



This is particularly important given that hazard classification decisions are typically based on high dose testing under extreme conditions, which do not reflect the low-level, controlled exposure associated with actual cosmetic use.

The Omnibus preserves a rigorous, science-based system to protect consumers while enabling regulatory processes to be more transparent and predictable.

Question 3. Why are these changes necessary now?

Short answer:

Adjustments were needed immediately to prevent safe ingredients from being banned, avoid costly reformulations, and fix a flawed derogation process. We believe that waiting for the full CPR revision would have left companies and regulators without a workable solution for years.

Long answer:

The urgency of these adjustments stems from real and immediate consequences for ingredients affected by hazard-based classifications under the Regulation on the Classification, Labelling and Packaging of chemicals (CLP).

Without timely clarification:

- Safe ingredients risk being **banned by default**.
- The industry faces a **wave of disproportionate and unnecessary reformulations**.
- There is a risk of losing **iconic natural and heritage formulations,** as well as ingredients – including natural ones with a long record of safe use.
- Authorities would continue to deal with a **dysfunctional derogation** process.

According to the European Commission staff working document accompanying the Omnibus VI[1], approximately **10 fragrance ingredients** are currently undergoing harmonised classification and labelling (CLH) procedures with proposals or conclusions identifying them as **CMR Category 1B**. If these classifications are confirmed, they could trigger the **reformulation of up to 85% of the 500,000 cosmetic products** currently on the EU market **within the next 2–3 years**.

The reclassification of just these 10 fragrance ingredients would require the reformulation of approximately 425 000 products, resulting in a total cost of €6 750 000 000 for the cosmetics industry.

Considering that a single fragrance ingredient, p-cymene, is naturally present in around 300 essential oils and plant extracts, the impact of CLH procedures on natural ingredients would be far-reaching.

Additional costs include:

- Re-labelling and packaging changes, which can cost medium-sized companies 1–3% of their turnover. One company estimated a one-off cost of €2–5 million for allergen-related updates alone.
- Recruitment and operational impact, including up to 5 full-time employees to manage compliance. This seriously endangers SMEs that do not have the resources to absorb these costs and the additional workload.
- Product withdrawals and destruction, which can represent 0.5–3% of annual turnover, resulting in large volumes of wasted finished products and packaging with associated environmental impact.

[1] https://single-market-economy.ec.europa.eu/document/download/b2fab08c-b641-4ee5-b046-d7d710ee941b_en?filename=SWD_2025_531_1_EN_autre_document_travail_service_part1_v3.pdf

These figures demonstrate the **massive economic and operational burden** of the current system which particularly affects SMEs. Waiting for the CPR revision, which may take years, would leave industry and regulators without a workable solution. The Omnibus therefore provides **urgently needed legal and procedural clarity**.

Question 4. What is the SCCS and what role does it play in this new framework?

Short answer:

The **Scientific Committee on Consumer Safety (SCCS)** is an **independent expert group** established by the European Commission which helps to ensure that only safe cosmetics are being put on the EU market. Its role does not change under the Commission Omnibus VI proposal.

Long answer:

The **Scientific Committee on Consumer Safety (SCCS)** is an **independent expert group** established by the European Commission. It is responsible for **assessing the safety of cosmetic ingredients placed on the EU market.**

Composed of experts in toxicology, dermatology, exposure science, and related fields, the SCCS operates under strict principles of independence, transparency, and evidence-based assessment.

The SCCS continues to be the scientific gatekeeper for the safety of cosmetic ingredients. Any CMR-classified substance may only be used if and when the SCCS issues a positive opinion confirming its safety for the intended cosmetic use, based on:

- Realistic exposure scenarios,
- Scientific evidence,
- Conservative safety margins,
- Consideration of aggregate exposure

This ensures that **no CMR substance is used without a thorough, independent safety review**, aligned with the principles of consumer protection.

With the Commission Omnibus VI proposal, the SCCS work remains unchanged:

- Reviews data on **toxicity, exposure, and consumer use**.
- Applies **robust risk assessment methodologies**.
- Publishes its opinions and rationales **openly**.
- Functions independently of political or commercial considerations.

A positive SCCS opinion is a mandatory requirement before any CMR substance may be considered for continued use in cosmetics under Article 15, and this remains fully applicable even with the targeted adjustments introduced by the Commission's Omnibus proposal. This framework ensures that regulatory decisions are rooted in sound science and prioritise consumer health.

For more information, see in Annex I the infographic for the evaluation of ingredients used in cosmetics at large by the SCCS, also available on the Commission webpage.

Question 5. How does this affect the use of natural ingredients?

Short answer:

Natural ingredients include many complex substances, composed of a multitude of constituents present in variable concentrations, which can shift depending on factors such as climate, season, and geographical conditions. Their overall properties cannot be compared to the properties of each constituent taken individually. The Commission Omnibus VI proposal safeguards the continued use of natural ingredients like essential oils and plant extracts in cosmetics by providing legal clarity, ensuring a rigorous case-by-case safety evaluation of any classified constituent, and recognising the impracticality of substituting these naturally occurring constituents in many natural ingredients.

Long answer:

The Commission Omnibus proposal is particularly important for **safeguarding the use of Natural Complex Substances (NCS)**, such as essential oils and plant extracts, which may contain constituents classified as CMRs.

Under the existing rules, the regulatory approach for these natural ingredients creates severe legal uncertainty, which could severely affect the use of natural ingredients despite extensive evidence of safe use at those levels. This uncertainty particularly impacts ingredients where a constituent was classified as a CMR, even if present at low or very low levels and without actual risk under cosmetic use.

The Omnibus provides:

- A **clearer route** for NCS constituents under the CPR (via Article 31).
- A reaffirmation that the **safety of the constituent must be evaluated case-by-case by the SCCS**.
- Recognition of the **impracticality of substituting** a constituent within a range of natural complex substances.

Question 6. How is the difference between oral, inhalation, and dermal exposure handled?

Short answer:

The Commission's Omnibus VI proposal clarifies the **scope of the CMR ban under Article 15** of the CPR, confirming that prohibitions will not apply when the CMR classification in CLP Annex VI is explicitly linked only to oral or inhalation exposure**.** This ensures that **restrictions target the routes of exposure relevant to cosmetics' primary use (dermal)** while preserving existing high safety standards. Where incidental ingestion or inhalation could still present a risk for certain product types, the Commission will require an SCCS safety assessment before any use is authorized in cosmetics.

Long answer:

Under the CLP Regulation, CMR classifications typically include information about the relevant route of exposure (oral, inhalation, dermal) in the "Hazard statement Code(s)" column of Annex VI.

However, to date, the CPR does not differentiate between these routes: any CMR classification automatically triggered a ban in cosmetics, regardless of whether the exposure route is actually relevant for cosmetic use.

As a result, ingredients could be prohibited even when their hazard was identified solely through ingestion or inhalation, exposure routes generally not applicable to cosmetics, where dermal contact is the primary pathway and systemic absorption is usually much lower.

The Commission Omnibus VI proposal clarifies the CPR by introducing a new paragraph 5 in Article 15: **the automatic CMR ban will not apply if the CMR classification in CLP Annex VI is explicitly linked only to oral or inhalation exposure**. In such cases, if incidental ingestion or inhalation from a cosmetic product could still present a risk to human health (e.g., certain product types like lipsticks or aerosol sprays), the Commission will, without undue delay, request an SCCS opinion to assess the safety of that substance for those specific uses.

For example, for a substance which would be classified for CMR concerns linked to **oral exposure**, under the revised approach, its use in cosmetics would be assessed according to **dermal exposure**, which is the relevant route for cosmetic applications. **Industry would generate new dermal studies** to provide robust evidence for SCCS review, ensuring decisions reflect actual use conditions rather than unrelated exposure routes.

This means:

- A CMR classification based exclusively on oral or inhalation exposure will not automatically trigger a ban, provided those routes are not relevant for the intended cosmetic use.
- The SCCS continues to assess the relevant exposure routes, particularly dermal, to determine actual consumer safety in the context of cosmetics.
- Any incidental exposure through ingestion or inhalation that could present a risk will remain subject to immediate SCCS scrutiny and possible restriction.

This clarification ensures that hazard-based classifications are interpreted in a **scientifically sound, risk-oriented, and use-relevant way**, aligning regulatory action with **actual cosmetic exposure scenarios and preserving the highest level of consumer safety**.

Question 7. Why was the food safety criterion removed from the derogation process?

Short answer:

Food and cosmetics are distinct products and the fact that a product containing a substance is inedible does not mean that this substance will be unsafe when used in a cosmetic formula which is to be applied on the human skin.

Long answer:

The current Article 15.2 includes a requirement that any CMR1 substance can only be allowed in cosmetics if it also complies with food safety standards. This condition is based on the assumption that if a substance is safe enough for ingestion, it should be safe for topical use.

However, this logic has proven scientifically and regulatorily flawed for several reasons:

- **Cosmetic and food uses differ fundamentally** in exposure route, frequency, and systemic impact.
- Cosmetic products and their ingredients are **never intended for ingestion**. Any ingestion exposure, such as that which might occur accidentally from toothpaste, is unintended but must still be considered in the safety assessment. Comparisons with food are therefore not relevant.
- The requirement leads to the **automatic exclusion of safe ingredients** simply because they have not been assessed under relevant food legislations.

The Commission Omnibus proposal removes this criterion, reinforcing that topical safety for cosmetics should be assessed by the SCCS based on appropriate, route-specific data. This makes the process more relevant, science-based, and workable without compromising consumer protection.

Question 8. What has changed in the definition of a “suitable alternative”?

Short answer:

The Commission Omnibus proposal **clarifies “suitable alternative” by defining strict criteria** that ensure safety, efficacy, feasibility, and availability, replacing vague rules with a clear, enforceable standard.

Long answer:

One of the most important clarifications brought by the Commission Omnibus proposal concerns the concept of a “suitable alternative”, a key criterion under Article 15.2 for allowing the continued use of a CMR1 substance in cosmetics.

Previously, there was no formal definition of what a suitable alternative meant, leading to legal uncertainty and inconsistent expectations.

The Omnibus proposal introduces a clear and structured definition: a substance is considered a suitable alternative <u>only if all four of the following conditions are met:</u>

1. It **reduces overall risk** to human health and the environment.
2. It **performs an equivalent function and efficacy** in the finished cosmetic product.
3. It is **technically feasible and economically viable**.
4. It is **not restricted**, **not protected by exclusive rights**, and **available at scale** to meet current and future demand.

This is not a loosening of the rules, but a way to bring clarity and enforceability to an important requirement that had been impractical to apply.

Question 9. Do the proposed changes benefit only industry or also consumers and authorities?

Short answer:

Yes, all stakeholders are expected to benefit from the Omnibus proposal.

Long answer:

This proposal is designed to benefit **all stakeholders**:

- **Consumers** retain a high level of protection, as all decisions are subject to **SCCS risk assessments** and conservative safety thresholds. It also allows to maintain **consumer choice** towards safe, iconic fragrances and cosmetic products. These are at risk of disappearing if the derogation process is not applicable for safe ingredients, which the Omnibus aims to tackle.
- **Competent Member State authorities, including enforcement bodies,** benefit from a clearer, enforceable framework and are relieved from an unworkable system.
- **Industry** can retain safe ingredients and **target reformulation efforts where genuinely necessary**, allowing innovation to **deliver meaningful benefits for consumers**.

We believe the proposed amendments will generate a **more efficient, credible, and transparent regulatory process**.

Question 10. Do the transition periods under the Commission Omnibus VI allow unsafe cosmetic products to stay on the market?

Short answer:

No. Transition periods do not permit unsafe products to remain on the market. All cosmetics must continue to meet existing EU safety requirements. The SCCS safety evaluation, whether it concludes safe use is possible or not, directly determines whether an ingredient can continue to be used. The 12-24-month timelines proposed in the Commission Omnibus VI are intended to enable the reformulation process to happen in an orderly and enforceable way, and even with this phasing, managing all necessary supply-chain adaptations and operational steps remains highly challenging for the industry.

Long answer:

Transition periods are not a grace period for unsafe products. They are designed to ensure time for manufacturers to carry out reformulation, product dossier update, labelling updates, production and stock withdrawal where required. This ensures there is no waste of products or packaging, that innovation remains focused on sustainability and safety, and legal certainty.

During these periods:

- **Products remain subject to general product safety law**, **Responsible Person obligations**, and **consumer transparency requirements**.
- If the SCCS issues a **negative opinion**, regulatory action can follow swiftly, meaning the transition period does **not create an exemption for** unsafe products.
- If the SCCS confirms safe use under specific conditions, these can be implemented without disrupting supply chains.

This ensures that consumer protection is continuous and the implementation process is practical and enforceable, safeguarding both safety and regulatory credibility.

Annex I – Infographic for the evaluation of ingredients used in cosmetics at large by the SCCS