**CONCEPT NOTE**

**REALITY CHECK WORKSHOP**

ON THE POSSIBLE SIMPLIFICATION OF THE COSMETIC PRODUCTS REGULATION

Friday 16 May 2025, 14:00 – 17:30

# Simplification initiatives

In the Communication on implementation and simplification, the Commission stressed that in its approach to simplification it will be guided ‘*by the need to take stock of the past, navigate the present and shape the future’*. The Commission announced that it would review and adapt the EU regulatory framework to make it more responsive to the needs of people and businesses and that through all these actions, it would pursue a more effective and efficient delivery on the EU economic, social and environmental goals.

The Commission has been promoting the “reality checks” as a new consultation tool, at technical level, focused on ensuring that policy objectives are achieved, and administrative burdens are minimised. Commission services would like to, through the “reality check” seek detailed technical feedback from the businesses, competent authorities and other actors in the cosmetics area on the implementation of EU rules on cosmetics on possible measures to make them simpler and facilitate their implementation

# Potential areas for simplification and burden reduction

Although Regulation (EC) N° 1223/2009 on cosmetic products (Cosmetic Products Regulation, hereinafter as CPR) is currently subject to a full-fledged evaluation[[1]](#footnote-1) in accordance with the Better Regulation Guidance, the Commission is currently considering whether there is a potential for simplification and burden reduction that could benefit stakeholders, especially businesses in the short to medium term.

Based on previous exchanges with stakeholders, the Commission has identified the following elements for potential action:

## Reducing administrative and compliance burden relevant to CMR classified ingredients (Article 15)

Article 15 of the CPR establishes that substances that have been classified as carcinogenic, mutagenic or reprotoxic (CMR) in Annex VI to Regulation (EC) 1272/2008 on classification, labelling and packaging of chemical substances and mixtures (CLP Regulation) are prohibited for use in cosmetic products, unless an exemption has been granted. More specifically,

* Pursuant to Article 15(1) of the CPR, the use of a CMR substance of category 2, listed in Part 3 of Annex VI to the CLP Regulation, is prohibited in cosmetic products **unless** it has been evaluated by the SCCS **and** found safe for use in cosmetics.
* Article 15(2) provides that the use of substances classified as CMR substances of category 1A or 1B, listed in Part 3 of Annex VI to the CLP Regulation is prohibited in cosmetics, **except** when the following criterial **cumulatively** fulfilled:

1. *the substance complies with the* ***food safety requirements***
2. *there are* ***no suitable alternatives***
3. *the application has been made for a* ***particular use of the product category with a known exposure****, and*
4. *the substance has been* ***evaluated and found safe by the SCCS*** *considering the cumulative exposure from other sources outside cosmetics.*

As regards the deadline for the implementation of the exemption procedure for CMR 1A/1B substances, Article 15(2) 4th subparagraph of the CPR provides that the Commission shall amend the relevant Annexes to this Regulation within 15 months of the “*inclusion of the substances concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008*”.

Thus far, the Commission services have considered that the 15-month timeline for granting an exemption or banning CMRs in cosmetics should be calculated from the **date of entry into force** of the CMR classification. Each year, a review is conducted through the Omnibus Act on CMR substances to transpose substances with newly harmonized classifications under the CLP Regulation into the Annexes of the CPR. Specifically, prohibited substances are added to Annex II, while substances that have successfully obtained an exemption from the general ban are listed in Annexes III–VI to the CPR. **With the current process, the application date of the harmonised classification coincides with the application of the prohibition or restriction of such substances under the CPR** (i.e., the Omnibus Act on CMRs and the Delegated act for the harmonised classification and labelling of hazardous substances have the same application date).

Nevertheless, recent experience has highlighted certain challenges and limitations in the current system, indicating that the process leading to prohibition or restriction of substances from cosmetic products may not be functioning as effectively as intended.

*Growing number of cosmetic ingredients that receive CMR harmonised classification*

From 2009 to 2018, the CLP Regulation was amended 20 times, averaging two amendments per year. In contrast, over the past seven years (2018–2024), it has been amended 35 times, increasing the average to five amendments per year. This significant rise in regulatory updates underscores the need for a more structured and predictable framework, especially since more and more substances are classified under the CLP that are currently used in cosmetics.

In 2025, RAC adopted opinions for 110 substances, including several for which CMR 1B classification was proposed. Many of these substances are widely used in cosmetic products, such as Piperonal, a key ingredient in signature perfumes; Tea Tree Oil and p-cymene, a component found in 360 essential oils. This trend is expected to continue as an increasing number of non-industrial chemicals are being proposed for harmonised classification as CMR substances. Moreover, the grouping approach recently introduced will further accelerate the pace at which substances are subject to harmonised classification including as CMR, intensifying the regulatory impact with potential negative effects on the cosmetics sector.

*Impacts due to the lack of legal certainty and transitional periods*

Businesses argue that the absence of clear rules and well-defined timelines, along with the lack of justified transitional periods, undermine investment decisions often forcing companies to rely on assumptions about whether a substance will be classified and subsequently banned in cosmetics. Businesses also indicate that this uncertainty hampers the ability of companies to scale up, which is particularly critical for SMEs.

**Based on earlier discussions with interested parties, several changes could be made in Article 15 of the CPR to simplify it and reduce the burden on businesses without affecting the high level of protection of human health,** meaning that the harmonised classification of a substance as CMR category 1 or 2 would continue to trigger its prohibition in cosmetic products, unless a derogation request is submitted, and the derogation criteria are met.

1. ***Establishing a fixed period for submission of derogation requests***

The current CPR does not foresee a timeline for businesses to submit a request for derogation. According to the CMR Guidelines[[2]](#footnote-2), a submission should be made within six months after the publication of the RAC Opinion. To provide greater legal certainty, the CPR could explicitly set this deadline – proposing, for instance, a period of nine months following the publication of the RAC Opinion.

1. ***Introducing transitional periods for compliance with new bans or restrictions***

To enhance legal certainty and enable businesses to take appropriate measures, the CPR could introduce more realistic adaptation timelines – such as 24 months for products placed on the market and 36 moths for products available on the market – following the entry into force of amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substances concerned as CMR category 1A, 1B or 2. These timelines could be extended in cases where a derogation request has been submitted and the SCCS opinion was has been sought.

1. ***Simplifying derogation criteria under Article 15(2)***

Among the derogation criteria of Article 15(2), two criteria could be revisited:

a) the compliance with the food safety requirements and

b) the application which must be made for a particular use of the product category with a known exposure.

As regards the first criterion, advances in innovative techniques have led to the development of new substances on an almost daily basis. While the food safety criterion may have been justified 15 years ago, several stakeholders consider that it now risks becoming a barrier to the use of substances that are not present in food but are demonstrably safe when applied on the external parts of the human body.

Interested parties also pointed out that the added value of the second criterion seems redundant as the SCCS already evaluates the safety of ingredients based on the specific use and exposure relevant to each product category. In this context, interested parties took the view that it might be difficult to justify keeping this element as a separate criterion.

1. ***Clarifying the regulatory approach to natural complex substances containing CMR Cat. 1 or 2 constituents***

For the purpose of legal clarity and certainty, the CPR could provide that when a constituent of a multi-constituent substance has been classified as a CMR substance of categories 1A, 1B and 2, the prohibition from Article 15(1) and (2) would not apply to such a substance if it was extracted from plants or plant parts and which are not chemically modified.

1. ***Linking the ban to substances classified as CMR based specifically on dermal exposure***

Article 15 of the CPR prohibits substances based on the harmonised classification as a CMR category 1A, 1B or 2. However, it does not take account the route of exposure this classification may have. It could be that a substance has CMR properties only if it is inhaled or digested, but not if it comes into contact with the human skin.

It could be considered to better articulate the link between the exposure behind the harmonised classification as a CMR category 1A, 1B or 2 and the ban in cosmetics.

1. Fostering Innovation and Reducing Regulatory Uncertainty
   * 1. ***A comprehensive and clear procedure to facilitate the addition of colorants, preservatives, and UV filters to Annexes IV–VI***

Currently, the procedure laid down in Article 31(2) of the CPR is used to add colorants, preservatives and UV filters to Annexes IV, V and VI, respectively. However, specific provisions laying down the procedure for the possible inclusion of new colorants, preservatives or UV-filters in the Annexes to the CPR upon request from the cosmetics industry, would enhance clarity and legal certainty and support innovation and competitiveness on the EU cosmetics sector.

1. Streamlining requirements under Article 33
2. ***Eliminating the requirement of the publication of the glossary of cosmetic ingredients in the Official Journal of the EU.***

Article 33 of the CPR provides that for the purpose of labelling cosmetic products placed on the EU market, the Commission must compile and update a glossary of common ingredient names, via a Commission Decision, taking into account of internationally recognised nomenclature including INCI names.

Until now, such glossaries were published in the Official Journal of the EU in 2029 and 2022. The practice with the updates of the glossary has become suboptimal due to the following reasons:

* **Slow pace of updates**: the majority of common ingredient names used in cosmetics, rely on the International Nomenclature of Cosmetic Ingredients (INCI), which are developed by the Personal Care Products Council (PCPC). Although, new INCIs are constantly developed or updated by the PCPC, the update of EU glossary takes place approximately every three years, which results in slower adaptation to technical developments.
* **additional burden (duplication of work) on competent authorities and business**: Given the legal value of the Commission Decision establishing the list of common ingredients names, both the market surveillance authorities and business operators verify that the ingredient names used on product labels correspond to those listed in the Decision. To streamline this process, the CosIng database is often used as a first step to quickly identify the correct name, which is then cross-checked against the official entry in the Commission Decision.

The current scheme leads to additional work and unnecessary burden.

A solution could be to remove the obligation to compile the glossary and enable businesses and competent authorities to rely on the internationally recognised nomenclature and relevant information provided electronically in a Commission database[[3]](#footnote-3).

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| **Questions for consideration:**   * Do you consider that the above-mentioned solutions could simplify business operations and reduce the burden on the cosmetic industry? * If yes: could you provide data enabling to assess the burden reduction or expected benefits? * Which of the suggested solutions would bring the highest added value? * Are there other solutions related to the simplification and burden reduction for businesses? * Are there other solutions which could increase the number of authorised colorants, preservatives and UV filters in cosmetics? |

# Potential areas for reducing notifications and reporting obligations

1. ***Reviewing prenotification requirements for products containing nanomaterials (Article 16)***

According to the CPR, products containing nanomaterials (other than colorants, UV-filters, preservatives or nanomaterials in conformity with Annex III requirements) must be notified to the Commission six months prior to being placed on the market. This obligation is in addition to the notification obligation that applies to all cosmetic products under Article 13 CPR.

This double notification of products containing nanomaterials seems no longer justified as the cosmetic products containing nanomaterials should not be considered less safe than other cosmetic products as they are subject to the appropriate safety assessment under the responsibility of the responsible person. The Commission may request the opinion of the SCCS on the safety of nanomaterial in case of safety concerns and the responsible person should be obliged to provide any necessary data to the Commission on its request. The prenotification obligation laid down in Article 16 of the CPR could be therefore removed to reduce additional burden.

1. ***Evaluating the relevance and efficiency of market surveillance reporting obligations (Article 22)***

According to Article 22 of the CPR, Member States must perform appropriate checks of cosmetic products and periodically review and assess the functioning of their surveillance activities. Such reviews should be carried out at least every four years and the results should be communicated to the other Member States and the Commission.

Over the years different networks and tools have been created to inform about and coordinate the market surveillance activities by the competent authorities:

* the EU Product Compliance Network (EUPCN) has been established to structure the coordination and cooperation between market surveillance authorities in EU countries,
* PEMSAC group facilitates the exchange of information among the market surveillance authorities responsible for cosmetics,
* The ICSMS (Information and Communication System for Market Surveillance)[[4]](#footnote-4) functions as the comprehensive communication platform for market surveillance on non-food products and for mutual recognition for goods.

The ICSMS allows information on investigated products (test results, product identification data, economic operator information, accident information, information on measures taken by surveillance authorities etc.) to be quickly and efficiently shared between authorities. It supports market surveillance activities, by providing a register for their documentation, the identification of the products inspected and the results of the tests/checks.

The reporting obligation introduced in Article 22 of the CPR has become, therefore, an unnecessary burden on the competent authorities and it should be therefore removed.

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| **Questions for consideration:**   * Do you consider that prenotification of cosmetic products containing nanomaterial creates unnecessary burden and costs on the cosmetics industry? * Do you consider that the deletion of the reporting obligations would reduce burden on competent authorities? * If yes: could you provide data or evidence supporting the above claims? * Are there other reporting obligations which could be deleted? |

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## While we welcome and remain of course open to contributions and comments, we would be grateful for receiving them ideally by **31 May 2025**, via e-mail to: [GROW-CHEM-MEETINGS@ec.europa.eu](mailto:GROW-CHEM-MEETINGS@ec.europa.eu)

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1. [Cosmetic Products Regulation – evaluation](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14433-Cosmetic-Products-Regulation-evaluation_en) [↑](#footnote-ref-1)
2. https://ec.europa.eu/docsroom/documents/39989 [↑](#footnote-ref-2)
3. Existing Cosmetic Ingredients database (CosIng) provides information on cosmetic substances and ingredients including frequently updated common ingredients names. [↑](#footnote-ref-3)
4. https://webgate.ec.europa.eu/single-market-compliance-space/market-surveillance [↑](#footnote-ref-4)