

The Chemicals Package

A More Pragmatic Approach to the Cosmetics Regulation

EMEA - July 2025

On 8 July 2025, the European Commission released its Chemicals Simplification package. Under the umbrella of a European Chemicals Industry Action Plan, the package includes a series of initiatives aiming to boost the industry's competitiveness.

The package notably includes a <u>chemicals omnibus</u> <u>simplification proposal</u> (and its <u>annex</u>), proposing to simplify the recently amended Regulation (EU) 1272/2008 on classification, labelling and packaging (<u>CLP</u>), as well as Regulation (EU) 1223/2009 on cosmetic products (<u>Cosmetics Regulation</u>).

On the **CLP side**, the omnibus mainly addresses requirements on formatting and advertising, while also granting more flexibility to companies in relation to labelling updates following the issuance of a new harmonised classification.

Amendments to the **Cosmetics Regulation**, on the other hand, reveal that the regulator is looking to **recentre its approach on risk-based considerations**. We have provided an overview below.

A Rationalised Approach to the Presence of CMRs in Cosmetic Products

The proposal maintains and builds upon the general principle that a harmonised classification of a substance as carcinogenic, mutagenic or reprotoxic (CMR) category 1 (known) or 2 (suspected) under the CLP triggers its ban from use in cosmetic products. Derogations may, however, be granted for CMR 1 substances if specific conditions are met.

In this context, the proposed amendments present a more pragmatic approach, including through specific timelines, as well as re-placing risk at the centre of considerations.

Notably, the proposal introduces a consideration for the **route of exposure concerned** by the harmonised classification. Indeed, it foresees that a CMR 1 or 2 classification limited to exposure via oral or inhalation route would not trigger a ban. In such cases, if the Commission identifies a potential risk from incidental inhalation or ingestion, it is responsible for requesting, without undue delay, an opinion from the Scientific Committee on Consumer Safety (SCCS) on the safety of the substance concerned in specific product types.

Similarly, the classification of a constituent of a natural complex substance as CMR 1 or 2 would not automatically trigger a ban of the complex substance. It is only where the Commission identifies a risk that it should seek an opinion from the SCCS on the safety of that substance, again without undue delay.

The proposal also addresses the granting of **derogations** for products containing substances classified as CMR 1A or 1B. Once a substance is classified as a CMR (i.e. the corresponding entry of the CLP Annex has entered into force), companies would have **three months to seek a derogation**.

The proposal further **streamlines the derogation criteria for those hazard classes**. First, it clarifies that a derogation may be granted for particular use of a product category with a known exposure if the latter is evaluated and found safe by the SCCS. Moreover, compliance with **food safety legislation** would no longer be taken into account. Still, documented analysis showing that **no suitable alternative** is available would be required.

The assessment of the **alternative's suitability** would include considerations on the risks, the equivalence of functions between the two substances, the technical feasibility and economic viability of the alternative and its availability.

Finally, the proposal foresees that **new products containing a prohibited substance** may be placed on the market within **12 months** after the entry into force of the classification. For products already on the market, the delay would extend to 24 months.

Framing of a Procedure for Including New Colourants, Preservatives and UV Filters in Annexes IV to VI

Article 14 of the Cosmetics Regulation conditions the use of colourants, preservatives and UV filters to their listing in Annexes IV to VI. The **procedure** to amend such annexes is, however, not formalised.

The proposed amendments formalise a procedure in that regard. A request to include the substance in one of the three annexes, accompanied by scientific evidence on the safety of the concerned substance, may be submitted to the commission. It is, however, unclear by whom the request would be submitted. Considering the broader context, this could refer to the person responsible for submitting the Cosmetic Product Safety Report (CPSR).

The commission would then seek the opinion of the SCCS, which would have **12 months** to issue it (the delay could be extended in a nonlimited manner).





Removal of the Prenotification Obligation for Nanomaterials

The proposal **departs from a so-far very cautious approach to nanomaterials.** It acknowledges that 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".

As a result, such products would **no longer be subject to a prenotification obligation** but only to the specific information requirements applicable to them within the CPSR.

Next Steps

The Chemicals Omnibus will be subject to **examination** by the European Parliament and the Council in the coming months. During this period, each institution may propose amendments to the text. In this regard, the months to come are key for any interested actor of the sector to **submit input** to the representatives of the two institutions.

We remain available, should you require any assistance in this regard or need any further clarification on the implications of the proposed amendments.

How We Can Help

Since the start of the new commission mandate in autumn 2024, there has been a firm push from Member States and members of the European Parliament, as well as stakeholders, in favour of administrative simplification. This has accelerated the pace of decision-making within the commission, the European Parliament and the Council. In this instance, day-to-day monitoring, intelligence gathering and analysis, as well as an understanding of the interaction between these institutions, is key to remaining on top of the pace of change.

The Chemicals Omnibus is only part of a broader evolution of the commission's regulatory approach. Additional initiatives may be expected beyond traditional chemicals legislation, including potential funding opportunities, oriented towards the reinforcement of the EU's competitiveness.

Our lawyers stand ready to assist you with any institutional engagement, as well as in identifying the threats and opportunities that may arise for your business in relation to the current and upcoming initiatives.

Contacts



Thomas DelillePartner, Brussels
T +32 2 627 1104
E thomas.delille@squirepb.com



Marie Escorneboueu
Associate, Brussels
T +32 2 627 7622
E marie.escorneboueu@squirepb.com