

HEAL analysis: European Commission proposals for a chemicals omnibus – Cosmetic products

On 8 July 2025, the European Commission adopted its legislative proposal for a sixth simplification omnibus (COM(2025)531), targeting three chemical files: the CLP Regulation (Regulation (EC) No 1272/2008), the Fertilising Products Regulation (Regulation (EU) 2019/1009) and the Cosmetic Products Regulation (Regulation (EC) No 1223/2009).

In this document, the Health and Environment Alliance (HEAL) summarises key human health issues of the European Commission omnibus proposal on the Cosmetic Products Regulation.

THE CURRENT RULES OF THE COSMETIC PRODUCTS REGULATION: GENERIC PROHIBITION TO USE CARCINOGENS AND OTHER HARMFUL SUBSTANCES

The use of CMR substances (carcinogenic, mutagenic, and reprotoxic substances) has been prohibited in cosmetics and personal care products since 2003. This prohibition currently applies one and a half years after the EU wide classification of a CMR substance has entered into force. In exceptional cases, derogations from these prohibitions can be obtained for clearly defined and limited conditions. This framework safeguards consumers who use cosmetics and personal care products on a daily basis against exposure to these types of harmful chemicals.

THE OMNIBUS PROPOSALS: WEAKENING THE PROTECTION AGAINST CMR SUBSTANCES

In the omnibus proposal, the European Commission includes several proposals that would allow the continued use of known carcinogens, mutagens and reprotoxic substances in cosmetics and personal care products.

Firstly, the Commission proposes to significantly extend the existing period until the prohibition of the use of a newly classified carcinogen, mutagen or reprotoxic substance applies. This would mean that cosmetic products containing a newly classified CMR substance would be allowed to be sold for nearly five years after the classification has entered into force, leading to significantly prolonged exposure of consumers to these harmful chemicals.

Secondly, the Commission proposes a new exemption for CMR substances whose hazard statements refer to oral or inhalation route of exposure. According to the CLP Regulation, such hazard statements can only be applied to a CMR substance when it is conclusively proven that no other routes of exposure cause the hazard. Instead of a general prohibition for these CMR substances, the omnibus proposal foresees that the Commission shall in the future request a safety assessment of these substances in 'specific products', which present the potential for accidental swallowing or inhalation (for example because they are used in the mouth). This proposed exemption disregards the fact that small children, who are already more vulnerable to CMR

substances due to their low body weights, are prone to accidentally swallow products used on them. They do so not only with products that are used in their mouths (e.g. toothpaste), but also with products used on their skin. This proposal would therefore increase the risk of serious health effects in children and other vulnerable groups by introducing a way to keep using some CMR substances in personal care products.

Thirdly, the Commission proposes a new generic exemption for CMR substances that are constituents of plant-based complex substances (e.g. essential oils). Instead of the currently applicable automatic prohibition of CMR constituents, the Commission proposes to initiate a substance-by-substance evaluation of complex plant-based substances 'if a potential risk to human health arises'. The proposal fails to consider that the exposure of consumers to all CMR substances must be avoided, whether as mono-constituent substances or complex substances and independently of the synthetic or natural origin of the substance. Additionally, the proposal does not clarify how a 'potential risk' is to be identified, and it lacks a legal timeframe for regulatory action. This proposal would at the very least delay the removal of CMR substances that are constituents of plant-based complex substances from cosmetics and personal care products, lowering the level of health protection for consumers.

Finally, the Commission proposes criteria to define when a substance can be considered a 'suitable alternative' to a CMR substance in a cosmetic product. The proposed criteria for alternatives are restrictive, demanding that an alternative must have the same level of efficacy as the CMR substance that is to be replaced, and that the alternative is economically viable. In the future, these restrictive criteria will likely make it difficult to demonstrate that safe and suitable alternatives exist for CMR substances and risk that considerations of economic aspects, such as costs of reformulation, impede or prevent the prohibition of CMR substances in cosmetics. This proposal prepares the grounds to allow the continued use of known CMR substances in cosmetics and personal care products, based on restrictive criteria for suitable alternatives.

Each of these proposals on the use of CMR substances in cosmetics and personal care products would lead to prolonged and avoidable exposure of consumers to chemicals with very serious health hazards. This would lower the current level of human health protection and undermine the trust of the EU citizens in the safety of cosmetics and personal care products.

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