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HEAL's comments on the evaluation of the Cosmetic Products Regulation

The Health and Environment Alliance (HEAL) welcomes the public consultation on the evaluation of the Cosmetic Products Regulation No 1223/2009 (CPR).

Cosmetics and personal care products are being used by consumers on a daily basis, commonly with several products in combination[1]. Users include also population groups with a higher vulnerability towards harmful chemical effects such as pregnant women, teenagers and children.[2] Due to the continuous lifelong exposure of people to cosmetic products, the CPR is critical to ensure a high level of health protection.

While we note a high relevance of certain provisions of the CPR, such as the prohibition to use carcinogens, mutagens and reprotoxic substances (CMR substances) in Article 15, we also see major gaps in the regulation that need to be closed to achieve its aim of ensuring a high-level human health protection. Our main concerns are the absence of provisions on the use of endocrine disruptors, the missing consideration of co-exposures and mixture effects in the chemical safety assessment, the lack of a precautionary approach in the chemical risk management under the CPR and the unlimited validity of substance approvals. We urge the European Commission to address these gaps, in line with the commitments made under the Chemical Strategy for Sustainability for a stronger EU legal framework to address pressing environmental and health concerns.
Furthermore, we note that a revision of the CPR should be seen as a modernisation opportunity in line with the spirit of 'One Substance One Assessment' to align the CPR with other EU chemical legislations by introducing the aim of a high level of environmental protection and making use of organisational and procedural synergies by integrating the Scientific Committee on Consumer Safety (SCCS) into ECHA alongside its existing committees.

We have summarized our concerns and recommendations for a revision of the CPR below:

[1] Ficheux, A. S., Wesolek, N., Chevillotte, G., & Roudot, A. C. (2015). Consumption of cosmetic products by the French population. First part: frequency data. *Food and Chemical Toxicology*, *78*, 159-169.
[2] Marie, C., Garlantézec, R., Béranger, R., & Ficheux, A. S. (2022). Use of cosmetic products in pregnant and breastfeeding women and young children: guidelines for interventions during the perinatal period from the French National College of midwives. *Journal of Midwifery & Women's Health*, *67*, S99-S112.

1. Ensuring health protection from endocrine disruptors

It is essential that the current provisions on the prohibition of CMR substances in Article 15 are extended to substances classified as endocrine disruptors.

Endocrine disruption has recognised as a hazard class in the EU CLP Regulation, aligning the identification and classification of this hazard. Like CMRs, endocrine disruptors are associated with severe and irreversible damage to human health and the environment and have the potential to affect future generations[3]. Endocrine disruptors can act at extremely low levels and can have a significant impact, making the concept of a threshold inappropriate for endocrine disruptors[4]. Additionally, transient effects occurring during critical development periods that rely heavily on hormone signalling – such as specific time points during pregnancy, mini-puberty, and puberty – can lead to delayed effects later in life[5]. As also highlighted in our submission during the Call for Evidence earlier this year, today several care products and cosmetics on the EU market contain endocrine disruptors[6] [7]. Extending Article 15 provisions to endocrine disruptors would provide a fast and simple measure to close this gap in the level of protection of human health.

2. Addressing mixture effects from the co-exposure to chemicals

The provisions on the safety assessment of cosmetic ingredients should be updated to consider the cocktail effects of chemicals that consumers are simultaneously exposed to.

Data on the use patterns of cosmetics and personal care products shows that consumers are commonly using several products that fall within the scope of the CPR[8]. Additionally, citizens are in contact with various other products and commodities daily (e.g. drinking water, food contact materials, toys, electronics etc.). Human biomonitoring data shows that Europeans are exposed to complex mixtures of chemicals from these diverse sources[9][10]. However, currently the CPR does not address the combined effects of chemicals in mixtures in the safety assessments. In line with the call from 250 scientists for the consideration of mixture effects in REACH[11], we urge the European Commission to include provisions on the effects of chemical mixtures from (unintended) co-exposure of chemicals in the safety assessment under the CPR.

3. Taking precautionary measures for substances without conclusive evidence on safety

The precautionary principle should be integrated and applied in the CPR, to ensure that the risks of those substances without conclusive evidence for their safety can be managed.

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[3] Gore, A. C., Chappell, V. A., Fenton, S. E., Flaws, J. A., Nadal, A., Prins, G. S., ... & Zoeller, R. T. (2015). EDC-2: the endocrine society's second scientific statement on endocrine-disrupting chemicals. Endocrine reviews, 36(6), E1-E150.

[4] Endocrine Society (2025) "Endocrine-disrupting chemicals in the European Union": https://www.endocrine.org/ /media/endocrine/files/advocacy/position-statement/position_statement_endocrine_disrupting_chemicals_2025.pdf

[5] Svingen, T., Andersson, A. M., Angelova, J., Axelstad, M., Bakker, J., Baumann, L., ... & van Duursen, M. (2024). Enhanced identification of endocrine disruptors through integration of science-based regulatory practices and innovative methodologies: The MERLON Project. Open Research Europe, 4, 68.

[6] Chemistry tests conducted by the Danish Consumer Council Think (Forbrugerrådet Tænk)

[7] Chemistry tests conducted by Erase All Toxins (Tegengif)

[8] Ficheux, A. S., Gomez-Berrada, M. P., Roudot, A. C., & Ferret, P. J. (2019). Consumption and exposure to finished cosmetic products: A systematic review. Food and chemical toxicology, 124, 280-299.

[9] Husøy, T., Andreassen, M., Hjertholm, H., Carlsen, M. H., Norberg, N., Sprong, C., Papadopoulou, E., Sakhi, A.K., Sabaredzovic, A. & Dirven, H. A. A. M. (2019). The Norwegian biomonitoring study from the EU project EuroMix: Levels of phenols and phthalates in 24-hour urine samples and exposure sources from food and personal care products. Environment International, 132, 105103.

[10] Thépaut, E., Dirven, H. A. A. M., Haug, L. S., Lindeman, B., Poothong, S., Andreassen, M., Hjertholm, H. & Husøy, T. (2021). Per-and polyfluoroalkyl substances in serum and associations with food consumption and use of personal care products in the Norwegian biomonitoring study from the EU project EuroMix. Environmental Research, 195, 110795.

[11] Letter to the European Commission (2025)

Currently, the regulatory management of substances with known safety concerns for which the SCCS cannot reach a clear decision is insufficient and leads to the prolonged exposures of users. A lack of conclusive information about the safety of a substance must not lead to its unrestricted use with potentially negative consequences for exposed people. Therefore, we strongly recommend the uptake of the precautionary principle into the CPR.

4. Mandating regular reviews of approvals for preservatives, colorants and UV filters

The approvals of preservatives, colorants and UV filters should be subject to regular updates to ensure that new information is taken into account, and obsolete entries are swiftly removed.

Currently, the lists of approved preservatives, colorants and UV filters in Annexes III-VI are not regularly reviewed in an automated manner. This risks that new information on approved cosmetic ingredients is not considered and leads to the presence of several chemicals on the lists that are not registered under REACH anymore: For example, a third of approved cosmetics preservatives of environmental concern is not REACH-registered[12]. Regular reviews of the substance approvals would address these issues.

5. Aligning the CPR with other EU chemical legislations

The modernisation of the CPR should aim at aligning the regulation with provisions in adjacent chemical legislations, such as REACH ((EC) No 1907/2006), the Biocidal Products Regulation ((EU) No 528/2012) and the Detergents Regulation ((EC) No 648/2004), regarding the aim of ensuring a high level of environmental protection with a true One Health perspective.

While the above-mentioned chemical legislations aim at protecting the environment alongside human health, the CPR lacks a similar aim of environmental protection. This situation leads to unregulated environmental risks and to the diverging assessments of substances and thus contradicts the 'One Substance One Assessment' efforts that are currently being undertaken horizontally as well as the One Health approach. Two examples for this misalignment are the assessment and regulatory management of preservatives and surfactants in cosmetic products. More than half of the approved cosmetic preservatives are of environmental concern[11], which leads to situation that a substance that is hazardous for the environment can be approved as a preservative in cosmetics, but at the same time the same substance is not approved for use in biocidal products[13]. Likewise, surfactants used in detergents have to meet biodegradation requirements to ensure a high level of protection for the aquatic environment, while the environmental effects are not considered for surfactants used in cosmetic products. Apart from the regulatory mismatch, the lack of environmental risk assessment and risk management in the CPR is problematic as substances are being released to the environment for example via wastewater[14].

To further align the existing organisational structures on industrial chemicals, the SCCS should be integrated into ECHA alongside the committees that are already facilitated there (e.g. RAC). This would improve communication between the communities and with stakeholders and create synergies for example in the day-to-day secretariat work of the committee.

[12] Kättström, D., Beronius, A., Boije af Gennäs, U., Rudén, C., & Ågerstrand, M. (2024). Out of REACH: Environmental hazards of cosmetic preservatives. Human and Ecological Risk Assessment: An International Journal, 30(1-2), 122-137.

[13] Kättström, D., Beronius, A., Rudén, C., & Ågerstrand, M. (2022). Stricter regulation applies to antimicrobial substances when used as biocides compared to cosmetics under current EU legislation. Emerging Contaminants, 8, 229-242.

[14] Wieck, S., Olsson, O., & Kümmerer, K. (2016). Possible underestimations of risks for the environment due to unregulated emissions of biocides from households to wastewater. *Environment international*, *94*, 695-705.

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