Proposal for a "Chemicals Omnibus"
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L'Oréal strongly supports the new proposal for a Chemicals Omnibus, and in particular the proposed changes to Article 15 of the Cosmetic Products Regulation – CPR (Regulation 1223/2009). The proposal clarifies the procedure to continue using substances which are classified as CMRs (Carcinogenic, Mutagenic, or Toxic for Reproduction) under the Classification, Packaging and Labelling (CLP) Regulation **when they can still be safely used in cosmetic products**.

The proposed changes will allow industry to continue using safe, effective, and often natural ingredients in cosmetic products, driving innovation and consumer choice. And for consumers, it ensures products remain "safer than safe" by focusing on rigorous, real-world safety assessments, preventing unnecessary bans of safe products, without compromising health. Regarding the proposed changes to Article 16, we welcome the removal of pre-notification requirements for products with nanomaterials, but we ask to remove the proposed modification of Annex I, which is already complete, and instead, to clarify that the Commission can initiate ingredient evaluations for new nanomaterials as needed.

Why we support the new Article 15 as proposed in the Chemicals Omnibus

- **While the use of CMR 1 substances in cosmetics continues to be banned, the proposed text clarifies the procedure to obtain a derogation once a substance is classified as a CMR 1.** It does so in two ways: 1) the proposal more clearly defines what make an alternative "suitable" and 2) the additional criterion of "safe use in food" is removed because it's not scientifically relevant for cosmetics, which are mainly applied to the skin and not eaten. Under the proposed regime, a derogation could therefore be granted if a) there are no suitable alternatives based on objective criteria, b) the derogation is requested for a specific use or product, c) the substance has been evaluated safe by the Scientific Committee for Consumers Safety (SCCS) – a group of independent scientific experts providing opinions to the Commission on the health and safety risks of non-food consumer products and services.
- **Under the Commission's proposal, if CLP indicates that a substance is classified as a CMR1 only when humans are exposed to it through ingestion or** inhalation (i.e. only because of how it might harm us if we eat it or breathe it in), **it will no longer be automatically banned for use in cosmetics. This is because these are not the ways one is exposed to cosmetics, which are applied on the skin. In this case, the European Commission could still ask the SCCS to give an opinion on the use of this substance in cosmetics, if it has concerns.** This change simplifies the process in those (rare) cases where a CMR is only classified for a specific route of exposure (e.g., if ethanol is only classified as a CMR when ingested).
- If a natural ingredient which is a multi-constituent ingredient (like an essential oil) contains a constituent classified as a CMR 1 (e.g. P-cymene), the natural ingredient

will no longer be automatically banned. Instead, the Commission will ask the SCCS for their expert opinion on whether the specific constituent is safe for use in cosmetics.
- The Commission's proposal makes the previous deadlines for reformulating products more reasonable and adds "transition periods" to remove products from the market, without unnecessary constraints on manufacturing and supply chains and impact on safety.

These changes make the process for cosmetic products "safer than safe," because their safety is checked by both a product safety assessment and opinions from the SCCS.

Why was this proposal necessary?

While the Cosmetic Products Regulation foresees a derogation procedure to continue using certain substances classified as CMR 1 in a safe way, when this is scientifically proven to be possible, no derogation has so far been granted. In the first 12 years of application of the Cosmetic Products Regulation, i.e. since 2011, only two substances were considered for a derogation. Both requests were ultimately denied, even though the SCCS concluded that those two substances could be safely used in certain types of cosmetics. As in the last 18 months, 13 ingredients that are safely used in cosmetics have been identified as CMR 1, we are concerned that if the rules are not clarified these situations will reoccur. Furthermore, the European Chemicals Agency (ECHA), which manages for these classifications, is now often looking at whole groups of substances instead of individual ones which makes the analysis leading to the classification less granular and its impact disproportionate. ECHA recommends also taking the most cautious approach when looking at scientific information, which could mean that a large number of substances could end up being classified as CMRs.

The base rule of the Cosmetic Products Regulation (CPR) is that all cosmetic products placed on the European Union market must be safe. Substances that are classified as CMRs under the Classification, Packaging and Labelling (CLP) Regulation cannot be used in cosmetics, unless specific conditions are met. As a reminder, the main aim of the CLP is to have a common way to label chemicals based on their hazardous profile so that people, and in particular workers in specific circumstances, know how to deal with them. This classification is based on the hazardous profile of a substance, i.e. its potential to cause harm, regardless of how much of the substance is used, or how it comes into contact with humans. The fact that a substance is classified as hazardous under the CLP doesn't mean that its use is dangerous for humans in all circumstances.

As more and more substances, including natural ingredients, are being classified as CMR1, but can still be used safely in cosmetics, the derogation regime, as currently written in the CPR, is no longer fit for purpose.

What is the current regime in Article 15 of the CPR?

If a substance (whether natural or synthetic) is officially classified as a CMR1, it is automatically banned. Industry can ask for a derogation if all of the following conditions apply:

- The substance can be safely used in food.
- There are no suitable alternatives available.
- The derogation is requested for a specific use or product.
- The substance has been evaluated safe by the Scientific Committee for Consumers Safety (SCCS) – a group of independent scientific experts providing opinions to the Commission on the health and safety risks of non-food consumer products and services.

The idea behind this risk-based derogation system was to help in situations where substances were classified as hazardous under the CLP Regulation, but could still be safely used in cosmetics. However, it hasn't worked well in practice because:

- The "food criterion" (whether it's safe in food) isn't relevant for cosmetics, which are mostly applied to the skin or hair, not eaten.
- It is not clear what a suitable alternative could be.
- The process to define what a suitable alternative is as well as to decide more broadly if a derogation can be granted isn't transparent.

As an extreme, but entirely realistic example, under the current regime a natural ingredient (which contains several constituents), like an essential oil, could be banned if it contains just only one constituent classified as a CMR1. For example, P-cymene, a substance found in all citrus fruits, could in the future be classified as a CMR1. This would mean that the essential oils derived by citrus fruits could be banned for use in cosmetics, while obviously we would continue to peel and eat the whole fruit.

As a further concern, the current rules demand that companies not only stop placing certain products on the market but also withdraw products, even when there is no immediate safety concern. This puts great and largely unnecessary constraints on manufacturing and supply chains, and demands the destruction of large amounts of products (e.g. when Lilial® was banned, EU cosmetic companies, especially smaller ones, struggled to remove products in time).

This is why it's so important to make the derogation process in Article 15 clearer, more predictable and more straightforward.

Article 16 as proposed in the Chemicals Omnibus and suggested modifications

Currently, Article 16 requires a separate pre-notification of products containing nanomaterials and a safety dossier for the nano ingredient, which duplicates the product notification under Article 13. This process can also trigger time-consuming SCCS reviews, often exceeding the foreseen six-month period.

The 'Omnibus proposal' aims to streamline procedures by suggesting the deletion of pre-notification requirements in paragraphs 3 and 7 of Article 16. However, it concurrently proposes a modification to Annex I, introducing new reporting requirements in paragraph 2.

We support the deletion of paragraphs 3 and 7 in Article 16.

We also call for the deletion of the last two paragraphs of Annex II of the proposal where it modifies Annex I of the CPR in force. These two paragraphs read:

"The specification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the preamble to Annexes II to VI, size of particles, physical and chemical properties.

The safety data of the nanomaterial (including its toxicological profile and exposure conditions) relating to the category of cosmetic product, as used in such products."

These paragraphs are highly problematic as these proposed additions would:

1. **Introduce significant and unnecessary administrative burden:** The current proposal mandates additional documentation within Annex I for aspects that are already adequately covered elsewhere, namely in paragraph 6 and 8. This creates a redundant layer of paperwork without enhancing safety or efficiency.
2. **Duplicate existing robust assessments:** Specifically, regarding nanomaterials, the safety assessor is already comprehensively tasked with evaluating all relevant aspects. Adding further requirements to Annex I, paragraph 2, would simply replicate an assessment process already in place, leading to inefficiency and increased workload without added benefit.
3. **Contradict the stated goal of streamlining:** Far from simplifying processes, these new requirements would complicate documentation and increase compliance costs for economic operators, directly undermining the stated objective of the 'Omnibus proposal' to rationalize and streamline the regulatory framework.

Removing these requirements in Article 16 and not adding new requirements in Annex I would avoid reporting twice the same information, streamline processes without compromising safety, as robust review mechanisms remain in place.

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