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REVISION AHEAD!

Regulations | A hot topic for cosmetics, the revision of the European Cosmetic Regulation (EC) No 1223/2009 is coming. Driven by the European Green Deal and the Chemical Strategy for Sustainability (CSS), its impact is expected to be significant. Caroline Bassoni shows the related concepts, associated risks but also some opportunities.

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A regulatory cross sectorial new approach is under development in Europe, under the umbrella of the **European Green Deal** for an environment free of toxic substances, the **Chemical Strategy for Sustainability** (CSS) was adopted in October 2020 and will ultimately impact the cosmetic product regulation. This strategy has a dual objective:

- On the one hand, ensure better protection of human health and the environment with regards to hazardous chemicals.
- On the other hand, stimulate innovation for safe and sustainable chemical products, starting from the design phase, also named as a principle of "safe and sustainable by design".

Achieving these objectives will inevitably lead to changes in **Reach** and **CLP regulations** and implies the revision of many sectorial regulations, including the **EU Cosmetics Regulation**. For cosmetics, this revision process started in October 2021 with the consultation on the roadmap and since March 2022 various consultations have been opened on the targeted revision of the cosmetics regulation N°1223/2009 and its associated impact.

Chemical strategy

More concretely, the **revision of the Cosmetic Product Regulation** targets five points to implement the goals of the chemical strategy:

The **automatic prohibition of the most harmful substances** unless their use is considered "essential": This is a shift from a risk assessment approach to a hazard-based approach that is not relevant from a scientific point of view. Indeed, such concepts do not consider the actual use and exposure for the consumer. This

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point also questions how the essentiality criteria will be defined and how it can be defended for cosmetic products substances and usage. While cosmetic companies do have arguments, this may diverge from the perspective of the public opinion.

The **consideration of combined effects** from daily exposure to a large mixture of chemicals from different sources and related risk this represents for human health and for the environment: Also known as the "cocktail effect", this concept of Mixture Assessment Factor (MAF) generates much uncertainty as to how it will be considered. It should be noted that safety assessors already apply safety margins in their risk assessment to protect consumers. The challenge for the cosmetic industry is to defend a scientific approach relevant to the real risk to which consumers are exposed.

Changes related to the governance of the SCCS, the scientific committee that assess substances used in cosmetics: This would imply a rationalisation of the scientific evaluation agencies within ECHA to improve the efficiency and coherence of the safety evaluation of cross legislations. There is a real risk of losing the current independence and the recognised cosmetic expertise of the SCCS and this would again be detrimental to a real and relevant risk assessment for consumers.

The **revision of the definition of nanomaterials** to ensure consistency between the various cross-sectorial regulations: This will bring some clarity expected by all actors of the cosmetic sector – even if the new definition would requalify some raw materials and lead to potential restrictions, bans or the need to update safety assessments, labelling and CPNP notification. This harmonisation should however help to stop diverging local interpretations that exist currently in some countries and that do not favour the free movement of goods in Europe.

Here, the point to monitor will be the relevance of the criteria selected for this new definition and any related interpretation aspects. In addition, the management of nanomaterials in cosmetics will have to be redefined with a clarified and achievable process.

The **improvement of the information provided to the consumer** with the option of a digital labelling: This constitutes an opening for the possible dematerialisation of certain information, which is more than welcomed to stop overloaded and non-readable labels and to ensure clear communication with real time updates to consumers. This opportunity is essential in a regulatory context that requires more and more information to be made available to consumers.

This digitalisation will also contribute to the green transition by limiting the size and frequency of packaging renewal. Finally, it will also allow the authorities easier access to data as part of their market surveillance mission. The point of vigilance that the cosmetic industry is relaying is that the transition should be progressive and that the modalities should ensure flexibility in the dematerialisation tools. Indeed, digitalisation constitutes a completely new approach for consumers and manufacturers that will require a phase to adapt practices on both sides.

The revision of the Cosmetic Product Regulation was launched last March with three simultaneous actions by the European Commission:

- The public consultation on the roadmap where all the actors of the sector were able to express their views on the different parts of the regulation subject to revision.
- A targeted consultation for stakeholders, with a more comprehensive and technical questionnaire covering scientific expertise and socio-economic impact studies on the various changes considered.
- Finally, targeted interviews with a representative panel of several companies.

In parallel, several workshops have been held on the horizontal concepts such as "one substance, one assessment" or "essential use", as a forum opportunity for the various stakeholders to share perspectives on those new concepts under consideration.

Conclusion

We can clearly see that the revision of the cosmetic product regulation is part of an overall objective to protect consumers and the environment. The associated intention is certainly laudable, but the risk is the application of a strict precautionary principle in a political context where pressure from NGOs and consumers is extremely strong and often associated with unrealistic fears. In the end, all of this could lead to regrettable future restrictions or bans on raw materials that are not relevant in terms of science.

We also note an **unprecedented complexity** with transversal legislations reviewed in parallel with high ambitions and very stretched timing.

Nevertheless, **opportunities are emerging** with some openness on the digitisation of labels, the harmonisation of the definition of nanomaterials, and ultimately a framework that should avoid certain national divergences that we have seen to date.

To sum up, a revision of the Cosmetic Regulation that even if targeted will significantly impact the cosmetic sector and an essential question for all: how to maintain European innovation in this framework?

We can expect quite an intense regulatory debate over the coming months, with key next milestones for the analysis of the various consultations and a proposal for the revision of the cosmetic product regulation expected by the end of the year by the European Commission. □