

12 Sep 2023 | Interviews

'Fully Caffeinated' Or Not, EU's Revision Of Cosmetic Products Regulation In Doubt Before 2024 Elections

by Ryan Nelson

The European Commission's proposal for revising the EU's regulation on cosmetic products is likely to release in the 2023 fourth quarter as a "caffeinated or slightly decaffeinated" distillation of the Chemicals Strategy for Sustainability, Cosmetics Europe director-general John Chave says. Prospects for the proposed regulation are questionable in light of EU elections slated for June 2024.

Cosmetics Europe expects some dose of the Chemicals Strategy for Sustainability (CSS) to be stirred into the European Commission's proposal for revising the Cosmetic Products Regulation (CPR), likely publishing within the next few months.

"We know, basically, the ideas that are going to go into CPR. But we're unclear exactly where the needle will fall in terms of a fully caffeinated or slightly decaffeinated version of the <u>CSS</u> finding its way into the CPL framework," Cosmetics Europe director-general John Chave said in a 5 September interview.

Generally, the trade group expects the CSS' generic risk management approach (GRA) to be reflected in the Commission's CPR proposal. Many industry stakeholders consider GRA a misnomer in that it threatens to dispense with exposure-based risk considerations in deference to hazard evidence.

The Commission's proposal also is likely to pay homage to the "one substance, one assessment" vision represented in the CSS for managing chemicals safety across EU sectors, laws and institutions, which industry has criticized for similar reasons, namely the seeming deemphasis on risk analysis in favor of blind hazard avoidance. (Also see "*EU's Planned Revision Of Cosmetics Regulation Makes For Uneasy Global Industry*" - HBW Insight, 15 Nov, 2021.)

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Also, "We've anticipated for a long time that this concept of essentiality, which is possibly the single most controversial part of a crowded field of controversial concepts in the CSS, probably will need to find its way into considerations around the Cosmetics Products Regulation," Chave said.

The CSS describes an EU system in which the "most harmful" chemicals are allowed – "in particular in consumer products" – only if their use is necessary for health or safety or is critical for the functioning of society and acceptable alternatives do not exist. According to the strategy, "Extending the generic approach will ensure that consumers, vulnerable groups, and the natural environment are more consistently protected, while still allowing for the use of these most harmful chemicals where proven essential for society [italics added]."

"We don't know exactly how that will be applied," Chave said. (Also see "<u>Cosmetics Europe Says EU's 'Radical' Regulatory Drift Sends Concerning Signal To World</u>" - HBW Insight, 6 Dec, 2021.)

In its *comments* submitted to the Commission, Cosmetics Europe says the unintended consequences of GRA, essentiality and other concepts included in the proposed CPR revision "will have a significant impact on ingredients across companies' portfolios, leading to the reformulation of potentially hundreds of thousands of cosmetic products or even their complete disappearance."

According to Chave, the Commission's proposal for revising the CPR was delayed, but recently cleared the Commission's regulatory scrutiny process through the Directorates-General. Cosmetics Europe now expects the proposal to be adopted by the Commission and published before yearend.

Key Takeaways

- GRA, "one substance, one assessment," and "essentiality" are likely to be incorporated to some extent or another in the Commission's proposal for a revised Cosmetic Products Regulation.
- Cosmetics Europe fears those concepts could lead unintentionally to hundreds of thousands of cosmetic products having to be reformulated "or even their complete disappearance."
- The initiative stands to roll over into the next institutional mandate where European Parliament and the political climate could be different.

"This is where it gets slightly bizarre.

Because of the delay, the proposal is going to run now into the last phase of the institutional mandate," Chave said.

The EU will elect Members of the European Parliament (MEPs) in June 2024. MEPs will form

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political groups and elect a president, as well as a new president of the European Commission. Next they will examine and approve the entire College of Commissioners.

"It's not entirely clear, therefore, what will happen. We know that there will be a proposal in public, and the proposal will be discussed and analyzed. How far it will get down the road to actual adoption into law is open to question. It's very likely it will just roll over into the next institutional mandate of the European Union," Chave said.

He added, "Then of course you'll have a potentially different complexion of the European Parliament. We don't know quite how that will play out. We already know that one of the individuals who was a main mover behind the European Green Deal, the Dutch vice president [Frans] Timmermans, has resigned from the Commission and gone back to Dutch domestic politics. There may be other changes and, again, it's difficult to predict with any certainty how that will affect the political climate around some of these more controversial measures the European Commission has pushed forward."

He said the EU's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation is in a similar state of uncertainty with regard to planned revisions pursuant to the EU Green Deal and CSS. (Also see "*EU Reg Consultant On CLP Revisions: Take A Breath, Cost It Out, Consider 'Lobbying And Pushing Back'*" - HBW Insight, 19 Dec, 2022.)

Regular Or Decaf?

Industry has not yet seen a draft legal text for the revised CPR. The Commission has garnered feedback on an *Inception Impact Assessment* that sets forth a framework of ideas it aims to implement.

"At some point that needs to be translated into a legal proposal. And as anybody who works in the legal or policy field knows, then it can get tricky because words matter. Emphases matter, nuances matter," Chave said.

Depending on how it is sliced, "will we get the fully caffeinated CSS with a wide range of substances caught up and subject to the generic risk approach, with all the potential consequences for restrictions and bans for our ingredients? Or will we get a relatively narrow group of ingredients? Will essentiality be left as something just slightly soft on the margins to bear in mind, or will it be absorbed as a core regulatory concept? I suspect more the former, but we don't know for sure," Chave added.

Chave said he was certain of one thing: The Scientific Committee on Consumer Safety, which currently provides cosmetic ingredient safety opinions to the Commission from its seat in Luxembourg, will be brought into the European Chemicals Agency.

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JOHN CHAVE, DIRECTOR-GENERAL AT COSMETICS EUROPE

"The open question is what form it will take, whether it will be really just a change of institutional setting – so instead of sitting out there in Luxembourg, the same experts essentially come together and sit in Helsinki and do the same sort of stuff they were doing before within the same sort of regulatory and professional parameters – or whether it will become a more ECHA-like committee with a potential shift towards, for example, a more hazard-based or more precautionary approach," Chave said.

Overall, Cosmetics Europe's director-general believes the proposed Cosmetic Products Regulation will have a precautionary tilt and that a greater number of cosmetic ingredients – eg, deemed endocrine disruptors – will be subject to a GRA approach similar to the existing framework for carcinogenic, mutagenic

and reprotoxic (CMR) substances under Article 15 of the CPR, which can entail automatic bans. Whether some portion of targeted substances under the revised regulation would be eligible for scientific review to determine if they can be used safely in cosmetic products, as certain CMR categories currently are reviewed by the SCCS, remains to be seen. (Also see "*EU Reg Consultant On CLP Revisions: Take A Breath, Cost It Out, Consider 'Lobbying And Pushing Back'*" - HBW Insight, 19 Dec, 2022.)

Chave noted, "Our point has always been that automatic bans on a hazard basis is unscientific – which it is. It's difficult to argue the other way. So I always point out that the general issue we're concerned about is safety, and safety trumps any considerations around essentiality. But if safety is your central concept, then that implies that you should be given the opportunity to defend ingredients."