Personal Care Products Council
Committed to Safety, Quality & Innovation

Personal Care Products Council Input to the EU's Cosmetic Product Regulation Inception Impact Assessment

On behalf of the Personal Care Products Council[1] we are pleased to provide our input to the Cosmetic Product Regulation Inception Impact Assessment.

As noted by the European Commission[2], the European Union and the United States have the largest bilateral trade and investment relationship, and our economies are the most integrated, of any in the world. U.S. cosmetic and personal care products manufacturers have invested heavily in manufacturing and other operations in the EU and U.S.-EU trade in cosmetic and personal care products exceeded $10.5 billion in 2019, contributing to the strength of industries on both sides of the Atlantic.

The European Cosmetics Regulation EC 1223/2009 ("CPR") and the US Food Drugs & Cosmetics Act are based on common regulatory principles and practices. PCPC regularly collaborates with our sister association Cosmetics Europe in advocating in favor of our common regulatory model vis-à-vis third countries that are considering reforming their cosmetics framework.

Maintaining alignment of US and EU cosmetics regulatory approaches will support continued two-way trade and investment in cosmetics and personal care products and will contribute to the strength and global competitiveness of industry on both sides of the Atlantic. However, in our view, certain policies that are being considered in the CPR Inception Impact Assessment could result in longstanding and intractable Technical Barriers to Trade that would be incompatible with the EU's commitments in the World Trade Organization. It is with a view toward these interests that we submit the following initial thoughts and concerns on the targeted revision of the CPR.

Generic Risk Management Approach

PCPC and our members share the Commission's goals of preserving the environment and reversing climate change; we welcome the objectives and vision of the European Green Deal and the Chemicals Strategy for Sustainability. However, we are concerned that, as presently drafted, the

[1] Based in Washington, D.C., PCPC is the leading U.S. national trade association representing global cosmetics and personal care products companies. Founded in 1894, PCPC's approximately 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. Our members include companies that export to and/or manufacture products in EU countries. As the makers of a diverse range of products millions of consumers rely on and trust every day – from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance – personal care products companies are global leaders committed to product safety, quality, and innovation.

[2] https://ec.europa.eu/trade/policy/countries-and-regions/countries/united-states/

1620 L Street, N.W., Suite 1200 | Washington, D.C. 20036 | 202.331.1770 | 202.331.1969 (fax) | www.personalcarecouncil.org

concept of a generic risk management approach ("GRA") framework could be implemented as a purely hazard-based approach that would undermine the risk-based approach, and indeed the fundamental principles of toxicology on which cosmetics regulations in the U.S. and EU are currently based.

Indiscriminate application of GRA to the CPR would lead to unwarranted reformulations and extra costs for industry without attendant benefits to consumers or the environment. Such an application of GRA could result in a ban on ingredients that have been commonly and safely used for thousands of years. As an illustrative example, we offer lavender and alcohol which are likely to be subject to bans. This would result in fragmented supply chains and disproportionately affect US SMEs that may not be able to maintain separate supply chains for the EU market.

Overall, we have serious concerns that the application of GRA to the CPR loses sight of the goal of CPR which is to ensure safe products. The GRA would function as a de facto sorting/ banning mechanism which does not take account of whether an ingredient would be safe for the intended purpose. While we understand GRA is intended to harmonize regulator approaches across various sectors under chemical management, we urge the Commission to acknowledge the preeminence of risk demonstrated safety in determining the suitability of a particular substance for use in cosmetic products. GRA should be limited to cases where such safety demonstration cannot be achieved, and the Regulation should continue to provide a derogation mechanism that would allow companies to demonstrate the safety of the ingredient as regards the environment and consumers.

We have concerns regarding the concept of "essentiality" as this is applied to GRA within the CSS. The characterization of a product as being critical for the functioning of society is a normative judgement and would necessarily entail biases. Cosmetic and personal care products, for example, have been demonstrated to contribute to overall hygiene, well-being, and improved self-esteem, which can only be appreciated subjectively.

Therefore, we suggest for purposes of the Cosmetic Products Regulation, 'essentiality' should, instead, be linked to the non-availability of suitable alternatives for the use or function of a substance within the specific application.

One Substance One Assessment

As we understand it, the "One Substance, One Assessment" policy relates to the hazard portion of chemicals management. A complete set of hazard data would be developed for each substance. In turn, this hazard data set would offer a common starting point for risk-based, sector-specific, regulation. In this regard, we see the policy tittle as a slight misnomer because a substance cannot be assessed once for all uses; different uses entail different exposure routes and therefore have different risk profiles. For example, ethyl alcohol protects human health when used as an active ingredient in hand sanitizers but may be judged detrimental to health when considering other exposure routes i.e., when imbibed excessively within alcoholic beverages.

1620 L Street, N.W., Suite 1200 | Washington, D.C. 20036 | 202.331.1770 | 202.331.1969 (fax) | www.personalcarecouncil.org

We would like to draw attention to the potential impact of the One Substance One Assessment policy on the CPR's animal test ban, and encourage the Commission to give consideration to specific provisions that may be necessary to accommodate those requirements.

As European policy makers consider the future of risk management for the cosmetics sector, we would be remiss if we did not highlight that the Scientific Committee on Consumer Safety has developed over 40 years of sector-specific experience and expertise in matters related to cosmetic and personal care product safety which is virtually unique. We hope that any future arrangement leverages the SCCS and maintains the principles and functions of the Committee as these have proven to be effective and efficient in safeguarding consumer protection.

Nanomaterials

We understand the differences between the definitions of nanomaterials in the CPR and the horizontal JRC definition may have caused confusion and discrepancies in how products are treated in different EU Member States. As such, we are supportive of the alignment of the definition of nanomaterials in the CRP with the JRC definition.

However, we would like to underscore that most regulatory authorities around the world, including the U.S. Food & Drug Administration, agree that nanomaterials are not inherently safe or unsafe.[3] The size of an ingredient, like all other ingredient properties, must be taken into consideration during the safety assessment process, and in light of the ingredient's intended use. In this way, nanomaterials do not inherently differ from any other cosmetic ingredient.

Digital Labeling

Our industry is committed to transparency and integrity in our communications with consumers and to providing clear and accurate information that enables them to make informed purchases. We believe that digitalization of labeling is a future-proof solution to a pragmatic problem. On one hand, cosmetic brand owners must contend with the reality of small packages; preserving pleasing artwork and design, and commitments to reduce packaging and packaging waste in support of environmental goals. At the same time, requirements for additional information to be included in product labeling, as well as consumers' growing interest in detailed information about product formulas, challenge those objectives. Beyond being a promising solution to labeling constraints, digitalization will offer industry the opportunity to rapidly and cost-effectively update information as needed.

Given that 447 million EU citizens, 86% of the EU population, have access to mobile phones,[4] digitalization of labeling will offer the overwhelming majority of consumers access to additional

[3] http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm301114.htm
[4] https://www.gsma.com/mobileeconomy/europe/

1620 L Street, N.W., Suite 1200 | Washington, D.C. 20036 | 202.331.1770 | 202.331.1969 (fax) | www.personalcarecouncil.org

information that would no longer be required on the package. We strongly support the proposed revisions in this area.

However, we would like to draw your attention to an important policy consideration, namely, that cosmetic product labeling must remain relevant to the product category. As such, we strongly oppose a link between the digitalization of cosmetic product labels and the initiative related to the 'digitalization & simplification of chemical labels' within CLP. CLP pictograms such as the environmental hazard pictogram, "dead fish", is not pertinent to cosmetics and would therefore send contradicting messages to consumers. For example, in the case of a shampoo, a consumer may wonder how to avoid getting a product that is intended to be rinsed off, from reaching the water ways.

Conclusion

Thank you for taking the time to consider the issues that we have raised in this letter. We remain at your disposal for any further information and look forward to participating in future consultations related to the review of the CPR.

Sincerely

Francine Lamoriello
Executive Vice-President
Lamoriellof@personalcarecouncil.org

1620 L Street, N.W., Suite 1200 | Washington, D.C. 20036 | 202.331.1770 | 202.331.1969 (fax) | www.personalcarecouncil.org