COSMETICS EUROPE

COMMENTS TO INCEPTION IMPACT ASSESSMENT ON THE REVISION OF THE COSMETIC PRODUCTS REGULATION

Introduction

Cosmetics Europe welcomes the opportunity to respond to the Inception Impact Assessment on the Revision of the Cosmetic Products Regulation ("CPR") and as a constructive stakeholder looks forward to contributing throughout the revision process.

Cosmetics Europe represents the cosmetics and personal care industry in Europe. Ranging from dermo cosmetics, antiperspirants, fragrances, make-up and shampoos, to soaps, sunscreens and toothpastes, cosmetics and personal care products play an essential role for quality of life, health, hygiene and well-being, self-esteem and social interaction in all stages of life. Our industry provides choice for all consumers whoever they are, wherever they are from, whatever their needs. Across Europe there are more than 6000 SMEs in our sector. The European cosmetics industry is the biggest in the world, valued at 76.7 billion € in 2020 and providing around 2 million jobs in Europe. Our industry is the largest global exporter, with an export value of 22.6 billion € in 2020.

We support the European objective for a robust chemicals policy framework that protects consumers and the environment, as set out in the Chemical Strategy for Sustainability (CSS). Safety is our number one concern. In this context we consider that any revision of the CPR should acknowledge the long history of a high level of safety of European cosmetic products and keep at its core, the principle of safe use based on risk assessment. The future CPR should support the cosmetic industry's innovation capacity and global competitiveness. This can only be achieved through a strong sectorial regulatory framework, that is science-based, proportionate, simple, effective and efficient for consumers, industry and authorities. The CPR must remain the "Gold Standard" and international reference that it has become worldwide.

Driven by innovation to meet consumer needs, European cosmetic products are recognised globally as representing the highest standard of consumer safety, due to a strict science-based, risk assessment approach. Therefore, Generic Risk Management Approach (GRA) must not supersede "demonstrated safe use". The current GRA mechanism already existing under the CPR could be adapted to manage the risks of the most harmful priority substance mentioned in the CSS.

Regardless of any hazard classification, a Generic Risk Management Approach (GRA) is only justified when a substance potentially poses an unacceptable risk and there is no specific risk assessment demonstrating safe use. Allowing hazard classifications to supersede the outcome of specific risk assessments goes against the established scientific principles of toxicology and the primary objective of chemicals legislation, i.e. ensuring safe uses of chemicals. With regard to human safety, the CPR already fully achieves the safe use of cosmetic ingredients and products, using a specific risk assessment approach based on real-life exposure. Application of GRA without a workable derogation mechanism would lead to unjustified loss of safe ingredients, including natural, plant-based substances with a further impact downstream on manufacturers of cosmetic products, professional end users (hairdressers, beauticians, etc.) and ultimately consumers.

The GRA mechanism for carcinogens, mutagens and reprotoxic substances (CMR) introduced in the CPR in 2003 fulfils in principle the criteria of a) setting default bans in cases where the safe use of a substance cannot be unambiguously demonstrated by industry, b) maintaining the possibility to derogate uses from the GRA measures when such safety can be demonstrated.

To maintain a coherent and strong sector legislation, this mechanism under the CPR can be adapted to manage the risks of GRA substances identified as a first priority under the CSS: CMR, endocrine disrupting or persistent substances. However, a further extension of GRA to immunotoxicity, neurotoxicicity, respiratory sensitisation and specific target organ toxicity is not justified. These hazards can be fully addressed under the mandatory Cosmetic Product Safety Assessment, which ensures a high level of protection for consumers and professional end users.

A GRA-derogation process must respect the principle of "demonstrated safe use". Future essentiality assessments should focus on the substance, not the product and should be based on the non-availability of suitable alternatives for the use or function of a substance and be used as a 'gate-keeper' to ensure the efficiency of a GRA-derogation process.

The societal value of cosmetics and personal care products is clear. Multiple studies show our products are essential to Europe's 500 million consumers and consumers across the world, contributing to their quality of life, health, hygiene and mental well-being, self-esteem and social interaction[1].

When considering the introduction of an 'essentiality' criterion in the GRA process, the focus should be on the substance, not the product it is used in and the principle of "Demonstrated safe use" should be the overriding principle. If the use of a chemical is demonstrated safe, the question of essentiality of that use becomes irrelevant.

It is the consumer that is the ultimate arbiter of what products are essential. Limiting consumers' choice without any proven safety benefit is problematic. The concept of 'essentiality' should be based on the non-availability of suitable alternatives for the use or function of a substance. Assessment criteria should include elements such as consumer benefits, performance, availability, economic feasibility, overall safety impact caused by substitution. Reassurance should be given that these assessments will be done by a competent body and in a defined, transparent and timely process.

Essentiality assessments should be at the correct step in the risk-management process. Essentiality assessment should be used to act as a proportionate 'gate-keeper', ensuring the efficiency of the GRA-derogation process, but it must not become a 'knock-out' criterion for safe uses.

[1] Cosmetics Europe (2017) Consumer Insights Report,
Industrieverband Körperpflege- und Waschmittel (2017) IKV Youth Studies,
Look Good Feel Better Initiative

Safety assessments of finished cosmetic products already consider potential combination effects of the ingredients

Safety assessments are case-by-case assessments and are based on science. Safety assessors of finished cosmetic products already now consider the potential combination effects of the ingredients as part of their routine practice, in line with the Commission's Implementing Decision 2013/674/EU (Guidelines on cosmetic product safety assessments). Furthermore, the GRA approach on CMR Cat. 1 substances in the CPR also systematically considers the safety of aggregate exposure from all uses.

A "One Substance One Hazard Assessment" approach could be a useful departure point for sector specific risk assessments but cannot replace them. The cosmetics risk assessment process requires a scientific committee with sector-specific experience, which upholds the principles of scientific excellence, independency, and effectiveness and has significant experience on the use of alternative risk assessment methods.

Cosmetics Europe supports the CSS objective of improving effectiveness, efficiency and coherence of safety assessments across EU legislation. Implementing OSOA in the form of 'One Substance One **Hazard** Assessment', can help achieve this. This approach could allow pooling all available hazard data across industry sectors, resulting in a single, common hazard characterisation of chemicals as the starting point for sector specific risk assessments[2].

It is important, however, that sector-specific risk assessments are not conducted in a 'one size fits all' manner. Cosmetics use and exposure patterns are sector specific and vary significantly within the cosmetic product palette.

Thus, risk assessment of cosmetic ingredients requires a dedicated and experienced expert committee. The Scientific Committee for Consumer Safety (SCCS) has built up and constantly evolved this unique cutting-edge expertise over more than 40 years. SCCS has also formalised an effective interaction with the risk managers (European Commission) and stakeholders. SCCS and its opinions are recognised internationally and have become the basis for cosmetic ingredient regulations in many jurisdictions of the world, thus facilitating trade and exports of cosmetic products from the EU. Furthermore, SCCS has evolved with the very specific Animal Testing Ban provisions under the CPR, which are different from the provisions under other pieces of chemical legislation and has developed a state-of the art scientific approach on alternative methods. This specific know-how and readiness to accept alternative methods must be maintained and must continue to be further developed.

A clear and workable horizontal nanomaterial-definition is key to legislative consistency and smooth functioning of the internal market

Discrepancies between the current nanomaterial-definition in the CPR and the horizontal Commission Recommendation 2011/696/EU of 18 October 2011, have led to diverging interpretations and practices between EU member state authorities, thus damaging the smooth functioning of the internal market of cosmetics. Cosmetics Europe supports a clear and workable nanomaterial-definition that applies across sectors, based on an update to the above Commission Recommendation.

[2] Note, however, that due to the Animal Testing ban under the CPR, not all data used to prepare the OSOA hazard characterisation may be subsequently used for the sector-specific risk assessment for cosmetic use. Respective filters on the use of animal data therefore need to be built in the OSOA assessment.

Such horizontal definition may cover a wide range of different materials used across different industry sectors. Therefore, when transposing the definition into sector legislation, it should be recognised that not all materials falling in this definition need to be managed in the same manner in the CPR to achieve a high level of consumer safety. Loss of nanostructure in the finished cosmetic product or after application (e.g. solubility) should be used to identify those nanomaterials that do not require specific provisions.

Cosmetic product labelling should evolve to be fit for the 21st century Consumer

The way consumers inform themselves about products, as well as their purchasing habits, have radically changed in recent years and continue to evolve. Indeed, the revolution in communication means and technologies has already led to significant changes in consumers' behaviour, with the latter increasingly looking to access information via digital means. E-commerce is constantly growing as more and more consumers make their purchases online. Also, many companies are reducing the amount of product packaging, therefore reducing the physical space available for information.

Today's labelling system for cosmetics, introduced in 1976 and amended in 1993, has remained largely unchanged since then, and is thus increasingly outdated.

Therefore, Cosmetics Europe welcomes and supports the consideration of digital labelling and of information simplification in the revision of the CPR. The digitalisation of information provides a range of opportunities for consumers, control authorities, the industry, as well as for the environment.

At the same time, consumer information must remain meaningful and relevant, which means that it must be adapted to the product and its use. For example, inclusion of cosmetics under environmental hazard-based labelling in the CLP would not meet these requirements. Any specific environmental information that may be required should be done under the CPR, in a manner that is relevant to the real-life use of products, and helpful and actionable for consumers in terms of safe use and disposal.

It is also essential to ensure regulatory coherence across political objectives, to avoid requirements that are inconsistent. For example, increased information requirements triggering larger packaging vs. environmental ambition to reduce packaging and packaging waste.

***END.

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