CTPA RESPONSE TO THE EU COMMISSION PUBLIC CONSULTATION FOR THE TARGETED REVISION OF THE COSMETIC PRODUCTS REGULATION

Introduction

Representing all types of companies involved in making, supplying and selling cosmetic and personal care products, the Cosmetic, Toiletry and Perfumery Association Ltd. (CTPA) acts as the voice of the UK industry. CTPA represents, at any given time, around 200 member companies of diverse sizes, from micro and SMEs through to multinationals. This collectively represents between 85-90% of a UK market valued at £7 billion in 2020 (at retail sales price).

The EU Cosmetic Products Regulation 1223/2009 (CPR) is seen as a positive reference across the world, with numerous third countries, including the UK, having implemented, or planning to implement the same principles in their own regulatory framework. This is because the CPR requires that only safe cosmetic products can be placed on the EU market and maintains a very high standard of protection for human health. The CPR currently has a risk-based safety assessment approach to cosmetic ingredients management, which regulates ingredients based on their hazard and exposure. Products complying with the EU CPR are highly regarded outside of the EU, facilitating trade and opportunities for businesses.

Following the departure of the UK from the European Union, the Northern Ireland Protocol to the Withdrawal Agreement requires, at the time of submission of this contribution, that cosmetic products placed on the market in Northern Ireland follow the CPR. This provides additional context to the relevance of the proposed measures and its impact on consumers and businesses in the UK.

In addition to considerations regarding the robustness of the CPR, it is important to remember that cosmetics are products used in every consumer's daily life; they do not only include make-up products, but a lot of other products that contribute to a person's hygiene, health and wellbeing (e.g. shower gels, shampoos, toothpastes, hand washes, etc.).

The below feedback outlines CTPA's and the UK cosmetics industry's response to the main themes presented as part of the EU Commission consultation on the targeted revision of the cosmetic products regulation. A summary has been provided, alongside full argumentation of the response.

Response summary

- **Generic Risk Approach (GRA).** The CPR ensures only safe cosmetic ingredients may be used through existing mechanisms, capable of managing all ingredients regardless of their chemical hazard classification. These mechanisms include the detailed safety assessment and the legal restriction on specific ingredients. A broadening of the existing GRA approach must allow for derogations where the use of a GRA-ingredient has been robustly demonstrated as safe. Further, where safety is demonstrated, an assessment of essentiality is not required.
- **Mixture Assessment Factor (MAF).** The cosmetic ingredient safety assessment already includes a globally accepted, conservative Margin of Safety (MoS) of 100 to account for uncertainties and combination effects. Most cosmetic ingredients evaluated in the past 10 years by SCCS have a MoS - between 100 and 1000 in leave-on uses and above 1000 in rinse off uses. It is CTPA view that an even more conservative approach will not improve consumer safety and will instead reduce the competitiveness of EU products in the global market.

- **Nanomaterials.** CTPA and the UK cosmetics industry support the harmonisation of the definition of nanomaterial. It would not only remove the differences in interpretation and implementation, but it can also promote a level playing field and can facilitate trade through a common understanding with international markets. However, when applying a horizontal definition into a sector specific legislation, it is worth considering that the scope of definition is widened and more materials would be classified as nanomaterials, but they may not need to be managed in the same way to ensure the maintenance of the current high level of consumer safety. The cosmetics industry welcomes measures to ensure a smooth transition to the horizontal definition.
- **Labelling.** Effective communication of relevant product information is one of the elements within the CPR that ensures consumer safety, and the inclusion of considerations to the availability of products both in physical stores and online will support the transition to an increasingly digital lifestyle. Digital provision of information will be key to allow products to be imported or exported effectively with the increasing requirements for mandatory information and demand from consumers to enable an informed decision-making process at the time of purchase.
- **Scientific Committee for Consumer Safety.** A restructure of the scientific committees should aim to keep the independence, transparency, cosmetics-specific expertise (including evaluation of use and exposure), and the application of New Approach Methodologies currently held by the SCCS.

On the EU Commission's proposal to introduce "an automatic ban of the most harmful chemicals (the 'generic approach to risk management'), allowing their use only where it is proven to be essential for society"

Generic Risk Approach (GRA)

The EU Cosmetics Regulation ensures a high level of consumer safety by assessing the safety of ingredients in a targeted, specific and relevant manner. A Generic Risk Approach (GRA) will not in itself improve this existing high standard of safety, unless the GRA takes into account the fact that just because a chemical carries a hazard, it does not mean it is unsafe in all situations. If this is not the case, there is a very real risk that consumers will lose access to certain safe and effective cosmetic products and ingredients. This will apply across all cosmetic product categories including suncare, toothpaste, deodorants, colour cosmetics, fragrance and more.

There will be many situations in which the ingredient can be used without this hazard presenting a risk to safety. For example, it may be used in very small quantities, or it may be used on the skin rather than ingested. The current Article 15 derogation process in the EU Cosmetics Regulation, which permits continued use of a very small number of CMR substances in cosmetics where proven safe, is a successful example of an effective and proportionate approach to managing the use of substances with a high hazard. For example, salicylic acid and titanium dioxide are two important cosmetic ingredients used in skincare, suncare, toothpaste and make-up products, which can continue to be safely used thanks to the Article 15 derogation process. This successful model for ingredient management has been introduced in other global cosmetics legislations, including the UK.

It is however important to ensure any extension to this existing CMR GRA approach is restricted to the most hazardous chemicals; for example, ED (human health), PBT or vPvB. Other hazards are already very well managed under the mandatory cosmetic product safety assessment.

Essential Use Concept

CTPA and the UK cosmetics industry would like to state the concern that a new EU system of prioritising a decision on whether a substance is 'essential for society' rather than whether it is safe will mean that

consumers will see a reduction in product performance, or loss of access to certain cosmetic products altogether, with no benefit to human health or the environment. These safe and effective products will still be available for sale in the UK and other global markets, harming the competitiveness of the EU market and the EU-based companies selling outside the EU.

If a cosmetic ingredient is proven safe for use under specific conditions, an assessment of whether it is essential or not is not required.

CTPA considers that, overall, the 'essential use' concept for cosmetic ingredient management poses very significant challenges. The definition of 'essential' is highly subjective and this concept is unlikely to simplify or streamline the regulatory process itself because it will predictably generate debate and disagreement between stakeholders. The EU Cosmetics Regulation already has stringent provisions in place to ensure that ingredients may only be used if they are safe. In addition, the Article 15 derogation process for CMR 1a or 1b (the most hazardous CMR substances) also includes an assessment of available alternatives, which is a component of the Montreal Protocol definition for essentiality.

The Montreal Protocol attempts to introduce criteria for 'essential' in terms of being necessary for health and safety or critical for the functioning of society, where there are no acceptable alternatives. Nevertheless, the interpretation of these criteria is subjective and dependent on individual circumstances, not only in regard to what is necessary for health and safety but also whether an alternative is acceptable. For example, there will be differing views between regulators, consumers, industry and other stakeholders on whether it is acceptable for an alternative to have a lower technical performance which does not meet consumer expectations.

The decision will impact the quality, price or performance of the products to which consumers have access. This is especially important for users of certain types of products from particular groups in society; for example, disabled users, patients, users from a specific ethnic group or gender. It is critically important that relevant groups are identified and fully consulted. Otherwise, there is a significant danger that equalities issues will not be considered - what may not be considered essential to one group in society might be seen as absolutely essential to another. Accidental discrimination or failure to take account of equalities issues is a major risk within the concept of essential use and may even incur legal challenges. In addition, essential use criteria will require constant updating. Society's essential needs are constantly evolving. For example, in 2019, an ingredient enabling a hand gel to be as effective as possible and easy to apply may not have been considered essential. In 2020, the spread of COVID-19 increased the essentiality of hand gels and their function.

The differences and similarities across countries within and outside of the EU would determine that the incorporation of the concept of 'essential use' not be dictated only from an EU perspective, but with the knowledge and understanding that a broad interpretation of essentiality is inherently derived from a particular cultural understanding. This would be introducing measures that would not be considerate of the wider global trade relationships, where a different understanding might allow the safe use of substances based on their essentiality.

CTPA considers that in the event an essential concept is progressed, the following factors must be respected for any integration of an essential use concept within the EU Cosmetics Regulation:

- An essentiality assesssment should not take precedence over an assessment proving that the ingredient can be safely used under specific conditions.

- Allowing the continued use of select substances from the hazard categories in question, where their use under specific conditions is proven safe by an indepednet scientific committee with the relevant expertise, and there is a strong justification for the importance of these ingredients.
- Removing the current criterion in Article 15 which requires proof that the ingredient is safely used in food, as this bears little relevance to its safe use in cosmetic products.
- Ensuring the system is managed through a formal, objective process with defined timelines. Defined timelines will assist companies trading outside of the EU to manage the expectations of their supply chains.

On the EU Commission's proposal to introduce "a new measure to take into account the combination effects from simultaneous or subsequent exposure to chemicals from different sources"

The intention of the introduction of a Mixture Assessment Factor (MAF) is to address potential risks from unintentional mixtures. However, cosmetic products are intentional mixtures of known composition and not unintentional mixtures. A MAF approach, as considered under REACH, will not improve the safety of cosmetic products and risks safe and effective cosmetic ingredients being unnecessarily banned or restricted.

The safety assessment, which is legally required under the EU and UK Cosmetics Regulations, is a vital part of ensuring the safety of cosmetic products and their ingredients. When characterising risk, it is usual for a safety factor of 100 to be applied for conventional forms of toxicity. This safety factor accounts for uncertainties in the data, and application of those data, to the risk characterisation. This demonstrates that conservative assumptions are already included within the safety assessment.

In addition to the existing Margin of Safety (MoS), the safety assessment also already accounts for consumers using combinations of cosmetic products. The calculations assume that the ingredient is used in all cosmetic product categories at the maximum permitted concentration, and that all these products are used on a regular basis by the consumer.

In addition, the existing Generic Risk Approach (GRA) under Article 15 of the Cosmetics Regulation, to manage CMR substances of most concern, takes into account exposure from other cosmetic and non-cosmetic sources.

Adding an additional MoS could invalidate the existing safety assessments for a large proportion of existing cosmetic ingredient and products, which have been used safely for many years. This would introduce huge divergence between the UK and EU Cosmetics Regulations, reducing the competitiveness of EU products as they would not contain as wide a range of safe and effective ingredients as products formulated for other global markets.

Retroactive reclassification of more than 80% of currently approved UV filters and preservatives would have a huge negative impact on public health.

On the EU Commission's proposal to conduct "a review of the definition of nanomaterial"

The EU Cosmetics Products Regulation (CPR) currently contains a specific definition of nanomaterial for cosmetic products. This is different from the horizontal definition issued by the EU Commission via a recommendation in 2011 and its updated version as of 10 June 2022. Having two different definitions of nanomaterials for the EU market currently causes issues of different uses and interpretations among raw material suppliers, but also competent authorities of the EU Member States. Despite having a legally binding

definition of nanomaterial under the CPR, this fragmentation of interpretation can be an obstacle to trade and make compliance more difficult for companies of all sizes.

CTPA and the UK cosmetics industry support the harmonisation of the definition of nanomaterial and the implementation of the horizontal definition into the CPR. This would not only remove the differences in interpretation and implementation, but it can also promote a level playing field at international level and have a widely accepted approach to what is a nanomaterial. This can facilitate trade and common understanding with international markets.

The main differences between the nanomaterial definition under the CPR and the 2011 recommendation are outlined below:

- removal of "*insoluble or biopersistent*"", which would add soluble materials into the scope of the nano definition;
- addition of "*natural and incidental*", which would add non-intentionally manufactured materials to the scope of the nano definition;
- addition of a "*50% or more*" threshold for the particle size distribution, which would add more materials under the scope of the nano definition;
- conditions to be met depending on particle size distribution, or share of the particles.

As explained, these different criteria will increase the number of raw materials under the scope of the nanomaterial definition, bringing additional labelling and notification requirements, as well as additional safety considerations. While these would be relevant for those materials that retain their nano properties also in the finished product, there will be some raw materials that would not. When transposing a horizontal definition into a sector specific legislation, it is important to consider the fact that the scope is widened and more materials would be classified as nanomaterials, but they may not need to be managed in the same way to ensure a high level of consumer safety. The implementation of the horizontal definition into the CPR should therefore consider these points and legislate accordingly to reduce the impact on companies; for example, derogation of the requirement to include the term "(nano)" in the ingredient list labelling or the notification requirements for those materials that lose nanomaterial status during manufacturing or product use. Measures to ensure a smooth transition shall also be implemented.

These considerations would not just be beneficial for EU-based companies, but also for international trading countries that sell to the EU. Whilst the long-term goal is to promote a harmonised definition of nanomaterials across other international markets, trade impact should still be minimised in the meantime. Additional Technical Barriers to Trade should not be raised. The UK and EU remain close trading partners, and the EU and UK Cosmetics Regulations remain with an overall alignment. Companies are still able to design and place the same products in both the UK and EU market without too many additional constraints. Harmonising the definition of nanomaterial without taking into account sectorial specificities of these ingredients, could add further constraints that limit trade with international partners.

On the EU Commission's proposal for "improving labelling information on cosmetic products"

The evolution of consumer communication into digital spaces and online retail has seen a marked growth in the latest years. This has been accompanied by an increased interest from consumers and consumer organisations on the provision of information readily available to enable consumers to make informed choices and have a greater understanding of not only the characteristics of the products for purchase, but also the impact of these products in the wider context.

CTPA and the UK cosmetics industry expressed support through the response to the Inception Impact Assessment consultation launched in October 2021 to the EU Commission's proposal to consider the inclusion of digital tools to enhance consumer information. The consumer research conducted by CTPA in the context of the provision of information on product labels, including environmental information, demonstrated that label comprehension is easily affected by the provision of excess or lack of information. The use of short and ambiguous information may be missunderstood or unclear, and yet cosmetic products face an ever-growing reduction in available space to be able to communicate effectively with consumers through their product labels. The ongoing efforts on environmental and sustainable governmental policies and business initiatives to reduce packaging and packaging waste pose a challenge to the provision of relevant and essential information to support the well-informed consumer.

The cosmetics industry in the UK has identified a need to address the applicability of the current legal requirements under the CPR to online retail spaces, including where products are sold in physical spaces too, ensuring there is a consistent approach to consumer information from both online and offline channels. Such a proposal could include the possibility of including some of the mandatory information primarily through a digital means, supporting not only the purchase decision but also the availability of this information through the product lifecylcle, including after sales and at the moment of disposal.

The labelling information of cosmetic products has not only the aim of ensuring an informed decision at the time of purchase, but also consideration to the safety of the product for the individual consumer. This level of consumer protection should be maintained through any digital labelling options provided, and the move to these options should be gradual and with sufficient transition periods to not only enable businesses to adapt to these solutions and build their internal technological capabilities, but also to provide time to enhance consumer understanding and enhance label literacy. There is a responsibility from both industry and regulators to ensure that consumers in their regions understand how products are regulated and how the information provided is to their benefit, and digital transition will no doubt require time to inform and educate consumers on how to engage with their product labels.

The development of digital solutions to the provision of information would require consideration of the global context, and the interaction with other jurisdictions to ensure that these are not introducing barriers to trade for other territories. As mentioned in the introduction, products placed in Northern Ireland are still regulated under the CPR and therefore digital considerations would benefit from being compatible to ensure that all consumers are able to access and understand their product labels. Such an initiative, where well applied, might actually be able to benefit the cosmetics industry by making it easier to create a product compatible with multiple jurisdictions and individual country requirements outside of the EU. For example, we understand the EU is currently considering extending the list of substances identified as likely to cause an allergic reaction significantly. While the labelling of allergens in cosmetics is now widely understood, this approach or extent is not shared by other countries which could make it harder for EU cosmetic products to be exported. These considerations would also be applicable to non-cosmetic related information or environmental information, which could make it difficult for products to be relevant to other jurisdictions where the presence of this information might not be relevant or could indeed be misleading.

Finally, the understanding that a gradual approach of the transition to digital labelling has to be supplemented by measures in place to protect consumers with low or no access to digital spaces, including access to mobile devices with internet capabilities or general internet access. There, current provisions on the display or availability of information at point of sale could be extended to the transition into digital information, ensuring fair and reasonable access.

It has been noted that the current proposal under consultation from the EU Commission is limited to the provision of mandatory information under the CPR, yet the reasoning is cross-cutting in many aspects with other labelling requirements and global considerations. Therefore, any proposal should consider the current need to adapt and improve the communication of information together with the need to ensure that the changes do not limit possible future innovations.

On the EU Commission's proposal for "streamlining scientific assessments of cosmetic products by reassigning the work of the Scientific Committee on Consumer Safety (SCCS) to the European Chemicals Agency (ECHA)"

The expertise of the current independent EU scientific committee responsible for the safety assessment of cosmetic ingredients, the Scientific Committee on Consumer Safety (SCCS), is highly respected globally. Some global regions directly use the SCCS opinions for ingredient regulations, and other regions, such as the UK, have implemented a similar model of independent scientific expertise.

In addition, SCCS expertise in evaluating New Approach Methodology (NAMs) data and its commitment to furthering the acceptance and uptake of non-animal methods is an asset of great benefit to the cosmetics industry, but also wider downstream user sectors. CTPA considers that the restructure of the scientific committees should not lose the independence, cosmetics-specific expertise (including evaluating use and exposure), and the use of NAMs.

The cosmetics industry, both in the EU and globally, appreciate the principles of transparency that the SCCS operates to. The transparent and detailed mandates, minutes and opinions add to the publicly available safety information on cosmetic ingredients which therefore assists individual companies with their safety assessments. The transparent approach also provides information to third country Governments on EU ingredient assessment priorities. This can assist the planning of their ingredient reviews and promote alignment between regulatory frameworks, therefore facilitating trade outside of the EU for EU-based companies.

Four impact assessment options have been proposed by the consultant conducting the impact assessment of the CPR revision on behalf of the Commission, summarised as follows:

- The SCCS remains with the Commission;
- the SCCS moves to ECHA, remaining a standalone committee but maximising synergies with the existing scientific capacities of ECHA;
- SCCS work is integrated into ECHA's Committee for Risk Assessment (RAC), ensuring sufficient expertise and continuity of existing SCCS methodologies; or
- SCCS work is integrated into ECHA's Committee for Risk Assessment (RAC), and the RAC framework, methodology and membership will apply.

It is CTPA's view that the first, second and to a lesser extent, the third, options are most appropriate to maintain the current expertise of the SCCS regarding the safety assessment of cosmetic ingredients. Maintaining this expertise ensures the SCCS continues to be a global reference point for cosmetic safety and non-animal approaches to chemical assessment, referenced by other downstream user sectors.

CTPA is concerned that option 4 will lead to a generic chemical safety assessment being performed for cosmetics, which will not produce a tailored outcome. A generic approach risks unnecessarily losing the use of safe and effective cosmetic ingredients.