Ensuring a strong CPR for the green and digital transition
Policy Options and Impacts

Cosmetics Europe contribution to Public Consultation 21 June 2022

I. Executive Summary

Cosmetics Europe fully supports the objectives of the Chemicals Strategy for Sustainability (CSS) of increasing the protection of health and environment, whilst boosting innovation and promoting EU competitiveness, and welcomes the opportunity to submit comments in relation to the revision of the Cosmetic Products Regulation (CPR).

- This revision of the CPR cannot be done in isolation and must be seen in the overall context of the various legislations stemming from the European Green Deal. The European Commission must take a holistic approach to the revision process, to ensure coherence and consistency across legislations.
- The revision of the CPR also needs to consider the cumulative impact of the various elements being implemented from the CSS, such as the Generic Risk Management Approach (GRA), the concept of essentiality and the need for a Mixture Assessment Factor (MAF) to address combination effects. Arguably, these concepts introduce restrictions on ingredients which are not based on the principles of cosmetic product safety assessment, which constitute the fundamental basis of the CPR. The unintended consequences of the introduction of these concepts in the CPR 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.
- Cosmetics Europe therefore asks that the revision process, whilst taking into account the objectives of the CSS, acknowledges the globally-recognised, high level of ingredient safety under the current CPR. A sufficient palette of ingredients is necessary to ensure, also in the future, the highest level of consumer safety and enable consumer choice.
- To this end, Cosmetics Europe stresses the necessity to maintain and adapt the already existing approach to GRA under Art 15 of CPR. This includes a safety-based derogation for the very limited number of ingredients where safety can be unambiguously demonstrated, and a ban will have disproportionate negative effects on the consumers, public health or industry. Essentiality is only relevant when safety is not or cannot be unambiguously demonstrated. This existing approach under the CPR should be extended from CMR substances to environmental GRA substances.
- Likewise, maintaining a dedicated independent scientific committee for cosmetics safety assessment would guarantee continued excellence for safety assessment of cosmetics ingredients, whilst meeting the objectives of the CSS to streamline and optimise the chemical substances review processes.
- An additional systematic safety margin for all cosmetic ingredients should not be introduced. It is not necessary and would have significant negative impacts on practically all cosmetic products, consumer choice and public health, without a demonstrated positive effect on consumer safety.
- Cosmetics Europe welcomes the introduction of a horizontal definition for nanomaterials and asks the Commission to ensure enough time for the industry to transition.
- Cosmetics Europe fully supports the Commission's objective for clear consumer communication to achieve the highest levels of consumer and environmental protection and asks that any mandatory digital labelling requirements should be introduced gradually, with clear steps and milestones to allow economic operators to adapt their systems to the new requirements.

II. General Introduction

Cosmetics Europe (CE) 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 mental well-being, self-esteem and social interaction in all stages of life.

Cosmetics and personal care products are highly valued by European consumers. The vast majority of Europe's 500 million people use cosmetic and personal care products every day. More than 70% of them perceive cosmetics and personal care products as important or very important in their daily lives, improving their quality of life and building up their self-esteem.[1]

The cosmetics industry provides choice for all consumers. A large product portfolio has been developed to meet an increasing demand for greater variety of products, corresponding to societal needs and changes. Consumers rely on product safety and value the tangible results of innovation, prioritising efficacy and quality with product performance being key.

Valued at €80 billion at retail sales price in 2021, the European cosmetics and personal care market is, along-side the USA, the largest market for cosmetic products in the world. The sector is a major trading industry with exports of cosmetic products from Europe totalling €24.2 billion (trade value) in 2021. The industry is entrepreneurial with, in 2021, close to 7,000 SMEs in Europe.[2]

The Cosmetic Products Regulation[3] has been the central piece of legislation for the sector for over 40 years. The CPR is a "gold standard" and inspiration for regulators and jurisdictions globally. Human and environmental safety is the industry's number one concern. Today, the responsibility for human and environmental safety is split between the CPR and REACh.

Science is the basis of the CPR. The current EU model of a strict science-based, risk assessment approach, is recognised as setting the highest, worldwide, standards of cosmetics safety. Safety assessment of cosmetic ingredients that considers the consumer exposure, is the method of choice to ensure cosmetic products are safe. A cosmetic ingredient can be characterized as unambiguously demonstrated as safe when it has been assessed by the European Commission's Scientific Committee for Consumer Safety (SCCS) and received a positive opinion for a particular use.

CE welcomes the opportunity to respond to the public consultation on the revision of the CPR. Any revision of the CPR should:

- foster a sustainable (globally) competitive cosmetics sector, entrepreneurship, innovation capacity;
- strengthen its science-based, proportionate, effective and efficient approach, addressing human and environmental safety in the interest of consumers, industry and authorities;

[1] See Annex 6, Cosmetics Essentials for Daily Life, European Consumer Perception Study 2022, Cosmetics Europe https://cosmeticseurope.eu/files/5716/5522/2324/CE_European_Consumer_Perception_Study_2022_Infographic_1pdf

[2] See Annex 7, Market Performance 2021, European Cosmetic, Toiletry & Perfumery Data.

[3] Reference: (EC) 1223/2009

- acknowledge the long history of a high level of safety of European cosmetic products and keep, at its core, the principle of scientific safety-based risk assessment;
- remain the “Gold Standard” and international reference worldwide;
- maintain a level of regulatory burden achievable and manageable particularly by SMEs; and
- be future-proofed by introducing digital labelling provisions.

The CPR should not be revised in isolation. The revision comes at a time when there is a plethora of legislative and policy initiatives that will impact the sector over the coming years to implement the green and digital transitions under the European Green Deal. As well as the Chemicals Strategy for Sustainability (CSS) (and its revisions of REACh and CLP), which has triggered the targeted revision of the CPR, wider initiatives on consumer information, eco design for sustainable products and packaging and packaging waste and the REACh restriction on intentionally added microplastics to products must be taken into consideration. All these initiatives will have a cumulative impact on the cosmetics sector on different levels. Companies will not have the capacity to work in parallel on all these changes which will be particularly impactful for SMEs. Their research and development activities will need to be considerably adapted to the new environment.

Therefore, the revision must be holistic and consistent with the overall stream of regulatory initiatives, and must provide for adequate transition measures.

Cosmetics Europe here below provides an overview of its impact assessment of the five areas of revision under the Public Consultation. More detailed information on each of the five areas can be found in the annexes.

III. Summary impact assessment of the five areas of revision under the Public Consultation

1. Generic Approach to Risk Management, concept of essentiality and safety-based derogations
2. Combination exposure to cosmetic ingredients is already implicitly considered though conservative assumptions in the safety assessment
3. A workable nanomaterial definition for cosmetics that is applied consistently along the supply chain and between national authorities.
4. Maintaining a strong expert committee on cosmetics safety assessment that benefits an OSOA environment
5. Digital labelling: future-proofing consumer information requirements and ensuring consistency across legislations

1. Generic Approach to Risk Management, concept of essentiality and safety-based derogations

Addressing substances of concern under the EU Cosmetic Products Regulation (CPR)

Over decades, the CPR has built and evolved a detailed and specific safety assessment approach that successfully ensures a level of consumer safety, going beyond a generic 'chemical safety' approach. Cosmetic ingredients can only be used following a safety evaluation by a qualified assessor who evaluates their toxicological profile and specific consumer exposure. Furthermore, the CPR provides for effectively addressing ingredients of specific concern brought to the attention of the European Commission. Such substances undergo an external safety assessment by the SCCS, followed by restrictions or bans determined by the Commission and Member States. EU regulation of cosmetic ingredients is directly taken over by jurisdictions across the world.

This detailed safety assessment approach under the CPR is currently only applied to the management of human safety concerns, with environmental risks of cosmetic ingredients being managed under REACh. To respond to the CSS ambition of a "stronger EU legal framework to address pressing environmental and health concerns", the strict safety approach under CPR would be suitable to manage all risks of cosmetic ingredients, independent of their chemical hazard classification, including for substances that would fall under the future Generic Risk Management Approach (GRA)[4].

Introduction of a GRA approach under the CPR

Cosmetics Europe understands that classification of a substance as GRA under one of the 'most harmful' categories (CMR Cat 1, ED Cat 1, PBT, vPvB) is an alert that requires efficient and effective risk management. However, it is important that any regulatory measure remains proportionate and not more restrictive than necessary to reach the legitimate objective of the CPR, i.e. a high level of consumer safety.

The CPR introduced a GRA for CMR substances[5] as early as 2003 via a delegation mechanism from REACh. In its current form, the approach has been a success story for managing a class of GRA substances by:

- implementing an efficient ban of the vast majority of CMR substances for use in cosmetics, no later than the application date of the CMR classification under CLP.
- granting safety-based derogations for a small number of exceptional cases where the continued use of the CMR substance was unambiguously demonstrated to be safe and a ban would have had a disproportionate negative impact on the industry or even on public health (e.g. loss of preservatives, UV filters, fluorides, pH adjustors).

[4] This principle is made explicit for CMR Cat 2 substances in Recital 32 of the CPR: *"As a hazardous property of a substance does not necessarily always entail a risk, there should be a possibility to allow the use of CMR2 substances where in view of exposure and concentration, they have been found safe for use in cosmetic products by the SCCS and have been regulated by the Commission via the CPR annexes*

[5] Substances classified as carcinogenic , mutagenic or toxic for reproduction, Category 1 or 2

The principle management mechanisms for GRA substances under Article 15 of the CPR should be maintained, including the differentiated approach between Cat 1 and Cat 2 substances. The current derogation criteria and process should be clarified and updated, based on the practical experience gained over the last 10 years.

Scope of GRA under the CPR

We believe that this mechanism under the CPR can be broadened to manage the risks of GRA substances identified as a first priority under the CSS (CMR, Endocrine Disrupting, PBT and vPvB). However, a further extension of the GRA approach under the CPR to immunotoxicity, neurotoxicity, respiratory sensitisation and specific target organ toxicity is not justified. These hazards can be fully addressed under existing CPR provisions allowing the Commission to mandate an SCCS evaluation for any ingredient of concern and restrict/ban its use accordingly.

Note that today, the CPR Annexes can only manage substances classified as GRA with regard to human safety, with substances classified for environmental reasons managed via the Annexes of REACh. With the expected increase of environmental GRA classifications (PBT, vPVB), contradictions between the two pieces of legislation may become a significant problem; i.e. substances allowed for use in cosmetics under the CPR and banned under REACh. CE therefore proposes to extend the existing delegation mechanisms under REACh and move the management of all GRA substances, for human and environmental safety, under the management of the CPR. This approach would bring a number of benefits:

- Consistency of regulatory status, avoiding contradictions between CPR and REACh
- Legal clarity for stakeholders and administrative simplification for SMEs though a regulatory 'one-stop-shop' on cosmetic ingredient
- Strengthen the role and recognition of the CPR Annexes as a regional and international reference[6] - fast international uptake of environmental GRA provisions for cosmetics
- Enlarging the detailed safety assessment approach for cosmetics to environmental aspects, going beyond a generic 'chemical safety' approach.
- Possibility of targeted environmental labelling provisions for cosmetics
- Facilitation of enforcement (no split between enforcement authorities between human safety and environmental safety of cosmetics)

Role of the essentiality concept under the CPR

Unlike for 'safety', an assessment of 'essentiality', in particular regarding the functioning of society, is not objective and impossible to be easily integrated in a technical regulatory expert process without subjective/political value judgement. Under the proposed 'most ambitious' scope of GRA, decisions would lead to bans of large numbers of cosmetic products and have far-reaching consequences for EU citizens. Such decision on societal choices needs to be taken in a transparent manner by the Co-legislator (EP, Council), representing public health, civil society and sociology expertise and diversity – accountable to the public for their decisions.

[6] Several regions countries in the world copy-paste the EU Annexes into their own cosmetics legislations, such as the 11 members of ASEAN, most Latin American and Middle Eastern countries, such an automatic uptake of EU regulations does not exist for REACh Annexes

Essentiality assessments should only be relied upon when safety is not / cannot be unambiguously demonstrated. They can potentially be a useful complementary tool in the regulatory management of 'most hazardous' substances.

Essentiality in form of "Lack of availability of suitable alternatives" can help setting priorities and timelines in a derogation process when the safety of a particular use of a substance is not yet unambiguously demonstrated as safe.

Essentiality in form of "Benefit for society" can be used to arbitrate between sectors or products when their individual uses are safe, but the combined uses exceed the safety limit.[7]

Through the ingredients they use, cosmetics and personal care products bring important functional and emotional benefits to consumers, contributing to well-being and mental health, thus providing essential societal benefits. 'Essentiality' must not be used as a 'knock-out criterion' to ban cosmetic ingredients (or effectively products/product categories), irrespective of the demonstrated safety. A derogation mechanism for GRA bans, based exclusively on a narrow interpretation of essentiality[8] would not be meaningful for cosmetic products, nor for the use of most ingredients. The concept of 'essentiality' needs to be interpreted much broader and consider the WHO definition of 'health' as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."

Potential impact of the 'most ambitious' implementation of GRA on EU cosmetic products

More than 1100 formulations of 37 cosmetic companies were checked against a reference list of potential GRA substances[9]. 94% of the formulations were found to contain one or more substances likely to become classified as CMR Cat 1. On average, there were 4-5 GRA substances per formulation. A limited number of substances (+/-20) are responsible for two thirds of the GRA occurrence in the formulations. These include alcohol, as well as a high number of substances that are naturally occurring in essential oils and plant extracts. There was no systematic difference in the number of GRA substances between natural/organic formulations and 'conventional' products.

- 68% of formulations contain one or more substances likely to become classified as CMR Cat 1
- 47% contain one or more substances likely to become classified as CMR Cat 2
- 33% contain one or more substances likely to become classified as ED(HH) Cat 1
- 76% contain one or more substances likely to become classified as ED(HH) Cat 2
- 77% contain one or more substances likely to become classified as respiratory toxic/sensitiser
- 72% contain one or more substances likely to become classified as toxic for specific target organs
- 68% contain one or more substances likely to become classified as neurotoxic or immunotoxic

[7] For instance, the same substance can be present in food, detergents and cosmetics, with each individual use being assessed as safe. However, safety may be insufficient, when considering the combined exposure from all sources. In this case, decisions to restrict certain uses may be taken based on essentiality (see also flowchart below).

[8] Which can be summarised as 'essential = necessary for the basic survival of the individual or group'

[9] Crosscheck of COSING with substances on the CEFIC/Ricardo list of potential GRA substances with the following classifications: CMR, ED(HH), STOT, respir., neurotox, immunotox

Currently, there are about 600.000 cosmetic formulations 'actively' placed on the EU market[10]. All these products have undergone a safety assessment carried by a qualified safety assessor and considering the hazard profile of the ingredients, including eventual GRA properties. Many of the most frequently found GRA substances have been specifically assessed by the SCCS and found safe for use in cosmetics. Despite their demonstrated safety, under the most ambitious GRA approach, 570.000 products would be deemed illegal due to the presence of a GRA substance.

Even with a full diversion of all research resources in the industry from innovation to reformulation, it would be impossible to reformulate this number of products. Direct reformulation costs would amount to at least 40 billion €[11]. Given the average number of 4-5 GRA substances per formulation, in many cases, reformulation of several ingredients would change the 'architecture' of the formulation to a point where manufacturing the product will simply no longer work and/or it will become unsellable because of lack of performance.

The overall impact on the industry would be the discontinuation of hundreds of thousands cosmetic products, despite their demonstrated safety for consumers. SMEs will be disproportionally affected due to limited research and development capacity.

It is unlikely that essentiality-based derogations could play any significant role in mitigating the impact of the most ambitious GRA approach (see section on essentiality above). However, the substances responsible for the majority of GRA occurrences can all be demonstrated to be safe for use in cosmetics[12]. Therefore, maintaining an exceptional safety-based derogation mechanism under the CPR would be the most appropriate tool to drastically mitigate the negative impact, whilst ensuring the main objectives of the CSS and CPR, namely a high level of consumer protection.

Please also see Annex 1.1 for case studies on the GRA and MAF impact on specific (types of) ingredients.

Conclusions

We strongly believe that the revised CPR should recognise the high level of safety already achieved through the current CPR ingredient management and build on the existing system to keep ensuring a high level of safety of cosmetic products while allowing for the continued safe use of cosmetic ingredients.

Whilst the existing GRA approach under the CPR could be extended from on CMR substances to CMR, ED, PBT, vPvB, there is no justification to include a wider range of substance classifications.

The delegation mechanism in REACh should be extended to enable management of all environmental GRA substances under the CPR. This would be in line with the legal basis of the CPR and would allow strengthened and more targeted management of the environmental risks of cosmetic ingredients, similar to the approach taken for human safety aspects.

[10] Source: CPNP database

[11] Assuming an average reformulation cost of 70.000 € per formulation).

[12] About 20 substances, including alcohol, plant extracts/constituents, basic inorganic chemicals account for two thirds of GRA occurrences in cosmetics.

Legislation must ensure that unambiguously demonstrated safety, validated by the SCCS, has primacy over hazard-based bans, and that interested stakeholders have the opportunity to demonstrate this high level of safety.

Essentiality assessments should only be relied upon when safety is not / cannot be unambiguously demonstrated.

The principle management mechanisms for GRA substances under Article 15 of the CPR should be maintained, including the differentiated approach between Cat 1 and Cat 2 substances. However, the derogation criteria and process should be clarified and updated, based on the practical experience gained over the last 10 years.

The small number of applications for CMR Cat 1 substances demonstrates that industry only asks for derogations in exceptional cases, where the use of an ingredient is crucial for the industry and its safety can be unambiguously demonstrated.

2. Combination exposure to cosmetic ingredients is already implicitly considered through conservative assumptions in the safety assessment

Absence of scientific rationale for a 'mixture assessment factor' in the safety evaluation of cosmetic ingredients and products

The concept of MAF may have some relevance for environmental risk management of unintentional mixtures of under REACh. However, cosmetics are intentional mixtures of known and clearly defined composition and a simple MAF approach, as considered under REACh for unintentional mixtures, is not an appropriate approach for cosmetics.

The safety assessment of cosmetic products not only considers the toxicological profile and exposure of each ingredient, but also potential interactions between ingredients (see CPR Annex I Guidelines 2013/674/EU). Simultaneous exposure to the same cosmetic ingredient from various cosmetic products and/or non-cosmetic sources is implicitly addressed though conservative assumptions in the ingredient exposure assessment. When calculating the margin of safety of ingredients (MoS), the SCCS assumes the ingredient to be present, at the maximum concentration, in every single cosmetic product that the model consumer uses during the day. Even under these exaggerated conditions, the ingredient must reach a MoS of > 100 in order to be considered as safe. Furthermore, for ingredients of specific concern[13] or in situations where significant exposure from non-cosmetic sources is expected, the SCCS carries out a resource intensive 'overall safety assessment', requiring collaboration between different European Commission services and agencies. It is not necessary for 'normal' ingredients, where combination effects are adequately addressed through the conservative exposure assumptions and the mandatory MoS of > 100.

The MoS-based safety approach described in the SCCS' Notes of Guidance is globally accepted considered as "the" international model for cosmetic product safety assessment. There is no indication that the current approach is leading to an insufficient level of consumer protection.

[13] Substances classified as carcinogenic, mutagenic or toxic for reproduction Cat 1

Impact of introducing a MAF in the in the safety evaluation of cosmetic ingredients and products

Adding a mandatory additional safety margin to cosmetic safety assessments would have significant negative impact across the whole industry:

A significant proportion of product safety assessments for leave-on cosmetic products on the market would be unjustifiably invalidated, impacting over 100.000 cosmetic products on the EU market.

Listing of the majority of substances in the Annexes of the CPR would need to be withdrawn, rendering the current use of the ingredients illegal.

Innovation on the basis of new cosmetic ingredients and listing of new positive list ingredients would be severely reduced.

The loss of the majority of preservatives would make it practically impossible to ensure microbiological protection of cosmetic products.

The loss of the majority of UV filters would make it impossible to manufacture a range of sunscreens offering adequate UV protection

Affected by MAF 10	
Hair Dyes (n = 132)	55%
UV filters (n = 14)	71%
Preservatives in full body leave-on (n = 16)	81%
Preservatives in other leave-on, mouthwash, makeup remover (n = 16)	56%
Preservatives in Rinse-off, Make-up, Toothpaste (n = 16)	6%
Annex III ingredients in full body leave-on (n = 27)	63%
Annex III ingredients in other leave-on, mouthwash, makeup remover (n = 27)	33%
Annex III ingredients in Rinse-off, Make-up, Toothpaste (n = 27)	7%

Tab. 1. Impact of a MAF = 10 on the use of ingredients evaluated by SCCS between 2005 and 2021[14]

Given the significantly reduced palette of ingredients remaining available, complete reformulation would be impossible, resulting in the discontinuation of a large proportion (at least 50%) of leave-on cosmetic products in the EU. This would not only have a significant immediate economic impact but would also severely damage the safety image of EU exports across the world. The reduced

[14] CE could not have access to individual company products and the MoS values for their constitutive ingredients within the timeframe of the present consultation(s). However, it was possible to carry out a review of MoS values stated in the 190 SCCS opinions issued between 2005 and 2021. (i.e. on 132 hair dye ingredients, 14 UV filters, 16 preservatives and 27 ingredients with other function(s)).

ingredient palette would also limit the European industry's capacity for innovation, thus further reducing its international competitiveness.

Conclusion

Cosmetics Europe strongly believes that the current safety assessment approach, i.e. MoS > 100 under exaggerated exposure conditions, sufficiently addresses the potential risks of combination exposure effects for the majority of ingredients. For specific cases of concern, the Cosmetics Regulation provides the tools to carry out deeper assessments of overall exposure or combination effects.

An additional systematic safety margin for all cosmetic ingredients is not necessary and would have significant negative impacts on hundreds of thousands of cosmetic products on the market. In particular, the loss of the majority of UV filters and preservatives could create a public health problem in the EU, without a demonstrated positive effect on consumer safety.

3. A workable nanomaterial definition for cosmetics that is applied consistently along the supply chain and between national authorities.

Discrepancies between the current 'nanomaterial' definition in the CPR and the horizontal Commission Recommendation[15] have led to diverging interpretations and practices between EU Member State authorities and across the supply chain, thus hindering the smooth functioning of the internal market. CE supports a clear and simple nanomaterial definition that applies across sectors, based on an update to Commission Recommendation 2011/696/EU of 18 October 2011.

It should be reminded, however, that the objective of the CPR is not the classification of raw materials as nano/non-nano, but rather to ensure a high level of consumer safety of finished cosmetic products. Specific requirements for nanomaterials under the CPR are therefore only warranted when a finished cosmetic product leads to systemic exposure to stable, solid nanoparticles.

Furthermore, through the alignment of the CPR definition with the horizontal definition, the number of cosmetic ingredients classified as nanomaterials is expected to increase from 27 to at least 220 ingredients and it can be estimated that approximately 30% of cosmetic formulas on the EU market (approx. 200.000 products) will contain at least one ingredient newly classified as nanomaterial. Newly classified nanomaterials will include more than 100 substances listed in the Annexes of the CPR (mainly cosmetic colorants listed in CPR Annex IV)). Those will require re-evaluation by the SCCS and re-listing in the CPR Annexes.

Cosmetics Europe supports a smooth implementation and transition towards the updated harmonized EU definition of nanomaterials, whilst still taking into consideration the aspects of risk to the human health (risk of systemic exposure to solid nano particles). Given the large number of newly classified nanomaterials, this will require careful planning and sufficient time to allow industry to prepare and submit nano-notifications and for SCCS to review positive list materials and possibly other nanomaterials. Also, clear guidance at EU level will be required to ensure an

[15] Recommendation 2011/696/EU of 18 October 2011

efficient implementation of the nano-specific requirements to finished products. All these steps are needed to ensure the regulatory continuity for a large number of ingredients.

Careful planning and sufficient time will be needed to allow industry to prepare and submit nano-notifications and for SCCS to review positive list materials and possibly other nanomaterials. Also, clear guidance at EU level will be required to ensure an efficient implementation of the nano-specific requirements for finished products. All these steps are needed to ensure the regulatory continuity for a large number of ingredients.

Any further-going bespoke nanomaterial definition for cosmetics would create an unmanageable workload for SCCS, Commission and industry whilst failing to address the main problem that the CSS tried to address, i.e. lack of a harmonised nanomaterial definition that applies in a cross-sector manner.

4. Maintaining a strong expert committee on cosmetics safety assessment that benefits an OSOA environment

The CSS introduces the concept of "One Substance One Assessment" (OSOA) with the objective of simplifying assessment procedures to avoid inconsistencies, slow procedures, inefficient use of resources and unnecessary burdens. This objective shall, *inter alia*, be achieved through the reallocation of the technical and scientific work on chemicals, including the work of the SCCS.

CE fully supports the CSS objective of seeking higher coordination and streamlining of safety assessments and believes that implementing OSOA in the form of 'One Substance One Hazard Assessment' (OSO(H)A), can help achieve this. This approach could allow collation of all available hazard data across industry sectors, resulting in a single, common, coordinated, and horizontal hazard characterisation of chemicals as the starting point[16]. Moreover, CE fully supports optimizing the use of resources and ensuring consistent and coordinated approaches on safety assessments. The current assessment by ECHA of Propylparaben exemplifies the need for coordination and prioritization of various initiatives on chemicals by authorities and scientific bodies across legislations, and the necessity of an adequate sequencing where the overall hazard characterization is made before the sector safety assessments[17].

Sector-specific safety assessments remain essential since use and exposure patterns are sector specific and can vary significantly, thus requiring specific scientific expertise and knowledge relating to the sector. For cosmetics, based on the three principles of scientific excellence, independence and transparency, the SCCS has built up and constantly evolved a specific and unique cutting-edge expertise over more than 40 years with regards to safety of cosmetic

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

[17] Propylparaben was included in 2013 in ECHA's Endocrine disruptor assessment list. The assessment has not been completed yet and its status is still under development. The substance has had several ECHA processes along the years and was later also listed as CMR 2 in the registry of intentions. Propylparaben has been evaluated six times by the SCCS between 2005 and 2013. During 2019 a call for data due to suspected endocrine disruptors concerns was launched and as a result a new SCCS evaluation took place during 2020.

ingredients and products. The SCCS and its opinions are recognised internationally and have become the basis for cosmetic ingredient regulations in many geographical jurisdictions (e.g., ASEAN, Latin America), thus facilitating not only trade and exports of cosmetic products from the EU, but also the use of the European model of performing safety assessments outside of the EU, and thereby creating the highest standards of safety in third countries.

Since 2004, the CPR imposes specific requirements with respect to animal testing. Therefore, continuation in the specific field of non-animal tests and safety assessment is imperative for the cosmetic sector. The SCCS has evolved with the very specific Animal Testing Ban provisions under the CPR and is continuously developing state-of-the-art scientific approaches on alternative methods. It is paramount that any reattribution of the technical and scientific work of the SCCS can guarantee that its globally recognized experience, scientific excellence and regulatory acceptance in the field of non-animal test methods & scientific assessments are maintained and strengthened.

The most important part of the safety assessment is the characterisation of the consumer's exposure, whereas the identification of the hazard may inform whether a safety assessment is necessary. The cosmetic sector and the SCCS have accumulated extensive and detailed understanding and data regarding how consumers are exposed to cosmetic products and their ingredients, enabling the preparation of accurate safety assessments leading to the bi-annual revision of the SCCS Notes of Guidance, a key reference tool for the safety assessment of cosmetic ingredients and products.

Expertise on the specificities of cosmetic exposures needs to be combined with a pragmatic approach based on sound safety assessment principles, e.g., Weight of Evidence approach. Further, as mentioned above, because of the animal testing ban in the CPR, the specific cosmetics safety assessment necessitates a cutting-edge expertise on the use and reliability of New Approach Methodologies (NAMs) and New Generation Risk Assessments (NGRAs).

In conclusion, in the new OSO(H)A environment, the reallocation of the technical work of the SCCS must at all moments be guided in its work by the three well established principles for scientific advice on consumer health, Scientific Excellence, Independence and Transparency, as regularly confirmed by the EU Commission in public Communications[18]. The re-allocated committee should remain composed of qualified cosmetic safety expert and shall be able to perform robust cosmetics safety assessment based on state-of-the art methodologies, including the use of alternative risk assessment methods. In Cosmetics Europe's view, only the proposed policy options 1 and 2 of the Public Consultation meet these needs and would be able to uphold the three above-stated principles.

Options 3 and 4 of the Public Consultation, integrating SCCS within RAC, would arguably add a significant amount of work to the already stretched RAC workload and create additional decision layers. Ultimately, both options 3 and 4 would lessen efficiencies and inevitably lead to a loss of cosmetics safety assessment expertise and reference to state-of-the art methodologies as well as the possibility to influence internationally the development of cosmetics safety assessments based on European standards in the future.

For further details and comments on each of the policy options, please refer to Annex 4.

[18] Communication from the Commission 30.04.1997 and Commission Decision of 07.08.2015 establishing scientific committees

5. Digital labelling: future-proofing the means to convey consumer information and ensuring consistency across legislations

Cosmetics Europe supports the European Commission's objectives related to the revision of the CPR with regard to consumer information and digital labelling.

Today, the CPR's provisions related to mandatory consumer information are limited to on-pack labelling. There is a clear need to introduce provisions related to digital labelling, to take account of the evolution of consumers' way of accessing information and of digital technologies.

The current revision of the CPR is occurring in the context of other sectorial or horizontal legislative initiatives related to consumer (as well as multi-stakeholder) information which add new requirements on content as well as on the means for conveying it (physical- vs digital vehicles and tools). Therefore, the Commission should apply a holistic, coherent and consistent approach across all of these pieces of legislation.

The ever-increasing labelling requirements for cosmetics, combined with obligations to reduce packaging, the need to improve[19] consumer protection by avoiding overloaded labels and the growing prevalence of digital means in consumers' daily lives, strongly require the future-proofing of Article 19[20] of the CPR through the introduction of digital labelling provisions. To this end, the Commission should be empowered to address digital labelling in secondary legislation in the near future, ahead of the next (full) revision of the CPR.

The benefits of digital labelling are many. For consumers, it offers – among others - the possibility to access additional and more easily legible information on individual products and ingredients. For the environment, regulatory changes to (digital) labelling requirements would no longer require modifications of artworks, re-printing of labels and destruction of packaging which does not comply with the new requirements. For industry, costs would be significantly reduced since changes due to regulatory obligations are more easily implemented on-line, as compared to the costs of changing on-pack labelling to ensure regulatory compliance; costs would also be significantly reduced by no longer having to manage obsolete products/packaging (e.g. through withdrawals from retail, discarding/destruction). Finally, market surveillance may be facilitated by digital labelling through quick IT-based searches.

Since consumers and control authorities need to adjust to the new ways of accessing information on cosmetic products and economic operators are at various stages of digitalisation and need to adapt their internal structures and information / labelling systems to the transition from on-pack labelling to digital information, Cosmetics Europe supports a gradual approach to digital labelling.

Most of the information required under Article 19.1 should be provided with the product offer where the product is made available on the market online or through other means of distance.

In conclusion, whilst ensuring that the labelling obligations of the CPR can evolve to be fit for the 21st century, the introduction of digital labelling provisions should be done gradually and in coherence with other horizontal framework, with the ultimate aim to ensure relevance and consistency for the consumer.

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[19] Fitness Check of the most relevant chemical legislation (excluding REACh) | European Commission (europa.eu)

[20] Today's labelling system for cosmetic ingredients was introduced via the 6th Amendment to the former Cosmetics Directive in 1993.

Annexes

Detailed assessments of policy options and impacts

Annex 1 – GRA/Essentiality

Annex 1.1 - Reformulation chart

Annex 1.2 - Case Studies: Impact related to specific ingredients

Annex 2 – Combination exposure/MAF

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Annex 1 - GRA /Essentiality

Generic Approach to Risk Management, concept of essentiality and safety-based derogations

Approach to Risk Management in EU Cosmetics Legislation

Over more than 40 years, the EU Cosmetic Products Directive/Regulation (CPR) has built a detailed and specific safety assessment approach that ensures a level of consumer safety, going beyond a generic 'chemical safety' approach. For each cosmetic product the hazard profile of all ingredients needs to be put in the context of the specific consumer exposure resulting from the use of the product (CPR Annex I). These cosmetic product safety assessments must be carried out by suitably qualified safety assessors (CPR § 10). Furthermore, the CPR provides for effectively addressing ingredients of specific concern. These ingredients are brought to the attention of the European Commission who will require an external safety assessment by a dedicated independent scientific committee (Scientific Committee for Consumer Safety, SCCS). Based on the scientific safety evaluation, the Commission and Member States manage the identified risks through restrictions or bans via the Annexes of the CPR (CPR §14 and §31).

Building on this solid basis, the CPR has introduced a GRA mechanism for CMR substances as early as 2003 via a delegation mechanism from the REACh GRA approach (REACh § 56[5a] & 67[2]). The process was refined over the years to ensure the right balance between a default regulatory measure (i.e. ban of CMR substances) and the need for exceptional derogations (i.e. when safety can be unambiguously demonstrated and validated by the SCCS and when a ban would have a disproportionate impact on the industry).

The specific and detailed safety assessment approach is suitable to manage cosmetic ingredients, beyond their chemical hazard classification. Indeed, it has been demonstrated on many occasions, by the SCCS that the presence of a hazardous substance does not prejudice the safety of cosmetic products, including for substances that would fall under the future CSS GRA approach21. Moreover, the presence of specific hazardous substances may even be essential for the overall positive health and safety profile of the cosmetic product, such as in the case of preservatives, UV filters, fluorides, pH adjustors, ethanol, ...

The system in place has proven to efficient to manage cosmetic ingredients and there is no evidence to indicate significant health/safety issues caused by EU cosmetic products. Indeed, European safety standards for cosmetics have effectively become an international model and inspired regulations in many regions across the world. We strongly believe that the revised EU CPR should build on the existing system to keep ensuring a high level of safety of cosmetic products while allowing for the continued safe use of cosmetic ingredients.

[21] This principle is made explicit for CMR Cat 2 substances in Recital 32 of the CPR: *"... As a hazardous property of a substance does not necessarily always entail a risk, there should be a possibility to allow the use of CMR2 substances where in view of exposure and concentration, they have been found safe for use in cosmetic products by the SCCS and have been regulated by the Commission via the CPR annexes*

Cosmetics Europe understands that classification of a substance under one of the 'most harmful' categories (CMR Cat 1, ED Cat 1, PBT, vPvB) is an alert that requires efficient and effective risk management. However, it is important that any regulatory measure remains proportionate and not more restrictive than necessary to reach the objective. This is not only a firm principle of EU legislation[22] but also an obligation under international trade agreements.[23] The primary objective of the cosmetics legislation is not to limit the use of hazardous chemicals to what regulators consider as 'essential' but to ensure that the use of chemicals is safe. A Generic Approach of Risk Management (GRA) that unconditionally puts 'essentiality' over 'demonstrated safety' would go beyond this legitimate safety objective and lead to disproportionate bans of safe uses of cosmetic ingredients - to the point of loss of whole product categories[24] - and possibly to regrettable substitutions.[25]

We strongly believe that legislation must ensure that unambiguously demonstrated safety, validated by the SCCS, has primacy over hazard-based bans, and that interested stakeholders have the opportunity to demonstrate this high level of safety. We fully acknowledge that in such cases the burden of proof is with the industry applicant and that, if industry fails to unambiguously demonstrate safety, the default regulatory measure for GRA substances is a ban.

Scope of GRA under the CPR

CPR already contains a GRA mechanism for CMR substances that satisfies the need to efficiently address concerns flagged by the hazard classification. Whilst a ban of CMR-classified substances is the default regulatory measure, the approach leaves the possibility of derogations, in cases where a use of the substance can be unambiguously demonstrated as safe (as confirmed by the SCCS). See specific chapter below for more details.

The CPR provisions on GRA are based on a specific delegation from the respective REACh provisions on CMR substances in consumer products (REACh § 56[5a] & 67[2]). We believe that this mechanism under the CPR can be broadened to manage the risks of GRA substances identified as a first priority under the CSS: CMR, endocrine disrupting, PBT and vPvB.

However, a further extension of the GRA approach under the CPR to immunotoxicity, neurotoxicicity, respiratory sensitisation and specific target organ toxicity is not justified. These hazards can be fully addressed under the existing provisions of Article 31 of the CPR, which allows the Commission to mandate an SCCS evaluation for any ingredient of concern and restrict/ban its use accordingly. Substances in scope of this enlarged list of GRA substances could include natural ingredients (e.g. essential oils such as rosemary oil), or pH adjustors (sodium hydroxide, sulfuric acid) whose safe use in cosmetics is undisputed. Banning these basic chemicals would have a huge negative impact on the industry, without any benefit for consumer safety. (see section on impact below for more details)

[22] Treaty of the European Union, Article 54: 4. Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.

[23] Article 2.2 of TBT Agreement: Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade.

[24] See case studies below

[25] An example would be the widespread replacement of parabens as cosmetic preservatives due to 'blacklisting' as potential endocrine disruptors, despite the confirmation of safety by the Scientific Committee for Consumer Safety. The replacement substance, MIT, was not identified as ED but led to a large wave of skin allergies across the EU.

Note that today, the CPR Annexes only manages substances classified as GRA with regard to human safety, based on a delegation mechanism from the REACh GRA approach (REACh § 56[5a] & 67[2]). Substances classified as GRA for environmental reasons are managed via the Annexes of REACh. This can lead to contradictions in the regulatory status of substances between the two regulations, i.e. a substance can a the same time be allowed for use in cosmetics under the CPR and banned under REACh. Today, such contradictions are today rare, due to the limited number of REACh restrictions of cosmetic ingredients triggered by environmental concerns. However, with the expected increase of environmental GRA classifications (PBT, vPVB), such contradictions will become a significant problem economic operators. CE therefore proposes to extend the existing delegation mechanisms under REACh and move the management of all GRA substances, for human and environmental safety, under the management of the CPR. This approach would bring a number of benefits:

- Consistency of regulatory status of substances, avoiding contradictions between CPR and REACh
- Legal clarity for all stakeholders and significant administrative simplification for SMEs though a regulatory 'one-stop-shop' on cosmetic ingredient
- Strengthen the role and recognition of the CPR Annexes as a regional and international reference[26] - fast international uptake of environmental GRA provisions for cosmetics
- Detailed and specific safety assessments, going beyond a generic 'chemical safety' approach.
- Possibility of targeted environmental labelling provisions for cosmetics
- Facilitation of enforcement (no split between enforcement authorities between human safety and environmental safety of cosmetics)

Introducing the concept of essentiality under the CPR

Safety is an objective aspect of a use of a cosmetic ingredient, that can be integrated in a technical regulatory process leading to expert assessments and decisions. Decisions on essentiality, in particular regarding 'ensuring the functioning of society, are not objective and are impossible without subjective/political value judgement. Essentiality assessments cannot be easily integrated in a technical regulatory expert process.

Essentiality assessments should only be relied upon when safety is not / cannot be unambiguously demonstrated. Such assessments may potentially be a useful complementary tool in the regulatory management of 'most hazardous' substances. However, they must not be used as a 'knock-out criterion' to ban cosmetic ingredients (or effectively products or whole product categories), irrespective of the demonstrated safety.

[26] Several regions countries in the world copy-paste the EU Annexes into their own cosmetics legislations , such as the 11 members of ASEAN, most Latin American and Middle Eastern countries, such an automatic uptake of EU regulations does not exist for REACh Annexes

Essentiality has basically two aspects:

- Lack of availability of suitable alternatives
  This aspect can be applied at the level of the use of an ingredient in a specific cosmetic product/product category. It can help setting priorities and timelines in a derogation process when the safety is not yet unambiguously demonstrated as safe.
- Benefit for society
  This aspect can be used to arbitrate between sectors or products when their individual uses are safe, but the combined uses exceed the safety limit. In these cases, 'societal benefit' can be the criterion to decide which uses should be selected so that - in combination - the overall exposure still remains safe.[27]

A number of factors need to be considered when assessing 'availability of suitable alternatives' such as

i. Overall safety impact of ban and avoidance of regrettable substitution
   a. Full safety profile of the alternative (not only regarding GRA properties), proof that the alternative has an overall better safety profile
   b. safety impacts due to changed use pattern of other substances (palette effect)
ii. Technical function / task / performance and conditions of use
iii. Unique characteristics of the use/substance
iv. Available amount of alternative substance / time needed to reach sufficient supply
v. Economic and commercial availability of the alternative and its regulatory sustainability
vi. Sustainable sourcing of the alternative (life cycle)
vii. Restricted access to the alternative due to IP

Experience with the CMR approach under the CPR shows the need for a defined set of criteria and for a clear, structured process for the assessment of availability of suitable alternatives. Without this, the regulatory outcome is uncertain and there is insufficient legal certainty for industry applicants.

The presence on the market of a product claimed to be "similar product" without the substance is not a sufficient proof of the availability of suitable alternatives. It is important to compare 'like to like' when assessing availability of alternatives. For instance, an alternative may be available to replace the preservative in a normal shampoo. However, there may be no suitable alternative to the same substance when it is used as the active ingredient in an antidandruff shampoo. In other words, it is not possible to assess suitable alternatives for a substance in 'shampoo', but it is necessary to go into much deeper level of detail with regard to the product categorisation and function of the substance.

A narrow interpretation and application of essentiality under consideration under the CSS will be irrelevant for most cosmetic ingredients. In most cases, cosmetic ingredients provide a functional benefit to the overall product. Neither the cosmetic product, nor the use of the ingredient in the

[27] For instance, the same substance can be present in food, detergents and cosmetics, with each individual use being assessed as safe. However, safety may be insufficient, when considering the combined exposure from all sources. In this case, decisions to restrict certain uses may be taken based on essentiality (see also flowchart below).

product would satisfy the proposed narrow scope of essentiality, which can be summarised as 'essential = necessary for the basic survival of the individual or group'.

We believe that the concept of 'essentiality' needs to be interpreted much broader and consider the WHO definition of 'health' as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." Through the ingredients they use, cosmetics and personal care products bring important functional and emotional benefits to consumers, contributing to well-being and mental health, thus providing essential societal benefits. In a survey 71% of consumers said cosmetics and personal care products are important or very important in their daily lives.[28] Their positive perception extended across a range of cosmetic and personal care products. Consumers made a clear link between cosmetics and personal care products and quality of life; 72% of consumers said that the cosmetic and personal care products they use improve their quality of life. For instance, note that Canada recently reversed its decision that decorative cosmetics are not 'essential' after legal challenge by the LBGT+ community[29].

A predefined list of products or industry (sub)sectors cannot be taken as the basis for decisions on 'essentiality' for several reasons.

Sectors can be extremely diverse (e.g. cosmetics range include personal hygiene products as well as decorative cosmetics or sunscreens) and no overall assessment of essentiality can be given. Even within a product category, there can be big diversity of the specific benefits of individual products. For instance, the same substance could be used as a preservative in a shampoo for normal hair but as an antidandruff ingredient in a specialised shampoo

Conclusions on 'essential use ' will go through constant change following changing societal needs and innovative and technical development. The COVID-19 crisis is a good example of changes in societal need, where hand cleansing wipes and gels all of a sudden became vital tools for managing the pandemic. Data show increase of at-home hair colouring during lockdown, indicating a clear need for use of these products even in a confinement situation[30].

Consequently, any essentiality assessment can only be done 'case-by-case' on a specific product / use of a chemical and against a specific societal background. Application of essentiality should also be future proof and allow for re-evaluation of essentiality against changes of the societal needs and innovation.

To declare a product/use as 'non-essential' for society is impossible without a value judgement on the products/substance use in question. Under the proposed 'most ambitious' scope of GRA, decisions would lead to bans of large numbers of cosmetic products and have far-reaching consequences for EU citizens. Such decision cannot be delegated to technical experts and Commission administration in a regulatory process such as a Delegated Act. Rather, decisions on societal choices need to be taken in a transparent manner by the Co-legislator (EP, Council), representing public health, civil society and sociology expertise and diversity – and who can be held accountable by the public for their decisions.

See the following section for CE's proposal on how to conceptually introduce 'essentiality' in the GRA mechanism under the CPR.

[28] Cosmetics Europe Consumer Perception Study
[29] https://www.cbc.ca/news/canada/manitoba/cosmetics-essential-manitoba-public-health-orders-1.5851572
[30] JP Morgan, Mintel

GRA and derogation mechanism under the CPR

The CPR introduced a GRA mechanism for CMR substances as early as 2003. The process was refined over the years to ensure workability and finding the right balance between the default regulatory measure (i.e. ban of CMR substances) and the need for derogations (i.e. exceptional cases where safety of use can be unambiguously demonstrated).

It should be reminded that the original approach in 2003 was an unconditional ban of CMR Cat 1 without possibility of derogation. It was realised, however, that for some exceptional examples, (e.g. ethanol, certain hair dyeing ingredients, UV filters, preservatives) such a ban would lead to a devastating impact on industry – without any improvement of public health or consumer safety. This led to introduction of a derogation mechanism in 2009, by which even Cat 1 CMR substances can be derogated from GRA bans, provided that they can be unambiguously demonstrated as safe for consumers when considering combined exposure from cosmetic and non-cosmetic sources (external evaluation by SCCS). Additional criteria were included at the time as 'gate-keepers' to ensure that the SCCS would not be overwhelmed by a too large number of derogation applications. The small number of applications for CMR Cat 1 substances demonstrates that industry only asks for derogations in exceptional cases, where the use of an ingredient is crucial for the industry. The need for these 'gatekeeper criteria', which are difficult to apply in practice, should therefore be reassessed.

The GRA mechanism under the CPR works on the basis of strict timelines that ensure that the ban or derogation under the CPR becomes applicable a the latest at the application date of the CLP Regulation classifying the substance.

Overall, the GRA mechanism under the CPR has:

- implemented an efficient process of GRA, banning the vast majority of CMR substances for use in cosmetics, no later than the application date of the CMR classification under CLP.
- allowed the continued use of a small number of CMR substances for which industry provided to the SCCS clear evidence of unambiguous safety of specific uses
- limited derogations to a small number of exceptional cases where the continued use of the GRA substance was unambiguously demonstrated to be safe and a ban would have had a disproportionate negative impact on the industry

The principle of the Article 15 mechanism should be maintained. However, the criteria and process should be clarified and updated, based on the practical experience gained over the last 10 years and elements arising from the CSS:

- Reconsider the usefulness of the food safety compliance as a derogation criterion
- Clarify the derogation criterion on 'particular use of the product category with a known exposure'
- Adapt the existing derogation criterion on suitable alternatives to take into account a derogation/arbitration mechanism based on the essentiality concept
- Adapt and extend the derogation criterion on 'overall exposure from other sources' to cover also combined exposure' (see section on MAF)
- Introduce a formal process for derogations, including timelined steps and clear allocation of responsibilities

Assessment of Impact of the 'most ambitious' implementation of GRA

CE has assessed a set of more than 1100 cosmetic formulations made available by 30 SME and 7 multinational companies (30 products each), covering the whole range of cosmetic products.

The formulations were checked against a relevant extract of the CEFIC/Ricardo list of potential GRA substances (CMR, ED(HH), STOT, respirator., neurotox, immunotox that are listed as potential cosmetic ingredients in the COSING database).

Across all companies, 94% of the formulations (range of 75% - 100%) were found to contain at least one potential 'GRA' substance with an average of 4-5 GRA substances per formulation. There was no difference between companies specialising on natural/organic formulations and 'conventional' companies.

- 68% of formulations contain one or more substances likely to become classified as CMR Cat 1
- 47% contain one or more substances likely to become classified as CMR Cat 2
- 33% contain one or more substances likely to become classified as ED(HH) Cat 1
- 76% contain one or more substances likely to become classified as ED(HH) Cat 2
- 77% contain one or more substances likely to become classified as respiratory toxic/sensitiser
- 72% contain one or more substances likely to become classified as toxic for specific target organs
- 68% contain one or more substances likely to become classified as neurotoxic or immunotoxic

Note that a limited number of substances (+/-20) are responsible for two thirds of the GRA occurrence in the formulations. These include alcohol, as well as a high number of substances that are naturally occurring in essential oils and plant extracts.

Currently, there are about 600.000 cosmetic formulations 'actively' placed on the EU market (information from CPNP database). All these products have undergone a safety assessment carried by a qualified safety assessor and considering the hazard profile of the ingredients, including eventual GRA properties. Many of the most frequently found GRA substances have already been assessed by the SCCS and found safe for use in cosmetics. Despite their demonstrated safety, under the most ambitious GRA approach, 570.000 products (i.e. 95% of the all products on the market) would be deemed illegal due to the presence of a GRA substance.

Reformulation of a cosmetic formulation is a complex, multi-step process. There are many (over 30) steps to take in a standard reformulation process. These steps are set out below in chart 1. The average time reformulate cosmetic products if suitable alternatives are available is 4.5 years; this is a baseline. If suitable alternatives are not available, then companies will have to research and find alternatives before they can reformulate the product

Even with a full diversion of all research resources in the industry from innovation to reformulation, it would be impossible to reformulate hundreds of thousands of formulations, not only for the obvious reasons of direct costs (at least 40 billion €[31]). Given the average number of 4-5 GRA substances per formulation, the need to replace simultaneously several raw materials for one reformulation extends significantly the time needed for research of raw materials, designing of technologies, and ultimately products. In addition, it will be impossible to work simultaneously on all the technologies used to formulate thousands of products and deviate R&D resources to focus exclusively on product redesign. In many cases, reformulation of several ingredients would

[31] Assuming an average reformulation cost of 70.000 € per formulation).

change the 'architecture' of the formulation to a point where manufacturing the product will simply no longer work and/or it will become unsellable because of lack of performance. It is expected that a large proportion of the products concerned would not be able to be reformulated but rather have to be discontinued.

The overall impact on the industry would be the discontinuation of hundreds of thousands cosmetic products, despite their demonstrated safety for consumers. The impact on SMEs (there are over 7000 SMEs in Europe) will be significant; they will find it even more challenging to reformulate. SMEs have limited research and development capacity and are likely to be disproportionally affected.

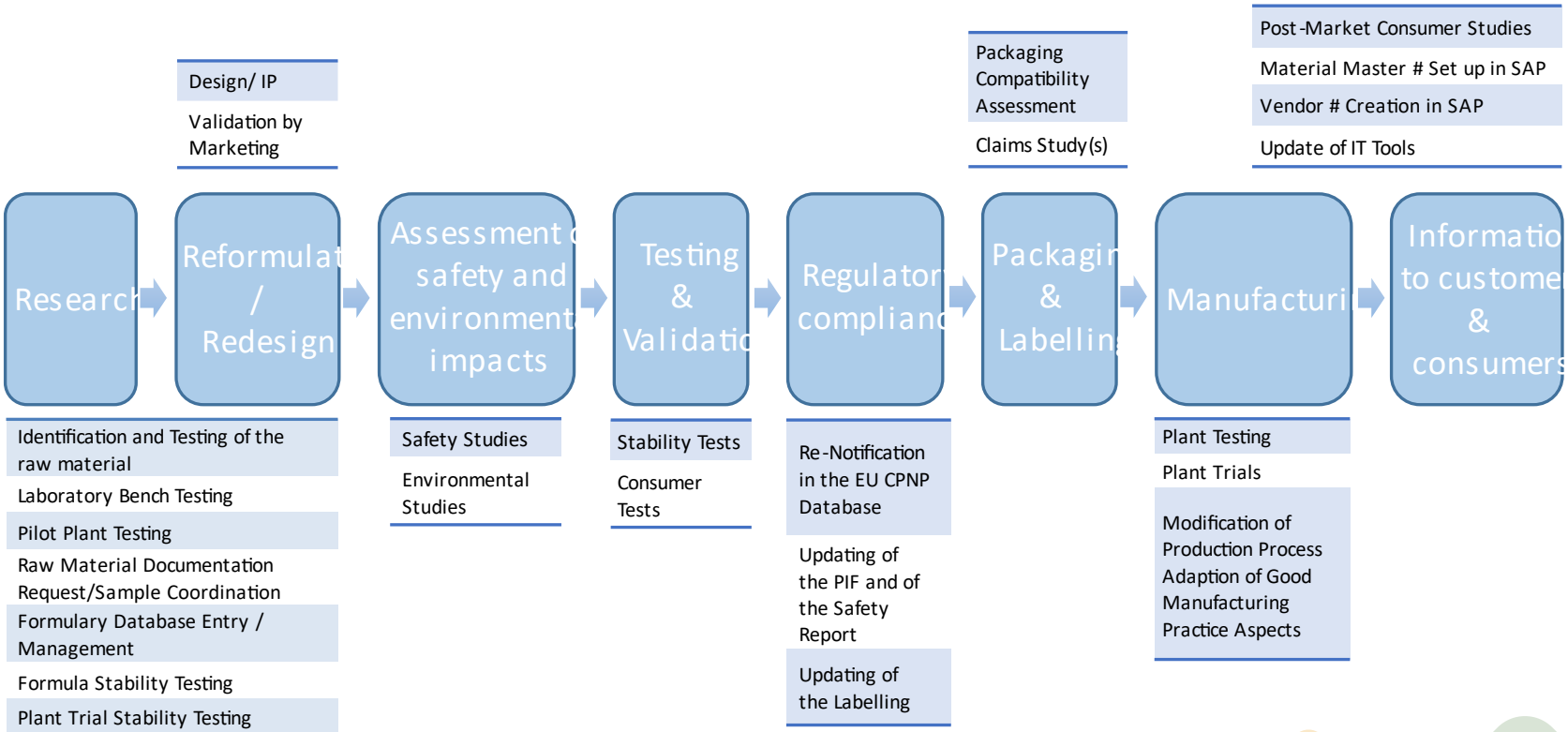
Loss of a huge number of products on the EU market, together with an inevitable loss of performance for the remaining/reformulated products, will lead to loss of consumer trust in EU products. A wide economic impact on the competitiveness of the EU cosmetics industry can be expected from having to build different product lines and production lines for the EU vs. rest of the world, where functionally superior products are still available.

Under the current interpretation of 'essentiality', it is unlikely that essentiality-based derogations could play any significant role in mitigating the impact of the most ambitious GRA approach (see section on essentiality).

The majority of GRA occurrences is linked to a limited number of substances, all of which can be demonstrated to be safe for use in cosmetics[32]. Therefore, maintaining an exceptional safety-based derogation mechanism under the CPR would be the most appropriate tool to drastically mitigate the negative impact, whilst ensuring the main objective of the CSS and CPR, namely a high level of consumer protection.

[32] About 20 substances, including alcohol, plant extracts/constituents, basic inorganic chemicals account for two thirds of GRA occurrences in cosmetics.

Complexity of the reformulation process



We personally care

Annex 1.2

Case Studies: Impact related to specific ingredients

Case Study Ethanol

Whilst most people know ethanol as (an ingredient of) alcoholic beverages and are aware of its protective, antimicrobial properties, its use and importance as a cosmetic ingredient are often less noticed. With the world gradually recovering from the COVID-19 pandemic, it is difficult to forget the contribution that ethanol-based hand cleansing products provided to controlling the spread of pandemic.

Ethanol is widely used in a wide range of cosmetic and personal care products for its refreshing, drying, and antimicrobial properties. Haircare, skincare, oral care, make-up, and deodorant products all benefit from various levels of ethanol to fulfil their intended functions. It is impossible not to mention here the contribution that ethanol-based hand cleansing products provided to controlling the spread of COVID-19 pandemic, due to the antimicrobial activity of ethanol.

Importantly, ethanol is the main ingredient for one of Europe's flagship industries[33], i.e. fine fragrances. For thousands of years, the presence of perfume and fine fragrance has been imprinted in human history, culture, and memory and has positively affected people's lives. In these products, ethanol not only acts as a solvent to the fragrance mixture but, upon application of the Eau de Toilette, Parfum, Cologne, … to the skin, it gradually evaporates, thereby controlling the olfactory development of the smell over time. This way, the fragrance can develop its whole range of notes, from the initial volatile 'light' ones to the heavy, long-lasting ones. This staged release of the various fragrance notes is artfully designed and depends strongly on the solution and evaporation characteristic of ethanol. There is no other suitable substance available that could fulfil the role that ethanol fulfills in perfumes. The physicochemical properties of isopropanol, which you may know as a skin disinfectant used in medical settings, are similar to these of ethanol. However, its strong, sharp and pungent smell makes isopropanol unusable as an alternative for ethanol in perfumes and most other cosmetic products. Other solvents like glycols, phatalates etc. all have solubility, odour, viscosity and/or safety issues. Water itself can only solubilize few fragrance ingredients.

Under the CSS approach, it is likely that ethanol will be classified as a GRA substance (carcinogenic, mutagenic and reprotoxic substance as well as endocrine disruptor and STOT). These toxic properties are well known to manifest themselves after long-term oral ingestion of high amounts of ethanol. However, expert toxicologists as well as daily experience and common sense tell us consistently that small amounts of ethanol applied via cosmetics to the hair skin, or teeth do not cause any harm. Banning ethanol due to its GRA classification would ignore the fact that its use in cosmetics is completely safe. Such ban would practically wipe out the fine fragrance industry, currently valued at 12 bn€, accounting for 15% of Europe's cosmetics market and directly employing 7,000 people, along with its iconic fragrance brands and products that are so much appreciated by consumers. All this without any benefit for consumer safety. The indirect impact would be even larger, affecting fragrance suppliers and traditional agriculture in the EU that supplies the plant extracts and essential oils used in perfumes, thus irreparably damaging European history and culture.

Implementation of the GRA approach under the EU Cosmetic Products Regulation must recognize that, in exceptional cases, safety-based derogations from automatic bans can and must be possible to avoid unjustified and disproportionate negative impacts on the economy and on consumers.

[33] See "Market Performance 2021, European Cosmetic, Toiletry & Perfumery Data" for key economic data of the industry

Case Study Sunscreens

Skin cancers (basal cell carcinoma, squamous cell carcinoma and melanoma) are globally by far the most frequent types of cancer[34] with UV light being the most important cause. Every single death from sun induced skin cancer is a tragedy that might have been prevented, as are the many chronic cancers requiring regular surgery of the affected skin areas and leading to scarring, numbness and immobility. Even if only a minority of the overall population will develop skin cancer, everybody's skin will ultimately appear older than they could because of chronic UV radiation exposure. It is estimated that 80% of the visible signs of ageing are caused by exposure to UV radiation[35] .

Together with protective clothing and seeking shade, sunscreens are globally recognized as an integral part of a comprehensive sun protection strategy. Sun protection products are considered as cosmetics in the EU. Sunscreen ingredients as well as the final formulations are subject to the strict safety requirements of the Cosmetic Products Regulation (CPR). Furthermore, UV filters are part of a "positive list" system, which ensures that every substance used as a UV filter must undergo a safety review by the European Commission's Scientific Committee for Consumer Safety (SCCS) and its specific use must be formally approved in the Annexes to the CPR. This strict approval system has made a small palette of UV filters that are recognized to fulfill the highest safety standards, available to the EU industry to use in cosmetics. Each UV filter included in this palette has its specific technical properties and benefits (e.g. UV protection spectrum, solubility, miscibility, spreadability, …). Modern sunscreen formulations are carefully selected mixtures of several UV filters that allow to achieve high protection, water resistance whilst maintaining a pleasant feeling on the skin.

Under the CSS approach:

- 40% of the UV filters may be classified as a 'human safety GRA substance' (carcinogenic, mutagenic and reprotoxic substance or as endocrine disruptor, respiratory sensitiser or neurotoxic). However, in several evaluations of their toxicological properties, the SCCS consistently found that, up to certain maximum use levels, these UV Filters are safe for consumers.[36]
- Introduction of a so-called 'mixture assessment factor' (MAF) would re-classify 70% of the UV filters as unsafe, although under current safety review they already must reach a Safety Margin of > 100 under exaggerated use conditions (daily, full body application throughout the whole year).

Banning UV filters simply due to GRA classification or the addition of an arbitrary additional safety margin would disregard a well- demonstrated high level of safety of UV filters and their important contribution to public health. Removing the majority of UV filters from the available palette would make it difficult to impossible to achieve the necessary skin protection. It would effectively remove one important pillar of a globally recommended sun protection strategy with potentially dramatic long term consequences to public health and cancer rates in the EU.

To avoid unjustified and disproportionate negative impacts on the economy and on consumer safety and public health, the implementation of the CSS under CPR must recognize that, in exceptional cases, safety-based derogations from GRA bans can and must be possible and that introduction of a MAF is not necessary to ensure consumer safety of cosmetics.

[34] J Amer Acad Dermatol International, Volume 2, 98-108, 2021

[35] "Photo-ageing / Photodamage as a Public Health Concern" Amer Acad Dermatol Consensus Conference, March 1988

[36] Note that even more UV filters might be classified as 'environmental GRA substance' under the REACh regulation.

Case Study Preservatives

Microorganisms which are always present on our skin and in the air around us can get into products during normal use. Water-based products in particular provide favourable conditions for the growth of a wide range of microorganisms. Cosmetics - just like food and other products directly handled by consumers - can become contaminated, leading to product spoilage, degrading of intended characteristics, and possibly adverse health reactions to consumers using them such as irritation, infections and other[37]. Providing microbial integrity of a cosmetic product is a legal obligation under the Cosmetic Products Regulation (CPR) to ensure consumer safety. Cosmetics do not have to be sterile, however, they must not be contaminated with pathogenic microorganisms, and the presence of non-pathogenic microorganisms must be kept to low levels, not liable to cause harm. Preservatives as integral cosmetics ingredients help reduce the risk of microbial contamination during extended use periods, thereby contributing to long term safety and sustainability of the products. Cosmetic preservatives are regulated in the EU via a "positive list" system, which ensures that every preservative must undergo a safety review by the European Commission's Scientific Committee for Consumer Safety and be formally approved in the Annexes to the CPR. This strict approval system has made a small palette of preservatives that are recognized to fulfill the highest safety standards, available to the EU industry to use in cosmetics. Each substances in this palette has its specific properties and benefits (activity against different types of microorganisms, solubility, miscibility with other ingredients, …). Therefore, cosmetic products typically contain carefully selected mixtures of preservatives that allow for reaching high protection against microoganisms with minimal use concentrations.

Under the CSS approach (including the most ambitious GRA approach and introduction of a Mixture Assessment Factor), the majority of preservative would no longer be considered safe. The loss of these preservatives would make it impossible to guarantee microbiological safety for many products. This would in particular be the case of products to be applied on sensitive parts of the body (e.g. eye or mucous area) or products for children or used by immunosuppressed individuals. Moreover, refillable cosmetics are a growing trend which, while contributing to environmental sustainability by reducing packaging waste, pose preservation challenges that can only be answered with a sufficiently large palette of preservatives.

For those products where reformulation is possible, the use of the remaining preservatives would significantly increase, both in terms of number of products and in terms of use concentrations, to ensure safety. This increased use could lead to an increase of undesirable effects (skin irritation, skin sensitisation) that are known to be inevitably linked to preservatives but are today minimised through the use of a large palette of different preservatives at low concentrations.

To avoid unjustified and disproportionate negative impacts on the economy and on consumer safety and public health, the implementation of the CSS under CPR must recognize that, in exceptional cases, safety-based derogations from GRA bans can and must be possible and that introduction of a MAF is not necessary to ensure consumer safety of cosmetics.

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[37] Lundov M D, Moesby L., Zachariae C, Duus Johansen. *Contamination versus preservation of cosmetics: a review on legislation, usage, infections, and contact allergy.* Contact Dermatitis 2009: 60: 70–78 - Alvarez-Lerma F, Maull E, Terradas R, Segura C, Planells I, Coll P, Knobel H, Vazquez A. *Moisturizing body milk as a reservoir of Burkholderia cepacia: outbreak of nosocomial infection in a multidisciplinary intensive care unit*. Crit Care 2008: 12: R10. - Kutty P K, Moody B, Smartt G J et al. *Multi-state outbreak of Burkholderia cenocepacia colonization and infection associated with the use of intrinsically contaminated alcohol-free mouthwash*. Chest 2007. - Wilson LA, Ahearn DG. *Pseudomonas-induced corneal ulcers associated with contaminated eye mascaras*. Am J Ophthalmol. 1977;84(1):112-119. Reid FR, Wood TO. *Pseudomonas corneal ulcer. The causative role of contaminated eye cosmetics*. Arch Ophthalmol. 1979;97(9):1640-1641.

Annex 2 – Combination Exposure / MAF

Combination exposure to cosmetic ingredients is already implicitly considered though conservative assumptions in the safety assessment

The Public Consultation introduces the topic by stating that « requirements to take into account consumer exposure to a number of chemical substances from multiple sources » (or 'unintentional mixtures') are broadly lacking from legislation.

The public consultation does not present a range of conceptual policy options, but exclusively concentrates on the introduction of an additional uncertainty factor (UF) to address mixtures (Mixture Assessment Factor, MAF) in safety assessments of cosmetic ingredients. Likewise, the targeted stakeholder consultation assesses the impact of different values for a MAF, but gives very little room to the question on whether a MAF for cosmetics is actually necessary and/or whether potential, theoretical combination effects are already sufficiently addressed under the current conservative practice of cosmetic ingredient risk assessment.

<u>Absence of scientific rationale for a 'mixture assessment factor' in the safety evaluation of cosmetic ingredients and products</u>

Whilst the concept of MAF may have some relevance for environmental risk management of chemicals under REACh to take into account unintentional mixtures, it needs to be recognised that cosmetics are intentional mixtures of known composition. A simple MAF approach, as is considered under REACh for unintentional mixtures, is therefore in our view not an appropriate approach for cosmetics.

Regarding cosmetics, there are two areas of 'combination effects' that may be relevant from a consumer safety perspective:

- Cosmetics are intentional mixtures of known composition. Indeed, unlike 'unintentional' mixtures of unknown composition, cosmetics are clearly defined mixtures whose composition is considered in the safety assessment of cosmetic products. This safety assessment not only considers the toxicological profile of each ingredient, the qualitative and quantitative aspects of consumer exposure to each of these ingredients, but also potential interactions between them. Potential interaction between cosmetic ingredients within a product is adequately taken care of when reviewing the safety profile of their constitutive ingredients. Additionally, such theoretical combination effects/interactions between cosmetic ingredients are also thoroughly evaluated by the numerous tests and evaluations performed by cosmetic industry safety assessors on cosmetic finished products in order to ensure their skin safety (see CPR Annex I and Commission Guidelines 2013/674/EU).
- There may be simultaneous exposure to the same cosmetic ingredient from various cosmetic products and/or from cosmetics as well as non-cosmetic sources.

  Potential simultaneous exposure to a substance from various cosmetic products is considered by conservative assumptions in the ingredient exposure assessment. When calculating the margin of safety, the SCCS assumes the ingredient to be present, at the

maximum concentration, in every single cosmetic product that the model consumer is assumed to use each day. Even under these exaggerated exposure assumptions, the ingredient must have a nominal margin of safety (MoS) value of > 100 in order to be considered as safe. As a consequence, the « real life MoS » is much higher than the nominal MoS value calculated by the SCCS and/or in industry dossiers. This approach for evaluating consumer exposure to cosmetic ingredients is considered to be sufficiently conservative to cover potential exposure to the same substance via various sources.

For ingredients of specific concern (CMR Cat 1) or in situations where significant exposure from non-cosmetic sources is expected (e.g. iodine from food/IPBC, Vit A from food/Retinol and derivatives, Aluminium…), industry and the SCCS carry out an overall exposure assessment, thoroughly assessing exposure from cosmetic and non-cosmetic sources. Such overall exposure assessments are resource intensive, requiring collaboration between different industry sectors and/or different Commission services and agencies. They may be justified by the specific level of concern over CMR Cat 1 substances but are not necessary for usual cosmetic ingredients, where combination effects are adequately addressed through the above conservative exposure assumptions and the mandatory nominal MoS/UF value of > 100.

Finally, it might be argued that potential/theoretical combination effects resulting from co-exposures of consumers to cosmetic ingredients and other chemicals stemming from other sources are not sufficiently taken care of by the overall EU regulatory framework, EU CPR included. The actual scientific need to take account of such theoretical combination effects of co-exposures to different chemicals -each at exposure levels (far) below their respective effect/toxic levels,- is still heavily debated. Specifically for cosmetic ingredients, where a large fraction may be considered as “commodity chemicals”, we strongly think that the traditional risk assessment model is sufficiently conservative to take care of such potential/theoretical effects.

This model, as thoroughly outlined in SCCS Notes of Guidance, contains the following layers of built-in conservatism, in addition to the above considerations related to external exposure assessment:

- The extent of potential internal consumer exposure to an ingredient (systemic exposure dose) is evaluated through the application of default, over-conservative dermal penetration factors, or following the conduct of in vitro dermal absorption studies, which results and their interpretation largely overestimate any potential internal consumer exposure.
- The so-called Point of Departure (PoD) -used to derive theoretical safe levels of exposure to a cosmetic ingredient- is most of the time conservatively derived using the lowest No Observed (Adverse) Effect Level (NO(A)EL) value obtained in a series of toxicity studies performed by the oral route. This route-to-route extrapolation, i.e. the use of results obtained by the oral route to evaluate the safety of dermally-applied cosmetic ingredients, is well known to be conservative thus err on the safe side, given the intrinsic differences in toxicokinetic profiles resulting from administration by these two different exposure routes.
- Oral NO(A)EL values used as PoDs for the safety assessment of cosmetic ingredients are corrected for their oral bioavailability by using default, over-conservative factors. The mere use of such correction factors for the oral bioavailability of cosmetic ingredients represents an additional layer of conservatism: in order to yield a MoS value, it leads to comparing internal (systemic exposure) doses stemming from oral toxicity studies on the one hand (oral NO(A)EL values corrected for oral bioavailability), and from estimates of consumer

systemic exposure on the other hand (consumer external dose x dermal penetration rate). Indeed, when comparing systemic exposure doses, the "target", required MoS value should be of 25 since no uncertainty factor to take account of interspecies toxicokinetic differences (default value of 4) is warranted: while a "target" MoS value of 100 is required when comparing external exposure doses, the well-accepted WHO model for allocating uncertainty factors suggests that a MoS value of 25 is sufficient when comparing internal (systemic exposure) doses.

The MoS-based safety standard described above is globally accepted and facilitates trade in cosmetics between the EU and all its major trading partners. Indeed, the SCCS "Notes of Guidance" describing this conservative approach to the overall risk assessment of cosmetic products and their constitutive ingredients are considered as 'the' international standard for cosmetic product safety assessment.

There is in our view no indication that the current approach is currently leading to an insufficient level of consumer protection. On the contrary, EU cosmetic products are recognised worldwide for their high safety standards thanks to the framework set by the Cosmetic Products Regulation and the supporting SCCS Noyes of Guidance.

Impact of introducing a MAF in the in the safety evaluation of cosmetic ingredients and products

The negative impact of adding a mandatory additional UF/MAF to cosmetic safety assessments would be significant across the whole industry.

Whilst CE could not have access to individual company products and the MoS values for their constitutive ingredients within the timeframe of the present consultation(s), we could still carry out a review of MoS values stated in the 190 SCCS opinions issued between 2005 and 2021. (i.e. on 132 hair dye ingredients, 14 UV filters, 16 preservatives and 27 ingredients with other function(s)).

The following table shows the proportion of uses that, although considered safe today, would no longer be considered as safe after introducing an additional Uncertainty Factor of 10, i.e. those uses of cosmetic ingredients that would need to achieve nominal MoS values of >1.000 to be considered as safe :

Affected by MAF 10	
Hair Dyes (n = 132)	55%
UV filters (n = 14)	71%
Preservatives in full body leave-on (n = 16)	81%
Preservatives in other leave-on, mouthwash, makeup remover (n = 16)	56%
Preservatives in Rinse-off, Make-up, Toothpaste (n = 16)	6%
Annex III ingredients in full body leave-on (n = 27)	63%
Annex III ingredients in other leave-on, mouthwash, makeup remover (n = 27)	33%
Annex III ingredients in Rinse-off, Make-up, Toothpaste (n = 27)	7%

As a consequence,

- a significant proportion of product safety assessments for leave-on products on the market would be invalidated, impacting over 100.000 cosmetic products on the EU market.
- the safety assessment of the majority of cosmetic ingredients in the Annexes of the CPR would need to be re-evaluated versus this new approach and standard, dramatically increasing the industry and SCCS workload, and possibly rendering a large fraction of their current uses illegal.
- innovation on the basis of new cosmetic ingredients and listing of new positive list ingredients would be severely reduced.
- the loss of the majority of the uses of preservative ingredients would make it practically impossible to ensure the mandatory microbiological safety of cosmetic products
- the loss of the majority of current UV filter uses would make it impossible to formulate/manufacture a large fraction of sunscreen products which currently offer adequate UV protection to various consumer categories, thereby contributing to public health.

In particular, the last two consequences could create a real, concrete and massive public health problem in the EU without a demonstrated positive effect on consumer safety, i.e. in order to address potential, theoretical concerns related to combination effects related to unintentional mixtures of chemicals.

With the current safety methodology and its exaggerated external exposure assessment and overall built-in conservatism, it would not be possible to simply recalculate the MoS of the ingredients affected. Given the significantly reduced pool of ingredients remaining available, reformulation would be also impossible for tens of thousands of products. The discontinuation of a large proportion of leave-on products in the EU would not only have a significant immediate economic impact, but would also severely damage the safety image of EU exports across the world which are at the core of the EU cosmetic industry business model. The reduced ingredient palette would also limit the EU' industry's capacity for innovation, thus further reducing its international competitiveness.

Conclusion

As outlined above, cosmetic products are intentional mixtures of well-known composition. Thorough safety evaluation & safety documentation adequately takes care of any possible combination effects/interactions between their constitutive ingredients.

Additionally, the current safety assessment approach for cosmetics is sufficiently conservative to implicitly address considerations of overall exposure stemming from different sources through its exaggerated, worst-case approach to exposure assessment. If potential, overall exposures was supposed to be explicitly taken care by an additional mandatory Uncertainty Factor this would only be workable if, at the same time, the underlying exposure assessment is changed from the current worst-case exaggeration used by industry safety assessors on a daily basis to a more realistic real-life exposure assessment. This would require a systematic and continuously updated market analysis of every cosmetic ingredient (market penetration, statistical distribution of use levels, consumer use pattern, etc.). For ingredients regulated in the Cosmetics Regulation Annexes, SCCS would need to develop the tools and methodologies to systematically obtain and assess such cross-industry market data. Similarly, the EU safety assessor community would need

to obtain and assess the same kind of market research data for every product on the EU market. In particular fore SME's, this will be prohibitively expensive.

Finally, we believe that, in addition to the above conservative exposure assessment, the other layers of built-in conservatism in the usual risk assessment paradigm applied to cosmetic ingredients are sufficiently protective to address any potential combination effects resulting from unintentional mixtures (of cosmetic ingredients with other chemical substances stemming from other sources).

In conclusion, we strongly believe that the current safety assessment approach applied to cosmetic ingredients -i.e. to produce nominal MoS values >100 under exaggerated exposure conditions and using a model with different layers of built-in conservatism- is sufficiently conservative to address any potential, risks of « combination effects ». Additionally, for very specific cases of concern, the Cosmetics Regulation provides the tools to carry out deeper assessments of overall exposure or combination effects. Accordingly, an additional systematic Uncertainty Factor (MAF) for all cosmetic ingredients is in our view not scientifically necessary and would have significant negative impacts on hundreds of thousands of cosmetic products currently on the EU market and exported worldwide.

Annex 3 – Nanomaterial definition

A workable nanomaterial definition for cosmetics that is applied consistently along the supply chain and between national authorities.

Discrepancies between the current nanodefinition in the CPR and the horizontal Commission Recommendation[38] have led to diverging interpretations and practices between EU member state authorities and across the supply chain, thus hindering the smooth functioning of the internal market. CE supports a clear and simple nano definition that applies across sectors, based on an update to Commission Recommendation 2011/696/EU of 18 October 2011.

The main objective of the CPR is not the classification of raw materials materials as nano/non-nano, but rather to ensure a high level of consumer safety of finished cosmetic products. Specific requirements for nanomaterials under the CPR are only warranted when a finished cosmetic product leads to systemic exposure to stable, solid nanoparticles. Specific requirements are not necessary when such exposure is excluded, e.g. when a nanomaterial ingredient loses its nano properties in the cosmetic product formulation or during application (e.g. solubilisation) or is not biopersistant in the body (i.e. rapidly metabolised and excreted). So far, this was achieved by directly adding specific criteria in the CPR nanomaterial definition (e.g. solubility criterion). However, this approach led to the discrepancies of definition and interpretations across the supply chain and across member states, as mentioned above. It would therefore be preferable, at the level of cosmetic raw materials, to fully align the definition in the CPR with the horizontal EU definition, but to restrict the nano-specific requirements to finished cosmetic products that expose consumers to stable, solid nano-particles.

Alignment with the horizontal definition will classify a large number of solid raw-materials as 'nanomaterial', mainly because the qualifying criterion of 'intentionally manufactured' is not included in the horizontal definition in contrast to the current CPR definition. Consequently, a large number of cosmetic ingredients will be reclassified as 'nano', not due due to any specific intentional nano properties but rather due to unavoidable presence of traces amounts of nanoparticles.

CE assessed the cosmetic ingredient database, COSING, against a reference list of nanomaterials[39] based on the definition in the current Commission Recommendation. An assessment of > 800 cosmetic formulas from 27 companies indicates that approximately 30% of cosmetic formulas on the EU market (approx. 200.000 products) will contain at least one ingredient newly classified as nanomaterial.

Compared to 25 recognised nanomaterials under the CPR definition today, the number of nanomaterials is expected to increase to at least 220 ingredients, about half of which are listed in Annex IV of the CPR as cosmetic colorants. This will result in a large number of substances (probably > 100) requiring preparation of safety dossiers, SCCS evaluations and technical adaptations to the Cosmetics Regulation Annexes. For non-positive list nanomaterials, many

[38] Recommendation 2011/696/EU of 18 October 2011

[39] Combination of EUON database, FR Inventory of nanomaterials and BE inventory of nanomaterials

individual company dossiers may be notified in parallel for the same ingredient. Consolidating those for the preparation of a single opinion would further add to the SCCS workload.

Cosmetics Europe supports a smooth implementation and transition towards the updated harmonized EU definition of nanomaterials, whilst still taking into consideration the aspects of risk to the human health (risk of systemic exposure to solid nano particles). Given the large number of newly classified nanomaterials, this will require careful planning and sufficient time to allow industry to prepare and submit nano-notifications and for SCCS to review positive list materials and possibly other nanomaterials. Also, clear guidance at EU level will be required to ensure an efficient implementation of the nano-specific requirements to finished products. All these steps are needed to ensure the regulatory continuity for a large number of ingredients.

Any policy option definition of nanomaterials that is going beyond the updated harmonised definition, such as Option B presented under the Targeted Questionnaire, would pose similar practical issues as the simple alignment with the horizontal definition. These issues would, however, be amplified to a point that the regulatory approach would become unworkable. Furthermore, having again a 'bespoke' definition for cosmetics that is different from the (updated) horizontal EU definition, would fail to address the main problem that the CSS tried to address, i.e. lack of a harmonised nanomaterial definition that applies in a cross-sector manner.

Annex 4 – Future of SCCS/OSOA

Maintaining a strong expert committee on cosmetics safety assessment that benefits an OSOA environment

Introduction

The CSS introduces the concept of One Substance One Assessment (OSOA) with the objective of simplifying assessment procedures to avoid inconsistencies, slow procedures, inefficient use of resources and unnecessary burdens. This objective shall, *inter alia*, be achieved through the reallocation of the technical and scientific work on chemicals, including the work of the Scientific Committee on Consumer Safety (SCCS).

CE 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' ("OSO(H)A"), can help achieve this. This approach could allow collation of all available hazard data across industry sectors, resulting in a single, common, coordinated, and horizontal hazard characterisation of chemicals as the starting point[40]. Moreover, CE fully supports optimizing the use of resources and ensuring consistent and coordinated approaches on safety assessments. The current assessment by ECHA of Propylparaben exemplifies the need for coordination and prioritization of various initiatives on chemicals by authorities and scientific bodies across legislations, and the necessity of an adequate sequencing where the overall hazard characterization is made before the sector safety assessments[41]. This hazard assessment would then be the basis for respective sector-specific safety assessments, carried out in the various sectors in parallel and coordinated by the various assessment bodies.

Sector specific safety assessments remain essential since use and exposure patterns are sector specific and can vary significantly, thus requiring specific scientific expertise and knowledge relating to the sector. For cosmetics, the SCCS has built up and constantly evolved a specific and unique cutting-edge expertise over more than 40 years with regards to safety of cosmetic ingredients and products. The SCCS and its opinions are recognised internationally and have become the basis for cosmetic ingredient regulations in many geographical jurisdictions (e.g., ASEAN, Latin America), thus facilitating trade and exports of cosmetic products from the EU which are at the heart of the EU cosmetic industry business model.

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

[41] Propylparaben was included in 2013 in ECHA's Endocrine disruptor assessment list. The assessment has not been completed yet and its status is still under development. The substance has had several ECHA processes along the years and was later also listed as CMR 2 in the registry of intentions. Propylparaben has been evaluated six times by the SCCS between 2005 and 2013. During 2019 a call for data due to suspected endocrine disruptors concerns was launched and as a result a new SCCS evaluation took place during 2020.

Since 2004, the CPR imposes specific requirements with respect to animal testing. Therefore, continuation of the work by the existing regulatory stakeholders in the specific field of non-animal tests and safety assessment is imperative for the cosmetic sector. The SCCS has evolved with the very specific Animal Testing Ban provisions under the CPR and is continuously developing state-of-the-art scientific approaches on alternative methods.

It is paramount that any reattribution of the technical and scientific work of the SCCS can guarantee that its globally recognized experience, scientific excellence and regulatory acceptance in the field of non-animal test methods and scientific assessments are maintained and strengthened.

The Cosmetics Safety Assessment – Confirming the principles for a future committee on cosmetics safety assessment

The European Union is recognized with its current model as setting the highest, worldwide, standards regarding cosmetics safety. Safety assessment of cosmetic ingredients that considers the consumer exposure is the method of choice to ensure cosmetic products are safe for consumers and professional users of cosmetics. The most important part of the safety assessment is the characterisation of the consumer's exposure, whereas the identification of the hazard may inform when a safety assessment is necessary. The cosmetic sector and the SCCS have accumulated extensive and detailed understanding and data regarding how consumers are exposed to cosmetic products and their ingredients, enabling the preparation of accurate safety assessments leading to the bi-annual revision of the SCCS Notes of Guidance, a key reference tool for the safety assessment of cosmetic ingredients and products.

Expertise on the specificities of cosmetic exposures needs to be combined with a pragmatic approach based on sound safety assessment principles, e.g., Weight of Evidence approach. Further, as mentioned above, because of the animal testing ban in the CPR, the specific cosmetics safety assessment necessitates a cutting-edge expertise on the use and reliability of New Approach Methodologies (NAM)/New Generation Risk Assessments (NGRA).

In conclusion, cosmetic safety assessments therefore require a dedicated committee with special expertise and knowledge of cosmetic products, their ingredients and consumer use and exposure.

Irrespective of the final responsible agency or EU Commission service in charge of cosmetics safety assessment, this body must at all moments be guided in its work by the three well established principles for scientific advice on consumer health, Scientific Excellence, Independence and Transparency, as regularly confirmed by the EU Commission in public Communications[42].

The Principle of Scientific Excellence infers that, cosmetics safety assessments should at all moments be guided by up-to-date scientific expertise, performed by experts with a proven scientific expertise and experience demonstrated by the candidates for the defined range of disciplines, including on NAMs/NGRAs. Members should be selected based on their scientific qualifications and represent their own independent views.

The Principle of Independence requires any committee on cosmetic safety assessment to observe the highest level of independence. Experts should be free of interests which may conflict with the

[42] Communication from the Commission 30.04.1997 and Commission Decision of 07.08.2015 establishing scientific committees

requirement to give independent advice as necessary. It further implies that experts should be nominated in their personal capacity based on a public application process that allows any interested expert to apply. The committee should act independently and in the public interest. Scientific opinions should be based on sound science related to consumer safety, and not guided by external interests.

Finally, the principle of Transparency covers easy access to information on committee working procedures and their advice as well as transparency towards stakeholders about the different steps of the establishment of the advice, including on the scientific reasoning and minority opinions.

Maintaining a strong expert committee on cosmetics safety assessment in an "OSOHA" environment

Therefore, in view of the above established principles, Cosmetics Europe would like to make the following comments to the proposed impact assessment options[43]:

- *Option 1: Baseline scenario – The SCCS remains with the Commission.*
  This is the current scenario which, based on Cosmetics Europe's experience works very well and perfectly implements the three above principles. Members of the SCCS hold a high level of scientific expertise (including on NAMs), and the current SCCS benefits from a strong international recognition in terms of quality of its safety assessments and its contribution to the current branding of the European Union as a state-of-the art scientific flagship for cosmetics safety. Processes are transparent, with a good understanding by the stakeholders of the SCCS scientific reasoning, based on the SCCS Notes of Guidance as a reference tool. A dedicated committee allows the management of cosmetic sector specific priority tasks, e.g., the Commission hair dye strategy[44] in the past or the assessment of priority cosmetic ingredients potential of ED properties[45]. This option also provides the EU Commission with continuity of high caliber safety assessments from which appropriate cosmetic risk management actions can be implemented. The EU Commission should not underestimate the value of this consistent, reliable and forward-thinking scientific body. The current SCCS model and rules of procedure could still in Cosmetics Europe's view be improved through a more-systematically implemented dialogue with stakeholders including industry, such as those adopted by EFSA. If this option is maintained, it could be further built upon to respond to the needs of OSO(H)A. Cosmetics Europe would indeed support an improved cooperation with other agencies, to ensure further consistency and adequate prioritization and sequencing.

[43] The comments are made only with respect to the cosmetics safety assessment. It should not be forgotten however that the remit of the SCCS covers all non-food consumer products and services

[44] https://ec.europa.eu/growth/sectors/cosmetics/cosmetic-products-specific-topics/hair-dye-products_en

[45] https://ec.europa.eu/growth/sectors/cosmetics/cosmetic-products-specific-topics/endocrine-disruptors_en

- *Option 2 – The SCCS remains a stand-alone committee within ECHA. The SCCS is strengthened in order to maximise synergies with existing scientific capacities of ECHA. Existing high-level expertise and methodologies of the SCCS are preserved.*
  This option may constitute a workable solution, provided indeed that the existing high-level expertise, rules of procedure, SCCS Notes of Guidance and inherent methodologies of the SCCS are preserved, and the change constitutes a mere move of the SCCS Secretariat to ECHA. A commitment to enable and continuously grow the expertise of the SCCS would in turn allow continued development of non-animal test methods applicable to the safety assessment of cosmetic ingredients and products thus allowing an expansion of the database of non-animal test data. Under this assumption, the positives from Option 1 would be safeguarded, whilst responding to the desire to enhance efficiencies, coordination, and synergies in an OSO(H)A approach. In such a scenario, both the environmental and human health assessments could be with the SCCS. This would allow strengthened and more targeted management of the environmental risks of cosmetic ingredients, similar to the approach taken for human safety aspects.[46] Finally, such a policy option would maintain the SCCS as the only scientific advisory committee of the risk managers currently within DG GROW, thus enabling a smooth management and coordination of priorities.

- *Option 3 – SCCS work is integrated into RAC of ECHA, after adaptation of the RAC framework/structure and membership to ensure sufficient capacity to deal with a higher number of assessments and ensuring sufficient expertise and continuity of existing methodologies developed by the SCCS*
  It is difficult to evaluate this proposal in the absence of a clear understanding of a potential reform of RAC. It is indeed unclear whether this solution equals the creation of a "cosmetics sub-committee" to RAC, composed of already existing RAC members, or whether the experts of the SCCS would likely stay and be integrated to such a "sub-committee" of the RAC. In the latter case, RAC should characterize horizontally the hazard (OSO(H)A principle) and the sub-committee should then perform the safety assessment, whilst presumably having RAC as the final body adopting the scientific opinion.
  In any event, this option is likely to lead to a significant change to the current organisation of the SCCS. Arguably, such a change will neither guarantee that the three above mentioned principles are upheld, nor that the desire of efficiency of the agencies is reached. It would require a significant reform of the RAC in terms of expertise, resources, and processes. Changes to the SCCS itself would likewise be important if it must adopt the RAC Rules of Procedure. Processes would likely be slowed down since RAC would need to validate/review and adopt the significant work of the SCCS that will need to be done by the sub-committee, adding a layer to the adoption process of scientific opinions and an increased workload on RAC. As a reminder, today, the main activities of the SCCS cover the review of cosmetics ingredients safety dossiers[47], the regular revision of the SCCS Notes of Guidance, and the representation of the SCCS externally at academic and policy events. It

[46] Environmental expertise could be added to the SCCS through the merger of the current SCCS and SCHEER
[47] The SCCS delivered 18 scientific opinions in 2021, based on the assessment of industry submitted safety dossiers,

should however not be forgotten that the SCCS remit is broader than only cosmetics and covers all non-food consumer products and services.
Further, the principle of scientific excellence would not be upheld since members of RAC would have to adopt (at the level of RAC) cosmetic specific opinions whilst likely lacking the appropriate expertise related to cosmetic safety assessment mentioned above. This is unlikely to be acceptable in the long-term for the cosmetics experts in the sub-committee, leading to a potential loss of expertise, including on NAMs. Similarly, in this scenario, how can it be guaranteed that the maintenance and adaption of the current SCCS Notes of Guidance to new non-animal methodologies and knowledge get the attention they deserve, with regular updates and interactions between relevant stakeholders, particularly when ECHA is currently not committed to the elimination of animal tests whereas the CPR mandates no animal testing? Data access and cross-sector assessment may be facilitated by a common secretariat, but this would be at the expense of loss of expertise for the specific sector assessments and could be easily facilitated in other ways than moving the SCCS. Finally, because of the integration as a sub-committee to RAC, the international visibility of the SCCS would likely be reduced, and the priorities of the cosmetics risk managers (DG GROW) on cosmetic ingredients might be diluted amongst other agendas.

- *Option 4 – SCCS is absorbed by the RAC of ECHA, without adapting the RAC. In this case the RAC framework/structure, membership and methodology will apply*
  This option ignores all the principles on which the current SCCS is built and constitutes a fundamental change to the processes on cosmetics safety assessment as they are known today. The absorption of SCCS into RAC would likely lead to the experts of the SCCS being dismissed from their functions, with the cosmetics safety assessment being performed by regular RAC members who arguably lack the appropriate expertise in cosmetics safety assessment. Such a scenario would lead to the total loss of all expertise built up within the SCCS, and with only generic chemicals safety assessment being performed for cosmetics. It would mean a significant increase of the RAC workload and a loss of the current international leadership on specific cosmetics safety assessment embodied today within the SCCS, thereby also weakening the CPR overall as an international reference. It would also lead to the loss of any dedicated discussions on methodologies (and relevant discussions on the current Notes of Guidance) and NAMs applied to cosmetics ingredients, in contrast to current societal and policy trends, whereas other policy options above could position the SCCS as a champion within ECHA of the regulatory acceptance of NAMs & NGRAs. Finally, this option would lead to a significant change of internal process for national cosmetics authorities as well as for companies, leading to increased burden and costs for both companies and administrations to adapt to the new processes.

In conclusion, in the new OSO(H)A environment, the proceedings of the future scientific committee in charge of cosmetics safety assessment shall be based on the stated principles of scientific excellence, independency, and transparency. This committee should remain composed of qualified cosmetic safety expert and shall be able to perform robust cosmetics safety assessment based on state-of-the art methodologies, including the use of alternative risk assessment methods. Maintaining such an independent committee with dedicated experts within ECHA could enhance effectiveness and coherence in safety assessments, whilst contributing to further improve the ECHA knowledge on the use of NAMs in safety assessment.

Annex 5 – Digital Labelling

Future-proofing the means to convey consumer information and ensuring consistency across legislations

The current context

Today, the CPR's provisions related to mandatory consumer information[48] are limited to on-pack labelling. There is a clear need to include provisions allowing for digital labelling, to take account of the evolution of consumers' way of accessing information and of digital technologies.

One of the objectives of the EU is to reduce packaging waste; policy options being examined under the revision of the Packaging and Packaging Waste Directive include the reduction of packaging and of the packaging to product ratio.

The Fitness Check[49] of the most relevant chemicals legislation (excluding REACh) found that label comprehension and consequently consumer protection can be further improved by avoiding labels being overloaded with information and making labels more readable. Digital labelling provides opportunities for such improvement.

The current revision of the CPR is occurring in the context of other sectorial or horizontal legislative initiatives related to consumer (as well as multi-stakeholder) information; these, for example the future digital product passport, will add new requirements on content as well as on the means for conveying it (physical- vs digital vehicles and tools).

Rationale for the CE position

Increasing labelling requirements, decreasing packaging

Compared to other consumer products, cosmetics have a relatively smaller size. Manufacturers are already making efforts to reduce their packaging; legislative measures that go in this direction are expected to be introduced by the revised Packaging and Packaging Waste Directive.

The labelling requirements of the CPR are already comprehensive; additional labelling requirements are expected in the near future, for example:

- labelling of up to 60 additional substances that have been identified as likely to cause an allergenic reaction under the CPR;
- packaging-related labelling requirements under the revised Packaging and Packaging Waste Directive;
- information (sustainability labels) under the proposed Ecodesign Regulation;

In addition, several Member States have recently introduced national packaging-related information requirements.

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[48] Today's labelling system for cosmetic ingredients was introduced via the 6th Amendment to the former Cosmetics Directive in 1993.

[49] Fitness Check of the most relevant chemical legislation (excluding REACh) | European Commission (europa.eu)

Based on the two points above, it will be physically impossible to accommodate all the current and upcoming information requirements on the label of cosmetic products in a way that is readable and understandable by consumers.

Benefits of digital labelling

For consumers, it offers the possibility to: search and compare products; search individual ingredients; access additional information on ingredients, environmental properties, etc., in own language; improve legibility of the text; search information on products purchased previously; convert text into spoken information via existing applications. A large-scale consumer survey performed for Cosmetics Europe in 2018, including users and non-users on internet, found that "the digital ingredients list showed a real advantage over the on-pack list in terms of legibility, modernity and impact on the environment".

For the environment, regulatory changes to (digital) labelling requirements would no longer require modifications of artworks, re-printing of labels and destruction of packaging which does not comply with the new requirements. Depending on the % share of products to be potentially affected by on-pack labelling changes, figures are available[50] to demonstrate the cost of withdrawing and destroying even a small percentage of products from the market, as well as the quantities of packaging and formulations that would thus have to be disposed of.

For industry, regulatory changes to on-pack labelling entail significant costs for companies: changes to the design of artworks, withdrawal from retail and management of obsolete products including destruction (although still safe for use) and packaging, printing of new packaging, manual updates of the Product Information File, re-registration of products in non-EU markets, etc. Furthermore, in the case of (natural) ingredients, labelling changes are recurrent due to the fact that the composition of natural ingredients may be different from one harvest to another, depending on where they are sourced from geographically, the season, etc. Such costs would be avoided should the ingredients list be communicated digitally in the future.

For authorities: digital labelling "could lead to simplified processes of compliance checks of products (relevant to market surveillance authorities, e.g. through customised information, quick searches, languages)"[51]; the Commission proposal for an Ecodesign Regulation foresees comprehensive market surveillance requirements, including in relation to the digital product passport; it also foresees investments in equipment and IT tools as well as staff training.

Consumers more and more digitally savvy

As of the beginning of 2021, almost nine out of ten (89%) of individuals in the EU, aged between 16 and 74 years, used the Internet (at least once within the three months prior to the survey date)[52].

The proportion of the EU's population that had never used the Internet was 8% in 2021 (18 percentage points lower than in 2011 when it had stood at 26%)[53].

[50] As part of the CE contribution to the impact assessment study on labelling of fragrance ingredients 2019/2020
[51] Inception Impact Assessment for the revision of the CPR, Ref. Ares(2021)6011962 - 04/10/2021
[52] Eurostat, Digital economy and society statistics – households and individuals, 2021

In 2019, 73% of individuals aged 16 to 74 within the EU used a mobile device to connect to the Internet (compared to 48% in 2014, which is an increase of 25 percentage points over 5 years[54].

The percentage of online shoppers in the EU population aged between 16 and 74 years was 66% in 2021. Online sales of products in the 'cosmetics, beauty or wellness' category represented 27% of the total online sales[55].

A gradual approach to digital labelling would benefit consumers, control authorities and economic operators

Consumers and control authorities need to adjust to the new ways of accessing information on cosmetic products.

Economic operators are at various stages of digitalisation and need to adapt their internal structures and information / labelling systems to the transition from on-pack labelling to digital information.

Not all mandatory information is necessary or feasible at online/other distance points of sale

Two of the information items currently required on-pack are neither necessary nor feasible to be displayed at online or other distance points of sale:

- the batch number: it is not a relevant information for consumers at the point of purchase; this number is different for every batch and it would be impossible to keep the webpage up-to-date with all the batch numbers of the product items in stock; the batch number is always available on-pack for traceability purposes.
- the date of minimum durability: this information is changing for the same product as new items are manufactured and it is not possible to guarantee that the date on the webpage will be the same as on the actual item purchased online; furthermore, retailers may be de-selecting safe, fully compliant products based on the date which could result in unnecessary product wastage; this information is always available on-pack.

Such an approach is in line with practice at national level; for example, in France the authorities consider the batch number and the date of minimum durability as non-essential product characteristics which are optional information at online points of sale (without prejudice, of course, to the obligation of manufacturers to print this information on products' label).

Conclusion

Given that the revision of the CPR with regard to consumer information / digital labelling is occurring in the context of revisions[56] of existing regulations and introduction[57] of new ones, the Commission should apply a holistic, coherent and consistent approach to these, for the benefit of consumers, industry and control authorities.

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[53] Eurostat, E-commerce statistics for individuals, 2022
[54] Eurostat, Digital economy and society statistics – households and individuals, 2021
[55] Eurostat, E-commerce statistics for individuals, 2022
[56] For example, the revision of the Packaging & Packaging Waste Directive
[57] For example, the proposed Ecodesign Regulation, introducing a mandatory digital product passport

Given the (a) ever-increasing labelling requirements, (b) the need to improve[58] consumer protection by avoiding labels being overloaded with information and making them more readable, and (c) the increasing prevalence of digital means in consumers' daily lives[59], there is a strong need to update[60] Article 19 of the CPR and to make it 'future-proof' through the introduction of digital labelling provisions.

Our recommended solution would be to empower the Commission to address digital labelling in secondary legislation in the near future, ahead of the next (full) revision of the CPR. This could be prepared with involvement of all relevant stakeholders, on the basis of commonly agreed objectives and roadmap.

Any mandatory digital labelling requirements should be introduced gradually, with clear steps and milestones including an adaptation phase, and should be accompanied by sufficiently long transition periods to allow economic operators, especially the SMEs, to adapt their systems to the new requirements.

Responsible Persons should ensure that information accessed digitally in future (via a technology such as QR codes, barcodes, etc.) will be as accurate as it is on-pack today for all SKUs[61] in cases where different variants of the same product co-exist on the market.

The information required under Article 19.1 paragraphs (a), (b), (c) – period after opening only - (d), (f) and (g) should be provided with the product offer where the product is made available on the market online or through other means of distance sales.

Safety warnings should always remain on-pack. However, on-pack harmonised symbols (used instead of text) could further improve consumer protection. Such symbols should either be demonstrated to be understood by consumers and (in the shorter term) / or (in the longer term) further explanatory information could be provided digitally.

[58] Fitness Check of the most relevant chemical legislation (excluding REACh) | European Commission (europa.eu)
[59] Eurostat, Digital economy and society statistics – households and individuals, 2021
[60] Today's labelling system for cosmetic ingredients was introduced via the 6th Amendment to the former Cosmetics Directive in 1993.
[61] Stock keeping units

Annex 6 – Consumer perceptions of the benefits of cosmetics and personal care products

... USED MULTIPLE TIMES EVERY DAY

A EUROPEAN CONSUMER USES

over **7** different cosmetics **daily**

nearly **13** different cosmetics **weekly**

Women use, on average, almost **9** different cosmetic products **daily** and **15** **weekly.**

Young people between 18-24 years - as many as **16** different cosmetic products **weekly.**

... MORE THAN MEETS THE EYE

COSMETICS AND PERSONAL CARE PRODUCTS

Over 80% of European consumers identify body care, skin care and hair care as cosmetics and personal care products.

... USED BY CONSUMERS

1. 

For their personal hygiene – 88% of consumers believe cosmetics they use are effective in ensuring their personal hygiene

2. 

To feel good about themselves

3. 

To protect their skin or hair

"**Feeling good about oneself**"

one of the top 3 reasons to use cosmetics across ALL product categories

27% of consumers under 25 years of age use make-up to boost their self-confidence.

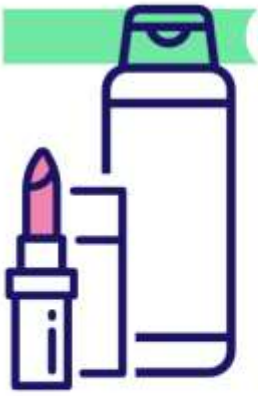
COSMETICS... →

... IMPROVE QUALITY OF LIFE

71%

of European consumers consider personal care and cosmetic products as important or very important in improving their quality of life.

... ENHANCE SELF-ESTEEM



IMPORTANT VERY IMPORTANT

70%

of European consumers said personal care and cosmetic products are important or very important for building up their self-esteem.

... ARE KEY FOR SOCIAL INTERACTIONS

62%

of European consumers believe cosmetics and personal care products are important or very important in how they are seen by others, and 62% for how they themselves interact with others.

Reference:
European Consumer Perception Study 2022 was conducted on behalf of Cosmetics Europe by Ifop in March 2022. Over 6000 consumers across ten European countries, i.e. Bulgaria, Denmark, France, Germany, Italy, Netherlands, Poland, Spain, Sweden and UK, were interviewed via an online questionnaire. Respondents were representative of each country's gender and age group distribution.

Cosmetics Europe
the personal care association

Cosmetics: Our Essentials for Daily Life
European Consumer Perception Study 2022

Annex 7 – Market performance data

Cosmetics and personal care industry Economic overview

Valued at €80 billion at retail sales price in 2021, the European cosmetics and personal care market is, along-side the USA, the largest market for cosmetic products in the world.

The largest national markets for cosmetics and personal care products within Europe are Germany (€13.6 billion), France (€12.0 billion), Italy (€10.6 billion), the UK (€9.9 billion), Spain (€6.9 billion) and Poland (€4.0 billion)*.

The following product categories hold the largest share of the European market: skin care (€23.2 billion) and toiletries (€20.6 billion), followed by hair-care products (€14.4 billion), fragrances/perfumes (€11.9 billion), and decorative cosmetics (€9.8 billion) *.

Exports of cosmetic products from Europe totalled €24.2 billion (trade value) in 2021. France and Germany were Europe's main exporters, exporting over €12.6 billion between them and accounting for over 50% of total global exports from Europe.

Including direct, indirect and induced economic activity, the industry supports over 2 million jobs. In 2021, over 255,111 people were employed directly, and a further 1.71 million indirectly in the cosmetics value chain.

In 2021, close to 7,000 SMEs were involved in the manufacturing of cosmetics in Europe.

*Based on Market Performance 2021, European Cosmetic, Toiletry & Perfumery Data.