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Targeted consultation for the revision of the Cosmetic Products Regulation

Fields marked with * are mandatory.

Introduction

The Cosmetic Products Regulation is the main regulatory framework for finished cosmetic products placed on the EU market. It establishes rules to be complied with by any cosmetic product, in order to ensure the functioning of the internal market and a high level of protection of human health.

The Chemicals Strategy for Sustainability outlines the European Commission's strategy to better protect citizens and the environment against hazardous chemicals and encourage innovation for the development of safe and sustainable alternatives in the framework of the EU Green Deal.

The Strategy fully recognises the fundamental role of chemicals for human well-being and for the green and digital transition of European economy and society. At the same time, it acknowledges the urgent need to address the health and environmental challenges caused by the most harmful chemicals. In this spirit, the Strategy sets out concrete actions to make chemicals safe and sustainable by design and to ensure that chemicals can deliver all their benefits without harming the planet and current and future generations.

The Strategy recognises the need for a targeted revision of the Regulation (EC) N° 1223/2009 on cosmetic products (or the Cosmetic Products Regulation) to achieve its objectives by addressing a number of problems that have been identified. To address the issues identified, a range of possible measures are being considered:

- An automatic ban of the most harmful chemicals (so-called "generic approach to risk management"), allowing their use only where it is proven to be essential for society;
- Taking into account the combination effects from simultaneous or subsequent exposure to chemicals from different sources;
- Review of nanomaterials definition;
- Improving labelling information on cosmetic products, and;

- Streamlining the scientific assessment on cosmetic products by reattributing the work of the Scientific Committee on Consumer Safety (SCCS) to the European Chemicals Agency (ECHA).

The overall objective of the targeted revision is to ensure that relevant provisions of the Cosmetic Products Regulation reflect the ambitions of the Commission on innovation for safe and sustainable chemicals and a high level of protection of health and the environment, while preserving the internal market, as provided for in the Chemicals Strategy for Sustainability.

This questionnaire targets specific stakeholders to provide evidence of the current activity (the baseline) and the potential impacts, costs and benefits of the policy changes under consideration. Based on your self-identification in the “About you” section, questions will be presented across seven sections as pertinent. The sections could include:

0. Baseline
1. Generic approach to risk management (GRA) and essential use
2. Combination effects from simultaneous exposure to chemicals from different sources
3. A review of the definition of nanomaterial and scope of application
4. Changing information provision on labels of cosmetic products
5. Scientific and technical work on cosmetics performed by the Scientific Committee on Consumer Safety (SCCS)
6. Additional information and feedback

Further, some respondents may only wish to focus their engagement on one or a few of the sections 1-5, as relevant.

* Please select as many of the following sections as you wish to focus on:
- [x] GRA and essential use
- [x] Combination effects
- [x] Review of nanomaterials definition and scope of application
- [x] Labelling
- [x] Scientific and technical work performed by the SCCS

This questionnaire will be open until midnight Tuesday, 21 June 2022.

You can save your progress as a draft and continue at a later time by following a link generated by the "Save As Draft" button

If you chose to download the survey as a PDF for reference, the PDF will contain every question, regardless of your selection for the 'About You' questions in the survey.

At the end of the survey, respondents will also be invited to a follow-up interview, which the consultants leading this project on behalf of the Commission will be organising for a more in-depth exploration of the evidence.

Finally, please note that, in this questionnaire, cosmetic products refer to “any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours” based on the “Glossary and Acronyms related to cosmetics legislation”.

About you

* This selection will determine what relevant questions you will see, please do not worry if there are gaps in the number/lettering of questions throughout the survey.

I am giving my contribution as

- ○ Academic/ public research institution
- ◉ Business association
- ○ Company/business
- ○ Consumer organisation
- ○ Consumer
- ○ Non-governmental organisation (NGO)
- ○ Public authority, Committee or another public organisation
- ○ Trade union
- ○ Other

* First Name

ANNA

* Surname

PATERA

* Email

manager@psvak.gr

* What geographic scope do your responses relate to?

- ○ International
- ○ Local
- ○ National
- ◉ Regional

* Organisation name

PSVAK THE HELLENIC COSMETIC, TOILETRY AND PERFUMERY ASSOCIATION

* Organisation size

- (●) Micro (1 to 9 employees or €2 million or less turnover)
- ( ) Small (10 to 49 employees or €10 million or less turnover)
- ( ) Medium (50 to 249 employees or €50 million or less turnover)
- ( ) Large (250 or more or more than €50 million turnover)

* Country of origin

Greece

Privacy and Data

The Commission will publish the contributions to this targeted consultation in an anonymised and non-identifiable format unless explicit permission is granted by the respondent.

Contribution publication privacy settings

The Commission will publish the responses to this targeted consultation in an anonymised and non-identifiable format (e.g., grouped by type of respondent, etc.) as part of a Study Report.

* Please select below the privacy option that best suits you to ensure that your response is managed accordingly.

- ( ) Anonymous: Your name will not be published. The type of respondent selected for this consultation and your country of origin may be published in a way that the respondent remains unidentifiable. Your name and contribution will not be published as received. Your response will be used in the development of a consultation synopsis, and part of an evidence-gathering exercise so that it cannot be traced back to the individual respondent. Please do not include any personal data in the contribution itself.
- (●) Public: Your name, the type of respondent selected for this consultation, your country of origin will be published. In this case, your contribution could also be published in a way that it is identifiable, albeit it is most likely that it would be published in aggregated way.

Data protection provisions

Please review the privacy notice attached below, concerning personal data protection provisions.

TSC_privacy_notice_final.docx.pdf

☑ I agree with the personal data protection provisions

Please remember that the questionnaire is targeted to different types of stakeholders. Stakeholders will only be referred to the relevant questions for you. Please do not worry if there are sections that are blank for you or the question numbering/lettering appears to have gaps.

Baseline

*

Question 0u.

Based on your understanding of the available science, what might the net impact of the current levels and types of consumption of cosmetic products be on human health in the EU-27?

Please select the most appropriate answer

- ○ **Significant negative** impact on human health in the EU
- ○ **Some negative** impact on human health in the EU
- ○ **Limited negative** impact on human health in the EU
- ○ **No** impact on human health in the EU
- ○ **Limited positive** impact on human health in the EU
- ○ **Some positive** impact on human health in the EU
- ◉ **Significant positive** impact on human health in the EU
- ○ Don't know

* **Question 0v.**

Based on your understanding of the available science, what might the net impact of current levels and types of consumption of cosmetic products be on the environment in the EU?

Please select the most appropriate answer

- ○ **Significant negative** impact on the environment
- ○ **Some negative** impact on the environment
- ◉ **Limited negative** impact on the environment
- ○ **No** impact on the environment
- ○ **Limited positive** impact on the environment
- ○ **Some positive** impact on the environment
- ○ **Significant positive** impact on the environment
- ○ Don't know

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1. Generic approach to risk management (GRA) and essential use

The Chemicals Strategy for Sustainability (CSS) announced extending the so-called "generic approach to risk management" (GRA), which means that the most harmful chemicals will be prohibited in cosmetic products by default, while allowing limited exemptions under conditions clearly defined in law. This differs from a specific approach to risk management requiring proof of an unacceptable risk for each use before introducing a restriction.

The CSS also introduced a new potential approach for managing exemptions with the essential use concept, which would allow the use of the most harmful chemicals only exceptionally and under very strict conditions.

The European Commission has highlighted[1] that the Cosmetic Products Regulation is not yet aligned with the CSS in terms of implementing the generic approach to risk management and the essential uses concept.

The targeted revision of the Cosmetic Products Regulation aims to align the legislation with the GRA and essential use concepts. Beyond the baseline, the extension of the GRA within the Cosmetic Products Regulation could capture new or additional requirements for: 1) chemicals classified as carcinogenic, mutagenic or toxic for reproduction (CMR category 1 = known or presumed; and/or category 2 – suspected); 2) endocrine disruptors for human health (EDC HH category 1 = known or presumed; and/or category 2 – suspected); 3) chemicals affecting the immune, neurological or respiratory systems; and/or 4) chemicals that are toxic to a specific organ (specific target organ toxicity repeated or single exposure STOT RE/SE). These extensions would be complemented by the pertinent essential use derogations.

According to the aims of the CSS, the “essential use” criteria will be developed and applied to allow the use of these most harmful chemicals only when proven essential for society, for example, for health and safety reasons or if a chemical is critical for the functioning of society and there are no alternatives that are acceptable from environment and health perspectives. The Commission is working to define the criteria, which will guide the application of the essential use concept in all relevant EU legislation for both generic and specific risk assessments.

At this stage, the policy measures under consideration are listed below:

1. CMR Category 2 - Extend current provisions applying to CMR Categories 1A/B to Category 2 substances
2. Address lactation - Extend current provisions to include adverse effects on or via lactation (as part of reproductive toxicity)
3. EDC Categories 1 and 2 - Introduce explicit provisions for both ‘known/presumed’ (Category 1) and ‘suspected’ (Category2) endocrine disruptors for human health
4. EDC Category 1 - Introduce explicit provisions only for ‘known/presumed’ (Category 1) endocrine disruptors for human health
5. EDC Category 2 - Introduce explicit provisions only for ‘suspected’ (Category 2) endocrine disruptors for human health
6. Immune system - Introduce explicit provisions for chemicals affecting the immune system
7. Neurological system - Introduce explicit provisions for chemicals affecting the neurological system
8. Respiratory system - Introduce explicit provisions for chemicals affecting the respiratory system
9. Specific organ toxicity - Introduce explicit provisions for chemicals toxic to specific organs
10. Revise exemptions 1 - Revise and/or extend exemption on compliance with the food safety requirements as defined in Regulation (EC) No 178/2002
11. Revise exemptions 2 - Revise and/or extend exemption on the lack of suitable alternatives
12. Revise exemptions 3 - Revise and/or extend exemption on the application if made for a particular use of the product category with a known exposure
13. Revise exemptions 4 - Revise and/or extend exemption on the use evaluated as safe by the SCCS in cosmetic products (based on exposure to these substances and taking into consideration the overall exposure from other sources, and specific vulnerable population groups)

14. Exemptions for essential use - Introduce a new criterion (that may replace parts or all of the existing exemptions) to only grant an exemption for uses proven to be essential for society, provided their use is safe for human health, no suitable alternatives are available and only if their use in cosmetics is necessary for health, safety or critical for the functioning of society.

The 'most ambitious' policy scenario would be:

- The current provisions for CMR 1A/B under Article 15(2) would be extended to CMR 2 substances and include the adverse effects on or via lactation;
- Explicit provisions introduced for both "known/presumed" (Cat. 1) and "suspected" (Cat. 2) endocrine disruptors for human health, aligned with the GRA for CMRs in cosmetics;
- Explicit provisions introduced for chemicals affecting the respiratory system, neurological system, immunological system and chemicals toxic to a specific organ (repeated and single exposure), aligned with the GRA for CMRs in cosmetics.
- The introduction of the essential use concept that allows the use of chemicals only if their use is safe for human health, no suitable alternatives are available and only if their use in cosmetics is necessary for health, safety or critical for the functioning of society.

[1] Inception Impact Assessment – Revision of the Cosmetic Products Regulation, https://ec.europa.eu/info/law/better-regulation/.

The following questions seek your views on how these policy options could affect you or other key stakeholders in the EU-27.

Question 1a.

Please share information on the **percentage of the number of cosmetic products** sold in the EU-27 market in 2019 that would contain substances that are or could be classified as follows. If you do not have information, please tick "don't know".

Please select the most appropriate for each drop-down

* CMR Cat 1A/B

>60 – 70%

* CMR Cat 2

>40 – 50%

* EDC Cat 1

>30 – 40%

* EDC Cat 2

>70 – 80%

* Chemicals affecting the respiratory system

>70 – 80%

* Chemicals that are toxic to a specific organ

>60 – 70%

* Chemicals affecting the immune and neurological systems

>60 – 70%

* Any of these 'classifications' (i.e., concerning products that have at least one of the classifications outlined above)

>90 – 100%

* **Question 1h.**

The 'most ambitious' GRA extension and essential use concept together could lead to…

Please select the most appropriate

- Significant (~90%) reduction in any direct negative impact on **human health** in the EU from the manufacturing and use of cosmetic products
- Some (~50%) reduction in any direct negative impact on **human health** in the EU from the manufacturing and use of cosmetic products
- Limited (~20%) reduction in any direct negative impact on **human health** in the EU from the manufacturing and use of cosmetic products
- No reduction in any direct negative impact on **human health** in the EU from the manufacturing and use of cosmetic products
- An increase in any direct negative impact on **human health** in the EU from the manufacturing and use of cosmetic products
- Don't Know

* **Question 1i.**

The 'most ambitious' GRA extension and essential use concept together could lead to…

Please select the most appropriate

- Significant (~90%) reduction in any direct negative impact on the **environment** from the manufacturing and use of cosmetic products
- Some (~50%) reduction in any direct negative impact on the **environment** from the manufacturing and use of cosmetic products
- Limited (~20%) reduction in any direct negative impact on the **environment** from the manufacturing and use of cosmetic products
- No reduction in any direct negative impact on the **environment** from the manufacturing and use of cosmetic products
-

An increase in any direct negative impact on the **environment** from the manufacturing and use of cosmetic products

- Don't Know

Please describe your assumptions and sources of evidence concretely.

Sources of Information:
1. Cosmetics Europe has checked 750 cosmetic formulations - covering the whole range of cosmetic products - against potential "GRA substances" and provided the percentages of products that contain ingredients that would be classified as "GRA substances". A limited number of 20 substances (alcohol, plant ingredients) are responsible for two thirds of the GRA occurence in the formulations.
2. A survey of Cosmetics Europe revealed that consumers regard cosmetics as very important in their daily lives, contributing to their well being and improving the quality of life. In the case that GRA extension and essentiality concept are introduced, a large number of cosmetic ingredients would be banned, despite the fact that they are proven to be safe for the specific usage. Those products, such as toiletries, oral care, hair care, skin care, sun protection etc, would be unavailable for consumers causing negative impact on human health - hygiene, protection, well-being.

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2. Combination effects from simultaneous exposure to chemicals from different sources

According to the Commission's Implementing Decision 2013/674/EU 'Guidelines on cosmetic product safety assessments', the safety assessors of finished cosmetic products must consider the potential combination effects of ingredients used in cosmetic products (intentional mixtures) taking into account the identified normal and reasonably foreseeable use.

- Under the Cosmetic Products Regulation, there are already a number of mixture-relevant provisions, including: requirement for the cosmetic product safety report under Annex I of the Regulation to consider cosmetic products (i.e. intentional mixtures), including the possible combination effects of substances in a given cosmetic product, before being placed on the market.
- The specification that the safety evaluation should cover additional assessment of the safety of the formulated product, which cannot be assessed by considering the substances/mixtures separately, including assessment of possible combination effects, such as one ingredient that can increase the absorption rate of another ingredient (in a given cosmetic product).
- The requirement under Article 15(2)(d), regarding safe use of CMR category 1A/1B substances, which specifies that they must have been evaluated and found to be safe by the SCCS, taking into consideration overall exposure to a given CMR substance from other sources.

However, other than CMRs, the Commission has highlighted[2] that the Cosmetic Products Regulation does not currently include requirements to protect humans or the environment from combination effects of the most hazardous chemicals due to the simultaneous exposure to multiple chemicals, whether from cosmetics or other sources.

As it is currently not realistic or economically feasible to assess and regulate the very large number of possible combinations of chemicals, a practical approach for the cosmetics safety assessment to evaluate the simultaneous exposure to multiple chemicals could be the application of a Mixtures Assessment Factor (MAF).

Applying a MAF could be a pragmatic approach to manage the unknown, since a safety assessor is not aware of all substances that could also affect human health. In practice, when applying a MAF, exposure levels that are considered sufficiently safe for single chemicals are reduced by a certain factor to safeguard against risk from the combined exposure to multiple chemical substances.

It is important to highlight that the MAF is not an approach to managing the risks of 'intentional' mixtures, whose composition is known. Instead, it is intended to address risks from 'unintentional' mixtures to which humans and the environment may be exposed, both from cosmetic products and from other sources of exposure to chemicals.

The Commission is also considering introducing a MAF within the cross-sectoral Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), as part of the targeted revision of that legislation. Various options are currently being considered in that context including, with MAF scores of 1-5, 10 and 100, the scientific basis for deriving a value for a MAF, whether the MAF would apply to consumers, the environment, and/or workers (and whether there should be different values for each; and which categories of substance hazards the MAF might apply to).

Introduction of a MAF within REACH and other chemicals legislation (including cosmetics legislation) should lead to a coherent approach to addressing the risks from exposure to unintentional mixtures of chemicals.

The Commission is considering two main options for the introduction of a MAF in the Cosmetic Products Regulation:

- The possible application of a MAF to address the combination effects of unintentional mixtures of all substances used in cosmetics.
- The possible application of a MAF to address the combination effects of unintentional mixtures of the most harmful chemicals in cosmetics.

Some questions on how the MAF might be applied in the Cosmetic Products Regulation are covered in the Commission's Public Consultation and these are not repeated here. Instead, the questions below are intended to elicit more information on the potential impacts of a MAF.

[2] Inception Impact Assessment – Revision of the Cosmetic Products Regulation, https://ec.europa.eu/info/law/better-regulation/.

* **Question 2a.**

Based on your knowledge of human and environmental exposure to chemicals, including those within cosmetic products, what value of a MAF do you think is necessary within Safety

Assessments to ensure protection of health and the environment?

Please select the most appropriate answer

- (●) No MAF is required
- ( ) MAF of < 2
- ( ) MAF of 2
- ( ) MAF of 3
- ( ) MAF of 4
- ( ) MAF of 5
- ( ) MAF of 10
- ( ) MAF of 100

* **Question 2b.**

Taking into account the Commission's intention to investigate introducing a MAF in REACH and other chemicals legislation, do you or your organisation think a MAF under the Cosmetic Products Regulation should:

Please select all answers that apply

- [ ] Address risks from unintentional mixtures of substances from different cosmetics products to which consumers may be exposed
- [ ] Address risks from unintentional mixtures of substances from different cosmetic products to which consumers may be exposed, as well as from other (non-cosmetics) sources of exposure
- [ ] Address risks from unintentional mixtures in the environment from cosmetics and other sources of release / exposure
- [x] Other

If other, please specify.

The current safety assessment process under the Cosmetics Regulation includes exposure assumptions which over predict exposure to cosmetic ingredients from all sources of cosmetic usage, so it covers the risk from mixtures from different cosmetic products. If more detailed exposure data in available - from other sources than cosmetics - then it could be assessed by the same safety assessment process. There is no need for an additional factor to assess human safety of cosmetics. Environmental aspects are already covered under REACH.

* Please recall that the introduction of MAF is intended to address risks from 'unintentional' mixtures to which humans and the environment may be exposed, both from cosmetic products and from other sources of exposure to chemicals.

Question 2p.

Based on the evidence you have available, introducing a MAF of 10 could lead to…

Please select the most appropriate

- ( ) Significant (~90%) reduction in any direct negative impact on human health in the EU from potentially harmful unintentional mixtures

- ○ Some (~50%) reduction in any direct negative impact on human health in the EU from potentially harmful unintentional mixtures
- ○ Limited (~20%) reduction in any direct negative impact on human health in the EU from potentially harmful unintentional mixtures
- ○ No reduction in any direct negative impact on human health in the EU from potentially harmful unintentional mixtures
- ◉ An increase in direct negative impact on human health in the EU from potentially harmful unintentional mixtures
- ○ Don't know

* **Question 2q.**

Based on the evidence you have available, introducing a MAF of 10 could lead to…

Please select the most appropriate

- ○ Significant (~90%) reduction in environmental exposure to potentially harmful unintentional mixtures
- ○ Some (~50%) reduction in environmental exposure to potentially harmful unintentional mixtures
- ○ A limited (~20%) reduction in environmental exposure to potentially harmful unintentional mixtures
- ○ No reduction in environmental exposure to potentially harmful unintentional mixtures
- ○ An increase in environmental exposure to potentially harmful unintentional mixtures
- ◉ Don't know

Question 2r.

Would you expect similar, higher or lower effects on exposure to potentially harmful unintentional mixtures from different MAF scores, when compared to your answers to previous questions on the effects of a MAF of 10?

Please select one of the three options for each statement under each MAF scenario, or select don't know

When introducing a **MAF of 2**…

Statement	Similar	Higher	Lower	Don't know
* the impact on human health in the EU from potentially harmful unintentional mixtures would be…	○	○	◉	○
* the effects on environmental exposure to potentially harmful unintentional mixtures would be…	◉	○	○	○

When introducing a **MAF of 5**…

Statement	Similar	Higher	Lower	Don't know
* the impact on human health in the EU from potentially harmful unintentional mixtures would be…	◉	○	○	○

* the effects on environmental exposure to potentially harmful unintentional mixtures would be…	◉	○	○	○

When introducing a **MAF of 100**…

Statement	Similar	Higher	Lower	Don't know
* the impact on human health in the EU from potentially harmful unintentional mixtures would be…	○	◉	○	○
* the effects on environmental exposure to potentially harmful unintentional mixtures would be…	◉	○	○	○

Please describe your assumptions and sources of evidence concretely.

Cosmetics Europe has reviewed 189 SCCS opinions assessing the impact of the introduction of MAF to products containing ingredients listed in the Annexes of the cosmetics Regulation and the result is that 71% of the UV filters would no longer be considered as safe, 81% of the preservatives in leave-on products, 56% of the preservatives in rinse-off products etc. Products that contain more than one of these ingredients, after the introduction of MAF would be no longer considered as safe, depriving consumers from necessary products such as sunscreens. Reformulation of those products would be very difficult as remaining ingredients for use would be not enough. Approximately 70% of all substances listed in the Annexes of Cosmetics Regulation would need to be re-evaluated by the SCCS and relisted with lower use concentrations. Finally, the impact on the environment from a human-health related MAF under the Cosmetics Regulation cannot be predicted, as environmental aspects are covered under REACH.

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3. A review of the definition of nanomaterial

The current Cosmetic Products Regulation defines the term 'nanomaterial' as an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm. This definition enables the CPR to lay down specific provisions for the labelling of substances in the form of a nanomaterial and to require their notification via the Cosmetic Product Notification Portal (CPNP) 6 months prior to their placement on the EU market.

The 2011 Commission Recommendation 2011/696/EU of 2011 provides a different definition of a nanomaterial: a "Natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm."

As noted in the Report on the use of nanomaterials in cosmetics, differences exist between the definition of nanomaterial in the Cosmetic Products Regulation and the Commission's Recommendation 2011/696/EU, creating discrepancies across different sectors concerning the classification of materials as nanomaterials. For example, REACH applies the 2011 Recommendation and hence some materials are considered

nanomaterials under REACH and not under the Cosmetic Products Regulation, and vice versa. This may create questions and divergent approaches amongst competent authorities and economic operators across the single market.

As per the Chemicals Strategy for Sustainability, Recommendation 2011/696/EU on the (horizontal) definition of nanomaterial is under review, following an extensive stakeholder consultation and the Commission is in the process of revising the Recommendation. Following the adoption of the first Recommendation in 2011, the Commission is committed to ensure consistency between nanomaterial definitions across EU legislation through the use of the revised Recommendation.

The Recommendation on the definition of nanomaterials is a naming convention for materials in order to allow a common understanding across sectors. It does not include consideration of aspects such as potential human health or environmental impacts, or specific sector particularities. As one of the key aims of the Cosmetic Products Regulation is to protect human health, it is necessary to consider the regulatory treatment of cosmetic products consisting of nano characteristics in ways that may potentially lie outside the Commission definition of a nanomaterial.
To do this, a few scenarios have been developed and are summarised below. We ask you, as participant in this survey, to review and familiarise yourselves with these scenarios and take special note of the differences between them, so that you can consider the potential impacts that could arise from adjusting the current provisions of Article 16.

- **Baseline scenario -** This scenario reflects the current Cosmetic Product Regulation terminology (below) and the way in which nanomaterials are currently regulated under the Cosmetic Product Regulation. “An insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.” Under this scenario the Cosmetic Product Regulation nanomaterial definition has not changed and there is a continued disparity between materials defined as nanomaterials under the CPR and other chemicals legislation such as REACH.

- **Scenario A -** In this scenario the scope of regulation of nano-scale materials under CPR would be adjusted to match the proposed revised horizontal definition. The revised horizontal definition is still under consideration, however using the 2011 Recommendation as a base, the recent stakeholder survey and recent literature[3] it is expected that the revised definition will contain the following elements:

  “A natural, incidental or manufactured material consisting of solid particles, in an unbound state or as an aggregate or as an agglomerate, where 50% or more of the particles in the number size distribution, fulfil at least one of the following conditions:

  - one or more external dimensions on the scale from 1 to 100 nm;
  - with elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm;
  - with a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.

Excluding materials with a specific surface area by volume of < 6 m2/cm3."

One non-contested consideration from the stakeholder survey adopted here is the 'generalization' of the initial derogation (i.e. the explicit addition of carbon –based allotropes with dimensions smaller than 1nm), now covering all similar elongated or plate like-shaped particles materials regardless of their chemical composition.

Under this scenario, only cosmetic products as defined above will require regulatory action (notification, potential assessment by the SCCS, labelling, etc.) under the CPR.

- **Scenario B -** To evaluate whether further protection of human health (and the environment) is needed, Scenario B has been identified in order to obtain views on whether a wider range of materials should be included in the scope of the CPR. As with Scenario A, the updated horizontal nanomaterials definition would be implemented under the CPR. However, an additional set of materials with features in the nanoscale (i.e. from 1 to 500nm) would be defined for regulatory action (notification and labelling). Inspired by a recent Open Letter by AVICENN et al, the following definition will be used under Scenario B to identify this set of "materials with nanoscale features /characteristics". Under this scenario, these materials would be subject to the same level of regulatory action (notification, potential assessment by the SCCS, labelling, etc.) as the horizontally defined nanomaterials. The following definition of "materials with nano-scale characteristics" is proposed:

  "A material which may not be a nanomaterial under the horizontal definition, but which has solubility below 33.3 g/L[4] and is a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate, where 10% or more of the particles in the number size distribution, fulfil at least one of the following conditions:

  - one or more external dimensions, or an internal structure, on the scale from 1 to 500 nm.
  - with an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 500 nm;
  - with a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 500 nm.

  Excluding materials with a specific surface area by volume of < 6 m2/cm3."

Under this scenario two sets of materials will be regulated under the CPR. One set of materials, defined as nanomaterials by the revised horizonal definition as described previously, and in addition a new set of materials defined as materials with nano-scale characteristics according to the definition above.

[3] Wohlleben W, Mielke J, Bianchin A, Ghanem A, Freiberger H, Rauscher H, Gemeinert M, Hodoroaba VD. Reliable nanomaterial classification of powders using the volume-specific surface area method. J Nanopart Res. 2017;19(2):61. doi: 10.1007/s11051-017-3741-x.
[4] as defined by US and European Pharmacopeias (European Pharmacopoeia 10th Edition (2019);

USP38 and USP38 NF33).

Scenario overview

For clarity, the scenarios have been summarised in the attached table.

NANO_DRAFT_SCENARIOS_Addendum_11.04.2022.pdf

Question 3a.

When considering the two scenarios for the revision of the nanomaterials' definition, one of the differences is the percentage of particles in the number size distribution required to initiate regulatory requirements. Which of the following do you deem most appropriate for cosmetic products?

Please select your preferred option

- (●) 50% (Scenario A)
- ( ) 10% (Scenario B)
- ( ) No threshold (Baseline Scenario)

Another figure (expressed as a percentage)

- ( ) 1%
- ( ) 2%
- ( ) 3%
- ( ) 4%
- ( ) 5%
- ( ) 6%
- ( ) 7%
- ( ) 8%
- ( ) 9%
- ( ) 10%
- ( ) 11%
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- 97%
- 98%
- 99%
- 100%

Question 3b.

When considering these two scenarios, one of the differences is the nature (i.e., solubility) required to initiate regulatory requirements. Of the proposed thresholds, which do you deem most appropriate for cosmetic products?

Please select your preferred option

- (•) No threshold (Baseline Scenario and Scenario A)
- ( ) Solubility <33.3g/L (Scenario B)

Another figure (expressed in g/L)

- ( ) <0.1g/L
- ( ) < 1g/L
- ( ) < 10g/L

Question 3c.

When considering the two scenarios, one of the differences is the origin required to initiate

regulatory requirements. Of the proposed choices, which do you deem most appropriate for cosmetic products?

Please select your preferred option

- (●) Natural, incidental or manufactured (Scenario A and B)
- ( ) Intentionally manufactured (Baseline Scenario)

Another choice

- ( ) Natural
- ( ) Incidental
- ( ) Manufactured

Please describe your choice further, as relevant

We support the alignment with the horizontal definition of nanomaterials. There is no scientific argument to differentiate between natural, incidental or manufactured materials.

Question 3d.

When considering the two scenarios, one of the differences is the dimensions required to initiate regulatory requirements. Of the proposed thresholds, which do you deem most appropriate for cosmetic products?

Please select your preferred option

- (●) One or more external dimensions is in the size range 1 nm-100 nm (Scenario A)
- ( ) One or more external dimensions is in the size range 1 nm-500 nm (Scenario B)
- ( ) One or more external dimensions, or an internal structure, on the scale from 1 to 100 nm (Baseline Scenario)

Another figure (expressed in nm)

Between 0.1 nm and <500 nm

Question 3k.

What impact on human health would you expect from Scenario A and Scenario B, if any?

Please refer to the scenarios in the section introduction

Please select the most appropriate per row

You expect that the alignment of CPR with the horizontal definition of nanomaterials, or extension to include both nanomaterials and materials with nanoscale characteristics would result in:

	Significant (~90%) reduction in any direct negative impact on human health in the EU from nanomaterials and materials with nanoscale characteristics	**Some (~50%) reduction** in any direct negative impact on human health in the EU from nanomaterials and materials with nanoscale characteristics	**Limited (~20%) reduction** in any direct negative impact on human health in the EU from nanomaterials and materials with nanoscale characteristics	**No reduction** in any direct negative impact on human health in the EU from nanomaterials and materials with nanoscale characteristics	**An increase** in direct negative impact on human health in the EU from nanomaterials and materials with nanoscale characteristics	Don't Know
* Scenario A	○	○	○	◉	○	○
* Scenario B	○	○	○	◉	○	○

Please describe your assumptions and sources of evidence associated with human health impacts.

The reclassification of some ingredients as "nano" under the new definition will not change the safety profile of them. There is a need for sufficient implementation time to submit the additional information according to Article 16, but we do not expect an impact on human health as safety requirements will remain unchanged for the final products. Cosmetics Europe assessed the cosmetic ingredient database and concluded that the number of nanomaterials will increase from 25 to 220, half of them listed as colorants. A large number of substances will require a safety dossier, SCCS evaluation and technical adaptation to the Cosmetic Regulation Annexes. About 30% of the cosmetic formulas in the EU market will contain an ingredient classified as nanomaterial under the new definition, according to an assessment of 450 cosmetic formulas from 15 companies. If the Scenario B is to be applied, the industry will be required to submit a huge number of dossiers according to Article 16. This administrative burden would lead to a loss of products and this would likely be negative for the public health.

Question 3l.

What impact on the environment would you expect from Scenario A and Scenario B, if any?

Please refer to the scenarios in the section introduction

Please select the most appropriate per row

You expect that the alignment of CPR with the horizontal definition of nanomaterials, or extension to include both nanomaterials and materials with nanoscale characteristics would result in:

	Significant (~90%) reduction in environmental impacts due to nanomaterials and materials with nanoscale characteristics	Some (~50%) reduction in environmental impacts due to nanomaterials and materials with nanoscale characteristics	Limited (~20%) reduction in environmental impacts due to nanomaterials and materials with nanoscale characteristics	No reduction in environmental impacts due to nanomaterials and materials with nanoscale characteristics	An increase in environmental impacts due to nanomaterials and materials with nanoscale characteristics	Don't Know
* Scenario A	○	○	○	◉	○	○
* Scenario B	○	○	○	◉	○	○

Please describe your assumptions and sources of evidence associated with environmental impacts

A change of the cosmetic definition of nanomaterials would not have any impact on the environmental management as the environmental impact of cosmetic ingredients is managed under REACH.

Remember you can save a draft and continue later - Use the "Save as Draft" Button in the top-right of the page

4. Changing information provision on labels of cosmetic products

The Cosmetic Products Regulation lays down rules for information to be labelled on the container and/or the packaging of a cosmetic product. There are currently no rules laid down for digital labelling, i.e. labelling the cosmetic product with for example a website or QR code that links to online information.

Given that labels are the primary means to communicate essential product information to users, clear communication is vital for the effectiveness of legislation in protecting human health. The Fitness Check 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. A possible solution could be moving information from a physical label (on-pack) to a digital label. This is meant to be an option, and not an obligation, left to the discretion of manufacturers to decide if they prefer to label information on the package or digitally. In case of digital labelling, possibilities to provide information to consumers without mobile internet access would also be considered.

There is ongoing reflection in the Commission concerning the possibility of digital labelling under the CLP , Detergents and Fertilising products Regulations, for more information please see simplification and digitalisation of labelling requirements of chemicals.

The broad options for assessment are:

1. “Do nothing” – maintain the current provisions for on-pack labelling only;
2. Require both on-pack and digital labelling, (for example, for the list of ingredients, all ingredients both on pack and by digital labelling)
3. Require certain information to be provided on-pack, and certain information to be provided by digital labelling, depending on the type of information. For example, for the list of ingredients, certain ingredients would be provided on pack and certain ingredients would only be provided by digital labelling
4. Move to digital labelling only (e.g. through a QR-code) with an alternative way of providing information to those with no mobile internet access; this option is particularly valid for small products or products to be filled in at shops
5. Move to digital labelling only (e.g. through a QR-code) with no alternative way of providing information to those with no mobile internet access; this option is particularly valid for small products or products to be filled in at shops

*

Question 4a.

In what context do you think digital product labelling should be used in place of all (or most) of the information provided via on-pack product labelling?

Please select one answer

- ○ Digital labelling should not be used for cosmetic products
- ○ Digital labelling should be useful for small products
- ○ Digital labelling should be useful for refill products, such as products soaps and shampoos sold directly from dispensers in some shops
- ◉ Digital labelling is a good idea for all products
- ○ Don't know

* **Question 4b.**

If digital labels are implemented, how the database with the digital information on products should be managed?

Please select one answer

- ○ There should be a central database for all cosmetic products placed on the EU market which are digitally labelled
- ◉ Each manufacturer should have a database for their own digitally labelled products placed on the EU market
- ○ Other
- ○ Don't know

If other, please specify.

* **Question 4h.**

If mandatory digital cosmetic product labelling is introduced whilst on-pack labelling remains as-is (Policy Option 2), will this have any implications on the environment when compared to the baseline?

Please select the most appropriate answer

- ○ Significant negative impact on the environment
- ○ Some negative impact on the environment
- ◉ Limited negative impact on the environment
- ○ No impact on the environment
- ○ Limited positive impact on the environment
- ○ Some positive impact on the environment
- ○ Significant positive impact on the environment
- ○ Don't know

*

Question 4i.

What if mandatory digital cosmetic product labelling were to replace on-pack labelling (Policy Options 4 or 5), would this have any other implications on the environment when compared to the baseline?

Please select the most appropriate answer

- ○ Significant negative impact on the environment
- ○ Some negative impact on the environment
- ○ Limited negative impact on the environment
- ○ No impact on the environment
- ○ Limited positive impact on the environment
- ◉ Some positive impact on the environment
- ○ Significant positive impact on the environment
- ○ Don't know

Please specify and describe your assumptions and sources of evidence.

Less on-pack labeling requires less labeling space and this would lead to packaging reduction

* **Question 4j.**

Would mandatory digital labelling affect the EU-27 Cosmetics industry's global competitiveness when compared to the baseline?

Please select the most appropriate answer

- ○ Significant negative impact on global competitiveness
- ◉ Some negative impact on global competitiveness
- ○ Limited negative impact on global competitiveness
- ○ No impact on global competitiveness
- ○ Limited positive impact on global competitiveness
- ○ Some positive impact on global competitiveness
- ○ Significant positive impact on global competitiveness
- ○ Don't know

* **Question 4k.**

Would the EU-27 Cosmetics industry's exports change as a result of the introduction of mandatory digital labelling when compared to the baseline?

Please select the most appropriate answer

- ○ Yes, there would be a significantly positive change
- ○ Yes, there will be a positive change
- ○ Yes, there will be a small positive change
- ◉ No change
- ○ Yes, there will be a small negative change

- Yes, there would be a negative change
- Yes, there would be a significantly negative change
- Don’t know

* **Question 4l.**

Would imports of cosmetic products change as a result of the introduction of mandatory digital labelling when compared to the baseline?

Please select the most appropriate answer

- Yes, there would be a significantly positive change
- Yes, there will be a positive change
- Yes, there will be a small positive change
- No change
- Yes, there will be a small negative change
- (●) Yes, there would be a negative change
- Yes, there would be a significantly negative change
- Don’t know

Please specify and describe your assumptions and sources of evidence for the previous questions.

Due to additional costs and administrative burden that is specific for EU.

* **Question 4m.**

Would it easier or harder to enforce that digital product labels comply with the Cosmetic Products Regulation, when compared to on-pack labels?

Please select the most appropriate answer

- (●) It would be much easier
- It would be easier
- It would be similar
- It would be harder
- It would be much harder
- Don’t know

Remember you can save a draft and continue later - Use the "Save as Draft" Button in the top-right of the page

5. Scientific and technical work on cosmetics performed by the Scientific Committee on Consumer Safety (SCCS)

Currently, different agencies and scientific committees provide scientific advice to the Commission on chemicals, including cosmetics. The Chemicals Strategy for Sustainability announces the reattribution of technical and scientific work on chemicals performed under the relevant pieces of legislation to EU

agencies. This includes the work of the SCCS.

The following broad options have been identified:

- Option 1: business as usual (baseline scenario) - SCCS remains with the Commission.
- Option 2: a stand-alone SCCS within ECHA e.g., following the example of Biocidal Product Committee. 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 (e. g., non-animal methods).
- Option 3: SCCS work is integrated into the Risk Assessment Committee (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.
- Option 4: SCCS is absorbed by the Risk Assessment Committee (RAC) of ECHA without adapting the RAC. In this case, the RAC framework/structure, membership and methodology will apply.

Question 5b.

To what extent do you agree with the following statements?

Statement	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
* Methodologies used for risk assessment of cosmetic substances are unique as they rely predominantly on non-animal methods and will need to be preserved during the reattribution	◉	○	○	○	○	○
* Expertise of the SCCS in risk assessment of cosmetic substances is unique	◉	○	○	○	○	○
* Expertise of the ECHA committees with current membership is sufficient to deal with risk assessment of cosmetic substances	○	○	○	○	◉	○
* ECHA committees have adequate capacity and resource to assimilate the work of the SCCS	○	○	○	○	◉	○

Question 5c.

Please rank each policy options in terms of their: a) efficiency, b) the opportunities for synergies, c) their coherence and d) transparency of procedures.

The highest ranked option should be placed at the top

* **Efficiency of safety assessments** (most relatively efficient option should be moved to the top of the ranking and so on)

Use drag&drop or the up/down buttons to change the order or accept the initial order.

- Option 1: baseline (SCCS remains with the Commission)
- Option 2: A stand-alone SCCS within ECHA
- Option 3: SCCS work is integrated into ECHA's RAC with adaptations
- Option 4: SCCS is absorbed by ECHA's RAC without adaptions

* **Opportunities for synergies across sectors** (option with the most synergy should be moved to the top of the ranking and so on)

Use drag&drop or the up/down buttons to change the order or accept the initial order.

- Option 1: baseline (SCCS remains with the Commission)
- Option 2: A stand-alone SCCS within ECHA
- Option 3: SCCS work is integrated into ECHA's RAC with adaptations
- Option 4: SCCS is absorbed by ECHA's RAC without adaptions

* **Coherence of safety assessments across sectors** (highest coherence option should be moved to the top of the ranking and so on)

Use drag&drop or the up/down buttons to change the order or accept the initial order.

- Option 1: baseline (SCCS remains with the Commission)
- Option 2: A stand-alone SCCS within ECHA
- Option 3: SCCS work is integrated into ECHA's RAC with adaptations
- Option 4: SCCS is absorbed by ECHA's RAC without adaptions

* **Transparency of procedures** (most relatively transparent option should be moved to the top of the ranking and so on)

Use drag&drop or the up/down buttons to change the order or accept the initial order.

- Option 1: baseline (SCCS remains with the Commission)
- Option 2: A stand-alone SCCS within ECHA
- Option 3: SCCS work is integrated into ECHA's RAC with adaptations

⠿ Option 4: SCCS is absorbed by ECHA's RAC without adaptions

Question 5d.

How would you expect the adoption of the following options to affect the overall administrative costs faced by public authorities, when compared to the baseline? Please note Option 1 has deliberately been omitted

Please select the most appropriate per option

	No impact on administrative costs faced by public authorities due to the Cosmetics Products Regulation	A reduction in administrative costs faced by public authorities due to the Cosmetics Products Regulation	An increase in administrative costs faced by public authorities due to Cosmetics Products Regulation	Don't know
* Option 2: A stand-alone SCCS within ECHA	○	○	○	◉
* Option 3: SCCS work is integrated into ECHA's RAC with adaptations	○	○	○	◉
* Option 4: SCCS is absorbed by ECHA's RAC without adaptations	○	○	○	◉

Remember you can save a draft and continue later - Use the "Save as Draft" Button in the top-right of the page

6. Additional information and feedback

Question 6.

To what extent do you believe that the proposed targeted revision of the Cosmetic Products Regulation would be consistent with the EU's climate neutrality objectives?

Please select the most appropriate

- ○ Very consistent
- ○ Consistent
- ○ Somewhat consistent
- ○ Inconsistent

- (●) Don’t know

Please describe your key assumptions and provide any evidence.

The revision is targeted and does not address environmental aspects such as climate change.

Question 7.

In case you would like to share anything else in addition to the previous questions related to the targeted revision of the Cosmetic Products Regulation, please provide any details.

Question 8.

In case you would like to share a document in view of the targeted revision of the Cosmetic Products Regulation, please upload it below.

Only files of the type pdf, txt, doc, docx, odt, rtf are allowed.

Please upload your file(s)

* **Question 9.**

Would you be willing to participate in a follow-up interview as part of the stakeholder consultation for the targeted revision of the Cosmetics Products Regulation?

- ( ) Yes
- (●) No

Thank you and your organisation very much for completing this online questionnaire and your continued support for this Study.

Contact

Contact Form