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Public consultation for the targeted revision of the Cosmetic Products Regulation

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Introduction

The Cosmetic Products Regulation is the main regulatory framework for finished cosmetic products placed on the EU market. It lays down the rules applicable to all cosmetic products to ensure a well-functioning internal market and to provide a high level of public health protection.

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

The Strategy fully recognises the fundamental role of chemicals for human wellbeing 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 specific measures 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 Cosmetic Products Regulation to achieve its objectives by overcoming a number of identified problems. To address these problems, the Commission is considering a range of potential measures:

- an automatic ban of the most harmful chemicals (the 'generic approach to risk management'), allowing their use only where it is proven to be essential for society;
- a new measure to take into account the combination effects from simultaneous or subsequent exposure to chemicals from different sources;
- a review of the definition of nanomaterial;
- improving labelling information on cosmetic products, and;
- streamlining scientific assessments of cosmetic products by reassigning the work of the Scientific Committee on Consumer Safety (SCCS) to the European Chemicals Agency (ECHA).

The overall objective of the targeted revision is to ensure that the Cosmetic Products Regulation reflects the Commission's ambitions 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.

In this questionnaire, we ask a series of general questions and we welcome your views and feedback. We

also include a set of additional 'expert' questions to cover more technical points of the Cosmetic Products Regulation that require prior knowledge and expertise. The questionnaire will ask you questions based on your answer to question 0.

The Commission will run a number of separate 'targeted' stakeholder consultations in parallel with this public consultation to seek more detailed, technical information on the potential changes to the Cosmetic Products Regulation.

About you

* Language of my contribution

- ○ Bulgarian
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- ○ Dutch
- ◉ English
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- ○ Non-governmental organisation (NGO)
- ○ Public authority
- ○ Trade union
- ○ Other

* First name

ANNA

* Surname

PATERA

* Email (this won't be published)

manager@psvak.gr

* Organisation name

255 character(s) maximum

PSVAK THE HELLENIC COSMETIC, TOILETRY AND PERFUMERY ASSOCIATION

* Organisation size

- ◉ Micro (1 to 9 employees)
- ○ Small (10 to 49 employees)
- ○ Medium (50 to 249 employees)
- ○ Large (250 or more)

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- Serbia
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- Sint Maarten
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- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka

- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
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- Greenland
- Grenada
- Guadeloupe
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- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
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- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Nauru
- Nepal
- Netherlands
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- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
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- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine

- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Papua New Guinea
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- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
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Question 0 - What is your level of knowledge of the Cosmetic Products Regulation?

For this consultation, there are a set of 'general' questions for respondents with no or little knowledge of the Cosmetic Products Regulation, and an additional set of 'expert' questions for respondents with good or excellent knowledge of this Regulation. 'Expert' questions will only appear if the corresponding reply has been selected.

- General
- General + expert

1. Generic approach to risk management

The Chemicals Strategy for Sustainability announced the proposal to extend the generic approach to risk management, which means that the most harmful chemicals will be banned in cosmetic products by default, while allowing limited exemptions under conditions clearly defined in law.
The proposal is to extend the general approach under the Cosmetic Products Regulation to cover chemicals that are endocrine disruptors for human health, affect the immune, neurological or respiratory systems or are toxic to a specific organ, based on their hazard and on generic exposure considerations. This differs from a specific approach to risk management requiring proof of an unacceptable risk for each use before restricting use.

Question 1. Would you buy cosmetic products that contain the following substances knowing the product itself is safe, on a scale from 1 (opposed) to 5 (strongly in favour)?

(Single answer per row)

	1 (opposed)	2	3	4	5 (strongly in favour)	Don't know
Substances that are carcinogenic, mutagenic or toxic for reproduction (CMRs)	○	○	○	○	◉	○
Substances that are disruptive to the endocrine system (endocrine disruptors)	○	○	○	○	◉	○
Chemicals affecting the immune system	○	○	○	○	◉	○
Chemicals affecting the neurological system	○	○	○	○	◉	○
Chemicals affecting the respiratory system	○	○	○	○	◉	○
Chemicals toxic to a specific organ	○	○	○	○	◉	○

Substances in cosmetics that are carcinogenic, mutagenic or toxic for reproduction

The Cosmetic Products Regulation already has provisions prohibiting or restricting (under certain conditions) the use of these substances following the generic approach to risk management (i.e. Article 15). Chemicals that have adverse effects on the environment, including endocrine disruptors for the environment and those that are persistent and bioaccumulative and toxic, are subject to regulatory measures under REACH.

Question 1a. To what extent do you agree with the following statements regarding existing (or missing) provisions on substances that are carcinogenic, mutagenic or toxic for reproduction (CMR substances) (Article 15) in the Cosmetic Products Regulation?

(Single answer per row)

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
The current exemption criteria for CMR Category 2 substances do not need to be changed	◉	○	○	○	○	○
The current provisions regarding CMR Category 1A/B substances should be extended to CMR2 substances as well	○	○	○	○	◉	○

The current provisions regarding CMRs should be extended to include the adverse effects on or via lactation	○	◉	○	○	○	○
The following exemption criteria for CMR Category1A/B substances should be revised: a) compliance with the food safety requirements as defined in Regu-lation (EC) No 178/2002	◉	○	○	○	○	○
b) lack of suitable alternatives	○	◉	○	○	○	○
c) application is made for a particular use of the product category with a known exposure	○	○	○	○	◉	○
d) use evaluated as safe by the SCCS in cosmetic products (exposure to these products and taking into consideration the overall exposure from other sources, and specific vulnerable population groups)	○	○	○	○	◉	○
e) a new criterion should be added to only grant an exemption for uses proven to be essential for society	○	○	○	○	◉	○

Endocrine disruptors

Endocrine disruptors are chemical substances that alter the functioning of the endocrine system and negatively affect the health of humans and animals. They may either be of synthetic or natural origin. Exposure to endocrine disruptors can occur from different sources, such as residues of pesticides or consumer products used or present in our daily life.

The Cosmetic Products Regulation does not have any explicit provisions prohibiting or restricting the use of endocrine disruptors as it does for substances that are carcinogenic, mutagenic or toxic for reproduction. According to the objectives of the Chemicals Strategy, the generic approach to risk management should also be extended to endocrine disruptors and they should be banned as soon as they are classified. As such, in the process of revising the CLP Regulation, the Commission is examining whether to include new hazard classes for endocrine disruptors. One option is to bring in two hazard classes for endocrine disruptors (one for human health and one for environment), with categories for each class (‘category 1: Known or presumed endocrine disruptors’ and ‘category 2: Suspected endocrine disruptors’).

The generic approach to risk management under the Cosmetic Products Regulation will cover endocrine disruptors for human health, whereas the process under REACH is envisaged to cover endocrine disruptors for the environment.

Question 1b. To what extent do you agree with the following statements regarding the extension of the generic approach to risk management to endocrine disruptors for human health in cosmetics?

(Single answer per row)

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
Explicit provisions are needed for both 'known/presumed' (Category 1) and 'suspected' (Category2) endocrine disruptors for human health	○	○	◉	○	○	○
Explicit provisions are needed only for 'known/presumed' (Category 1) endocrine disruptors for human health	○	○	○	◉	○	○
Explicit provisions are needed only for 'suspected' (Category 2) endocrine disruptors for human health	○	○	○	○	◉	○
Future provisions should be aligned with the generic approach to risk management on CMRs in cosmetics. Therefore, the following exemption criteria should be added: a) compliance with the food safety requirements set out in Regu-lation (EC) No 178/2002	○	○	○	○	◉	○
b) lack of suitable alternatives	○	○	○	○	◉	○
c) application is made for a particular use of the product category with a known exposure	○	◉	○	○	○	○
d) use evaluated as safe by the SCCS in cosmetic products (exposure to these products and taking into consideration the overall exposure from other sources, and specific vulnerable population groups)	○	◉	○	○	○	○
e) a new criterion should be added to only grant an exemption for uses proven to be essential for society	○	○	○	○	◉	○

Chemicals in cosmetics that affect the immune, neurological or respiratory systems and chemicals toxic to a specific organ

The Chemicals Strategy also announces the proposal to extend the generic approach to risk management to chemicals affecting the immune, neurological or respiratory systems and chemicals that are toxic to a specific organ.

To date, these substances can be restricted in the Cosmetic Products Regulation only when there is a potential risk to public health.

Question 1c. To what extent do you agree with the following statements regarding the extension of the generic approach to risk management on chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ in the Cosmetic Products Regulation?

(Single answer per row)

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
Explicit provisions are not needed as these substances are already adequately regulated when there is a potential risk to human health	◉	○	○	○	○	○
Explicit provisions are needed to extend the generic approach to risk management to chemicals affecting the immune system	○	○	○	○	◉	○
Explicit provisions are needed to extend the generic approach to risk management to chemicals affecting the neurological system	○	○	○	○	◉	○
Explicit provisions are needed to extend the generic approach to risk management to chemicals affecting the respiratory system	○	○	○	○	◉	○
Explicit provisions are needed to extend the generic approach to risk management to chemicals toxic to a specific organ	○	○	○	○	◉	○
Future provisions should be aligned with the generic approach to risk management on CMRs.						

Therefore, the following exemption criteria should be added: a) compliance with the food safety requirements set out in Regu-lation (EC) No 178/2002	○	○	○	○	◉	○
b) lack of suitable alternatives	○	○	○	○	◉	○
c) application is made for a particular use of the product category with a known exposure	○	○	○	○	◉	○
d) use evaluated as safe by the SCCS in cosmetic products (exposure to these products and taking into consideration the overall exposure from other sources, and specific vulnerable population groups)	○	○	○	○	◉	○
e) a new criterion should be added to only grant an exemption for uses proven to be essential for society	○	○	○	○	◉	○

Question 1d. Please indicate the expected impacts of extending the generic approach to risk management to the use in cosmetic products of endocrine disruptors and chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ on the following. Use a scale from 1 (strongly negative i.e. detrimental) to 5 (strongly positive, i.e. beneficial):

(Single answer per row)

	1 (strongly negative)	2	3	4	5 (strongly positive)	Don't know
As regards endocrine disruptors: Administrative burden on cosmetics companies, e.g. compliance costs	◉	○	○	○	○	○
Impacts on a cosmetics company product portfolio, e.g. extent of reformulation requested	◉	○	○	○	○	○
Resources of national public authorities	○	◉	○	○	○	○
Human health protection (e.g. impacts on professional workers such as hairdressers, beauticians) and consumers)	○	○	◉	○	○	○
Competitiveness of EU cosmetics companies	◉	○	○	○	○	○

Innovation and research on cosmetic ingredients	○	◉	○	○	○	○
Impacts on consumers in terms of price of cosmetic products	◉	○	○	○	○	○
Other (please specify)	○	○	○	○	○	○
As regards chemicals affecting the immune system: Administrative burden on cosmetics companies, e.g. compliance costs	◉	○	○	○	○	○
Impacts on a cosmetics company product portfolio, e.g. extent of reformulation requested	◉	○	○	○	○	○
Resources of national public authorities	◉	○	○	○	○	○
Human health protection (e.g. impacts on professional workers such as hairdressers, beauticians) and consumers)	○	○	◉	○	○	○
Competitiveness of EU cosmetics companies	◉	○	○	○	○	○
Innovation and research on cosmetic ingredients	◉	○	○	○	○	○
Impacts on consumers in terms of price of cosmetic products	◉	○	○	○	○	○
Other (please specify)	○	○	○	○	○	○
As regards chemicals affecting the neurological system: Administrative burden on cosmetics companies, e.g. compliance costs	◉	○	○	○	○	○
Impacts on a cosmetics company product portfolio, e.g. extent of reformulation requested	◉	○	○	○	○	○
Resources of national public authorities	◉	○	○	○	○	○
Human health protection (e.g. impacts on professional workers such as hairdressers, beauticians) and consumers)	○	○	◉	○	○	○
Competitiveness of EU cosmetics companies	◉	○	○	○	○	○
Innovation and research on cosmetic ingredients	◉	○	○	○	○	○
Impacts on consumers in terms of price of cosmetic products	◉	○	○	○	○	○
Other (please specify)	○	○	○	○	○	○
As regards chemicals affecting the respiratory system: Administrative burden on cosmetics companies, e.g. compliance costs	◉	○	○	○	○	○
Impacts on a cosmetics company product portfolio, e.g. extent of reformulation requested	◉	○	○	○	○	○

Resources of national public authorities	◉	○	○	○	○	○
Human health protection (e.g. impacts on professional workers such as hairdressers, beauticians) and consumers)	○	○	◉	○	○	○
Competitiveness of EU cosmetics companies	◉	○	○	○	○	○
Innovation and research on cosmetic ingredients	◉	○	○	○	○	○
Impacts on consumers in terms of price of cosmetic products	◉	○	○	○	○	○
Other (please specify)	○	○	○	○	○	○
As regards chemicals affecting the chemicals toxic to a specific organ: Administrative burden on cosmetics companies, e.g. compliance costs	◉	○	○	○	○	○
Impacts on a cosmetics company product portfolio, e.g. extent of reformulation requested	◉	○	○	○	○	○
Resources of national public authorities	◉	○	○	○	○	○
Human health protection (e.g. impacts on professional workers such as hairdressers, beauticians) and consumers)	○	○	◉	○	○	○
Competitiveness of EU cosmetics companies	◉	○	○	○	○	○
Innovation and research on cosmetic ingredients	◉	○	○	○	○	○
Impacts on consumers in terms of price of cosmetic products	◉	○	○	○	○	○
Other (please specify)	○	○	○	○	○	○

2. Granting exemptions for the use of the most harmful chemicals in cosmetics

The Chemicals Strategy for Sustainability outlines a number of commitments to tackle chemical pollution and exposure to better protect the public and the environment, and to step up innovation of safe and sustainable chemicals and products for the green transition. Extending the generic approach to risk management will ensure that consumers, vulnerable groups and the natural environment are more consistently protected, while still allowing for the use of the most harmful chemicals where this is proven to be essential for society.

The criteria for essential use must be properly defined ‘to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health’.

This means that the essential use concept would allow the use of most harmful substances only exceptionally and under very strict conditions.

Question 2. To what extent do you agree with the following statements?

It should be possible to continue using the most harmful substances in cosmetic products provided that:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
a) their use is safe for human health (as evaluated by an independent scientific committee)	◉	○	○	○	○	○
b) their use is safe for human health and no suitable alternatives are available	○	○	○	○	◉	○
c) 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	○	○	○	○	◉	○
Should not be allowed under any circumstances	○	○	○	○	◉	○

Question 2a. To what extent do you agree that the essential use concept, which allows exemptions for use of the most harmful substances in cosmetics, is needed in the Cosmetic Products Regulation as part of the application of the Generic Approach to Risk management (GRA)?
(Single answer)

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ◉ Strongly disagree
- ○ Don't know
- ○ Other (please specify below)

Question 2b. Please indicate the expected impacts of bringing in the essential use concept to manage the most harmful substances in cosmetics products, on a scale from 1 (strongly negative i.e. detrimental) to 5 (strongly positive, i.e. beneficial):

	1 (strongly negative)	2	3	4	5 (strongly positive)	Don't know
Administrative burden on cosmetics companies, e.g. compliance costs	◉	○	○	○	○	○
Impacts on a cosmetics company product portfolio, e.g. extent of reformulation requested	◉	○	○	○	○	○
Resources of national public authorities	○	◉	○	○	○	○
Human health protection (e.g. impacts on professional workers such as hairdressers, beauticians and consumers)	◉	○	○	○	○	○
Competitiveness of EU cosmetics companies	◉	○	○	○	○	○
Innovation and research on cosmetic ingredients	◉	○	○	○	○	○
Impacts on consumers in terms of price of cosmetic products	◉	○	○	○	○	○
Other (please specify below)	○	○	○	○	○	○

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

Over the years, a number of reports have highlighted that chemical substances may cause adverse effects to human health when they are combined, even if the individual substances are present at concentrations that are considered safe. Most pieces of chemicals legislation consider intentional/commercial mixtures and require a risk assessment of such mixtures. However, 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 Chemicals Strategy for Sustainability therefore announces that, in order to adequately address the combination effects of chemicals in unintentional mixtures, legal requirements need to be laid down consistently to take effective and systematic account of the risks from simultaneous exposure to multiple chemicals across chemicals-related policy areas.

Question 3. Consumers are exposed on a daily basis to a number of chemical substances (in soaps and detergents, paints and contaminants in food, water and air).
Do you think unintentional co-exposure to chemicals from different sources should be considered when cosmetic products are being assessed for their safety?
(Single answer)

- ○ Strongly agree
- ○ Agree
- ○

Neither agree nor disagree

- (●) Disagree
- ( ) Strongly disagree
- ( ) Don’t know

According to the Commission’s Implementing Decision 2013/674/EU ‘Guidelines on cosmetic product safety assessments’, the safety assessors of finished cosmetic products consider the potential combination effects of ingredients used in cosmetic products (intentional mixtures) taking into account the identified normal use and the reasonably foreseeable use. However, there is no obligation to consider combination effects for chemicals present in cosmetics with other substances that the consumer is exposed to, including substances present in other cosmetic products or from other sources, for example in of paints or contaminants in food and water.
As it is currently not realistic or economically feasible to specifically assess and regulate the almost infinite number of possible combinations of chemicals, a practical approach for the cosmetics safety assessment to evaluate the simultaneous exposure to multiple chemicals would be to use the mixtures assessment factor (MAF) approach.
The mixtures assessment factor (MAF) is a pragmatic approach to manage unknown risks since a safety assessor is not aware of all substances that could also affect human health. In practice, when applying MAF, exposure levels that are considered sufficiently safe for single chemicals are reduced by a certain factor to safeguard against the risk from the combined exposure to multiple chemical substances.

Question 3a. If the mixture assessment factor approach were brought into the safety assessment of cosmetic products, do you think it should apply to:
(Single answer)

- ( ) all substances used in cosmetics (i.e. addressing non-intentional co-exposure to all substances used in cosmetics with any other substance that the consumer may be exposed to)
- ( ) only substances that are carcinogenic, mutagenic and toxic for reproduction, endocrine disruptors, chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ (i.e. addressing non-intentional co-exposure of only these substances used in cosmetics with any other substances that the consumer may be exposed to)
- (●) Don’t know

Question 3b. To what extent do you agree with the following statements regarding the application of a mixture assessment factor (MAF) in the safety assessment of cosmetic ingredients?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don’t know

A single MAF should be used for all ingredients used in cosmetics	○	○	○	○	◉	○
Different MAFs should be used based on substance properties (e. g. toxicological properties, mode of action, chemical structure or physicochemical properties)	○	○	○	○	◉	○
Different MAFs should be applied for professional workers (e.g. hairdressers, beauticians, etc.) and consumers	○	○	○	○	◉	○
A MAF should be used during the exposure assessment	○	○	○	○	◉	○
A MAF should be used during the dose-response assessment	○	○	○	○	◉	○
A MAF should be used during the risk characterisation / margin of safety assessment (MoS)	○	○	○	○	◉	○

Question 3c. To what extent do you agree that the application of (a) mixture assessment factor(s) in the safety assessment of cosmetic ingredients will lead to the following:

(Single answer per row)

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
Greater consumer protection	○	○	○	○	◉	○
Greater protection of professional workers (e.g. hairdressers, beauticians)	○	○	○	○	◉	○
Increased competitiveness of EU cosmetics companies	○	○	○	○	◉	○
More innovation and research into cosmetic ingredients	○	○	○	○	◉	○
Economic benefits for industry	○	○	○	○	◉	○
A higher administrative burden on business, e.g. compliance costs	◉	○	○	○	○	○
A higher administrative burden on public authorities	○	○	○	○	○	◉

Increased reformulations for cosmetic products	◉	○	○	○	○	○
Higher prices of cosmetic products	◉	○	○	○	○	○
Other (please specify)	◉	○	○	○	○	○

If ‘other’, please explain (250 words maximum)

2000 character(s) maximum

Negative impact on public health: the application of a mixture assessment factor in the safety assessment of cosmetics would lead to the loss of a large number of preservatives and UV filters, making it impossible to ensure microbiological protection of products and to manufacture sunscreens with adequate UV protection.

4 A review of the definition of nanomaterial

Nanomaterials are characterised by their tiny size, measured in nanometres (i.e. one millionth of a millimetre), which make them impossible to be observed by the naked eye. They are present in nature, such as in beach sand, but they are also manufactured and added to consumer products since they exhibit or can provide novel characteristics (such as greater strength, chemical reactivity or conductivity, etc.) compared to the same material without nanoscale features.
The Cosmetic Products Regulation defines nanomaterials as ‘an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm’. In addition, it includes nanomaterial-specific provisions (including labelling) to ensure they are adequately assessed for safety if used as ingredients. In 2011, the Commission adopted a recommendation on the definition of nanomaterials, to be used as a horizontal definition, which was explicitly tailored to facilitate consistent and efficient regulatory application. As such, it is applied in several EU regulations including the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), the Biocidal Product Regulation (BPR) and the Medical Devices Regulation. This recommendation has just been reviewed.

Question 4. To what extent do you agree with the following statements?

(Single answer per row)

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don’t know
The definition of nanomaterial in the Cosmetic Products Regulation should be updated	◉	○	○	○	○	○
The definition of nanomaterial in the Cosmetic Products Regulation should be consistent with the definition applicable to multiple sectors (i.e. a cross-sectoral definition)	◉	○	○	○	○	○

According to the Cosmetic Products Regulation, ‘nanomaterial’ means 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. A Commission Recommendation of 2011 provides a horizontal definition of nanomaterials, stating that ‘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.’
Based on a Report/Review on the use of nanomaterials in cosmetics, there are differences between the definition of nanomaterial in the Cosmetic Products Regulation and in the Commission Recommendation of 2011. This creates some discrepancies across different sectors concerning the classification of materials as nanomaterials. For example, the cross-sectoral Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) applies the 2011 Recommendation and hence some materials are considered nanomaterials under REACH and not under the Cosmetics Regulation, and vice versa. This may create questions and inconsistent approaches amongst competent authorities and businesses across the single market.
As planned in the Chemicals Strategy for Sustainability, Recommendation 2011/696/EU on the (horizontal) definition of nanomaterial has just been reviewed, following an extensive stakeholder consultation. The Commission is in process of revising the Recommendation with minor changes. Since the first Recommendation was adopted in 2011, the Commission has been committed to ensuring consistency between nanomaterial definitions across EU regulations through the use of the Recommendation.

Question 4a. To what extent do you agree with the following statements?

The current nanomaterial definition under the Cosmetic Products Regulation is:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don’t know
a) sufficiently clear	○	○	○	◉	○	○
b) sufficiently comprehensive	◉	○	○	○	○	○
c) effectively implementable	○	○	○	◉	○	○
d) consistent with other EU definitions	○	○	○	◉	○	○

Question 4b. To what extent do you agree with the following statements as regards specific (present or missing) elements of the nanomaterial definition in the Cosmetic Products Regulation?

(Single answer per row)

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don’t know
The condition of ‘**insoluble or biopersistent**’ (i.e. sufficiently						

stable and persistent in biological media to allow for potential interaction with biological systems): a) is required as part of the nanomaterials definition in cosmetics	◉	○	○	○	○	○
b) should be removed as a condition for restricting a class of nanomaterials	○	○	○	○	◉	○
c) should be kept as a condition, but properly defined	◉	○	○	○	○	○
The condition of '**intentionality**': a) is required as part of the nanomaterials definition in cosmetics	○	○	◉	○	○	○
b) should be removed as a condition for restricting a class of nanomaterials	○	○	◉	○	○	○
c) should be replaced by 'natural, incidental or manufactured material'	○	○	◉	○	○	○
For implementation reasons, a **% threshold** for the particle number in the size distribution should be set a) a % threshold for the particle number in the size distribution should be consistent with the horizontal definition (i.e. 50%) (as in regulations such as REACH, BPR and Medical Devices)	◉	○	○	○	○	○
b) if there are any safety concerns, and irrespective of the horizontal definition of nanomaterial, the number size distribution threshold of 50 % may be lowered in order to follow the most appropriate safety assessment	○	○	○	◉	○	○
The scope of application of the future definition should take account of **additional or specific requirements and sector particularities** a) The scope of application of the current definition may be	○	○	○	○	◉	○

extended, but it should not contradict the future cross-sectoral definition						
b) The scope of application of the current definition may be restricted, but it should not contradict the future cross-sectoral definition	◉	○	○	○	○	○
Guidance documents are needed to ensure a proper application of the nanomaterial definition in cosmetics	◉	○	○	○	○	○

Question 4c. What impact would you expect an updated definition of nanomaterial in cosmetics to have in the EU?

	Very positive impact	Positive impact	No or limited impact	Negative impact	Very negative impact	Don't know
A new definition with revised conditions concerning '**insolubility**/**biopersistence**' would most likely have...regarding the following: a) Compliance and administration costs for the cosmetics industry (including testing costs, reformulation costs, etc.)	○	○	○	○	◉	○
b) Research and development / innovation for the cosmetics industry	○	○	○	○	◉	○
c) Competitiveness of the EU cosmetics sector and wider industry in the global market	○	○	○	○	◉	○
d) Laboratory capacity and associated costs	○	○	○	○	◉	○
e) Employment levels	○	○	○	○	○	◉
f) Public authorities' resources, including administrative burden and enforcement costs	○	○	○	◉	○	○
A new definition with revised conditions concerning '**intentionality**' would most likely have…regarding the following: a) Compliance and administration costs for the cosmetics industry (including testing costs, reformulation costs, etc.)	○	○	○	◉	○	○
b) Research and development / innovation for the cosmetics industry	○	○	○	◉	○	○
c) Competitiveness of the EU cosmetics sector and wider industry in the global market	○	○	○	◉	○	○
d) Laboratory capacity and associated costs	○	○	○	◉	○	○
e) Employment levels	○	○	○	○	○	◉
f) Public authorities' resources, including administrative burden and enforcement costs	○	○	○	○	○	◉

A new definition with revised conditions concerning '**% threshold for the particle number in the size distribution**' would most likely have…regarding the following: a) Compliance and administration costs for the cosmetics industry (including testing costs, reformulation costs, etc.)	◉	○	○	○	○	○
b) Research and development / innovation for the cosmetics industry	○	○	◉	○	○	○
c) Competitiveness of the EU cosmetics sector and wider industry in the global market	○	○	◉	○	○	○
d) Laboratory capacity and associated costs	○	○	◉	○	○	○
e) Employment levels	○	○	◉	○	○	○
f) Public authorities' resources, including administrative burden and enforcement costs	○	○	◉	○	○	○

5 Changes to the information provided 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. online labelling with the information accessible through a QR code, a website, etc.
Given that labels are the primary means to communicate essential product information to users, clear communication is vital for legislation to be effective in protecting human health. The Fitness Check of the most relevant chemicals legislation (excluding REACH) found that consumer understanding of labels and consequently consumer protection can be improved by avoiding overloading labels with information and making them more easily readable. One solution could be to move information from a physical label (on-pack) to a digital label. If the information is provided in a digital label, the manufacturers would need to find a way to provide this information to consumers without mobile internet access.
There is ongoing discussion in the Commission on the scope for digital labelling under the CLP, Detergents and Fertilising products Regulations. This is detailed in an ongoing study and an open public consultation on the simplification and digitalisation of labelling requirements of chemicals.

Question 5. Which way of providing information is best in your view for the following categories of information?

(Single answer per row)

	On-pack only	Digital labelling only (e.g. through a QR code) with an alternative way of providing information to those with no internet access	Digital labelling only (e. g. through a QR code) with no alternative way of providing information to those with no mobile internet access	Both on-pack and digital labelling, (for example, for the row 'list of ingredients', all ingredients both on pack and by digital labelling)	Depending on the type of information - certain information on pack and certain by digital labelling, (for example, for the row 'list of ingredients' certain ingredients on pack and certain by digital labelling)	Don' t know
The name and the address of the responsible person (manufacturer, importer, distributer, other)	○	◉	○	○	○	○
The country of origin if products are imported from outside the EU	○	◉	○	○	○	○
The nominal content (weight or volume) of the product	◉	○	○	○	○	○
The date of minimum durability of the products or the date of durability	◉	○	○	○	○	○

after opening of the product						
Safety warnings (e.g. ‘not to be used on eyelashes’, ’only for professional use’.)	◉	○	○	○	○	○
Batch number or the reference for identifying a cosmetic product	◉	○	○	○	○	○
The function of the product (e.g. anti-wrinkle cream, moisturiser, shampoo etc.)	◉	○	○	○	○	○
The full list of all ingredients	○	◉	○	○	○	○

Question 5a. In your view, what would be the impact of digital labelling of information in general?

	Very positive impact	Positive impact	No or limited impact	Negative impact	Very negative impact	Don't know
Economic impact (one-off costs)	○	○	○	◉	○	○
Economic impact (recurrent costs)	◉	○	○	○	○	○
Economic impact (other such as impact on reputation, costs of import/export, etc.)	◉	○	○	○	○	○
Environmental impact (e.g. due to smaller packaging, higher energy consumption due to digitalisation)	○	◉	○	○	○	○
Social impact (e.g. access to information)	◉	○	○	○	○	○
Impact for market surveillance authorities (in-market controls)	◉	○	○	○	○	○

Other comments: maximum 250 words

2000 character(s) maximum

The introduction of digital labeling provisions must be done gradually so as to ensure consumer acceptance and adaptation and elimination of product and packaging withdrawal and destroy. On-pack harmonised symbols could further improve consumer information and protection.

6 Scientific and technical work on cosmetics performed by the Scientific Committee on Consumer Safety (SCCS) and the potential to improve the efficiency, effectiveness and coherence of safety assessments across legislation

Currently, different agencies and scientific committees provide scientific advice to the Commission on chemicals, including cosmetics. The efficiency of maintaining several committees assessing the same chemical is questionable, for example in terms of secretariat support, data management and the time and resources needed for coordination with other committees. To improve the effectiveness, efficiency and coherence of safety assessments across EU legislation and to make best use of expertise and resources in the EU agencies, in line with the 'one substance, one assessment' approach, the Chemicals Strategy proposed reassigning the technical and scientific work on chemicals carried out under the relevant pieces of legislation to EU agencies. This includes the work of the SCCS.

Question 6. To what extent do you agree with the following statements?

Moving the SCCS to a European agency will improve:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
a) the efficiency of safety assessments across sectors	○	○	○	○	◉	○
b) synergies amongst different sectors	○	◉	○	○	○	○
c) the consistency of safety assessments across sectors	○	○	◉	○	○	○
d) the transparency of procedures	○	○	◉	○	○	○

Through the work carried out to implement the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation, the European Chemicals Agency (ECHA) is already responsible for the environmental risk assessment of ingredients used in cosmetics products. Therefore, to maximise synergies and ensure consistency in the risk assessment of chemical substances, the Commission proposed reassigning the scientific/technical work to ECHA.
The Commission intends to maximise the efficiency and consistency of chemicals' assessment across sectors, while maintaining the dedicated expertise and respecting the particularities of the cosmetics sector. Various options are being considered, depending on the level of possible integration of the work of SCCS into ECHA structures. ECHA implements the EU's chemicals legislation and has a wide knowledge base on multiple chemicals and extensive experience with the risk assessment of chemical substances, including in occupational settings and in non-food consumer products. 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. 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 6a. Please consider the impact of the four options outlined above for re-assigning the work of the SCCS, on a scale from 1 (strongly negative i. e. detrimental) to 5 (strongly positive, i.e. beneficial) as regards:

(Single answer per row)

	1 (strongly negative)	2	3	4	5 (strongly positive)	Don't know
a) Efficiency of safety assessments across legislation (e.g. timely delivery of opinions /assessments, cost and resource efficiency): Option 1 (baseline)	○	○	○	○	◉	○
Option 2 (stand-alone committee at ECHA)	○	○	○	○	◉	○
Option 3 (integration into RAC with adaptation)	◉	○	○	○	○	○
Option 4 (absorption into RAC without adaptation)	◉	○	○	○	○	○
b) Synergies amongst different sectors: Option 1 (baseline)	○	○	○	○	◉	○
Option 2 (stand-alone committee at ECHA)	○	○	○	○	◉	○
Option 3 (integration into RAC with adaptation)	◉	○	○	○	○	○
Option 4 (absorption by RAC without adaptation)	◉	○	○	○	○	○
c) Consistency of assessments across sectors: Option 1 (baseline)	○	○	◉	○	○	○
Option 2 (stand-alone committee at ECHA)	○	○	○	○	◉	○
Option 3 (integration into RAC with adaptation)	◉	○	○	○	○	○
Option 4 (absorption by RAC without adaptation)	◉	○	○	○	○	○
d) Preserving expertise and methodology on cosmetic ingredients (e.g. alternative methods to animal testing, notes of guidance, etc.): Option 1 (baseline)	○	○	○	○	◉	○
Option 2 (stand-alone committee at ECHA)	○	○	○	○	◉	○
Option 3 (integration into RAC with adaptation)	◉	○	○	○	○	○
Option 4 (absorption by RAC without adaptation)	◉	○	○	○	○	○
e) Transparency in procedures (e.g. information requirements, compliance checks, open hearings, consultations, etc.): Option 1 (baseline)	○	○	○	◉	○	○
Option 2 (stand-alone committee at ECHA)	○	○	◉	○	○	○
Option 3 (integration into RAC with adaptation)	◉	○	○	○	○	○
Option 4 (absorption by RAC without adaptation)	◉	○	○	○	○	○

f) Costs for businesses (industry and SMEs): Option 1 (baseline)	○	○	○	○	◉	○
Option 2 (stand-alone committee at ECHA)	○	○	○	○	◉	○
Option 3 (integration into RAC with adaptation)	○	○	○	○	○	◉
Option 4 (absorption by RAC without adaptation)	◉	○	○	○	○	○

Question 6b. Please elaborate on other impacts you consider important: maximum 500 words

4000 character(s) maximum

Options 3 and 4 would add a significant amount of work to RAC and create additional decision layers. Efficiency, as well as the expertise on cosmetics safety assessment and new methodologies would be lost .

Final (additional) feedback

Question 7. If 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 details here (optional):

Explanation of the previous answers:
1. "Safety" of the products is considered as an assessment based on the existing Cosmetic Products Regulation provisions.
1a. The criterion "compliance with food safety requirements" should be deleted / The criterion "lack of suitable alternatives" should be revised and the application more clearly formalised / The criterion "overall exposure" should be maintained, but its application revised.
1d. Cosmetics Europe assessed more than 700 cosmetic formulations and found out that 90% of the products contain at least one "GRA substance". If GRA is applied, more than 500.000 products on the market would require reformulation, which would have a negative impact on the costs and on the innovation research.
2a. The essential use concept should not be used to ban cosmetic ingredients which are already proven to be safe, but alongside with the lack of suitable alternatives it must be used to set priorities and timelines in a derogation process. The concept of essentiality must be interpreted as a physical, mental and social well-being. Cosmetic products are very important in the daily life of consumers and they contribute to their quality of life and well-being.
2b. The application of the extended GRA substances and the essential use concept would lead to the loss of the majority of the existing UV filters, preservatives, and other safe ingredients. This would lead to the loss of many products necessary for the hygiene and the protection of the consumers.
3. We disagree because: - cosmetics are intentional mixtures of chemicals, - the current safety assessment procedure takes into account the combination effects from different products and moreover they use the exaggerated exposure concentrations.
3a. We believe that if a mixture assessment factor is to be applied it should be limited to CMR 1 substances and Endocrine Disruptors 1 substances.
3c. We disagree with the greater consumer protection for the same reasons that we have stated on

explanation 2b: the loss of safe UV filters and preservatives would have a negative impact on public health.
4c. Complete removal of the criterion “insolubility/biopersistance” would lead to a very large number of ingredients reclassified as nano, leading to increased costs for reformulation or compliance and costs for the safety assessment by SCCS. Complete removal of the criterion “intentionality” would lead to a very large number of ingredients reclassified as nano, leading to increased costs. Finally, the “% threshold for the particle number in the size distribution” would have a positive impact in the harmonization and the application of the nano definition across the whole European market.
6b. We believe that a scientific committee independent and transparent, with the sector-specific excellence and with the scientific experience of using alternative methods for evaluating safety without animals, is crucial for the application of the Cosmetic Products Regulation provisions and the protection of consumers.

Question 8. If you would like to share a document related to the targeted revision of the Cosmetic Products Regulation, please upload it below (optional):

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

Contact

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