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European Commission

INCEPTION IMPACT ASSESSMENT

Inception Impact Assessments aim to inform citizens and stakeholders about the Commission's plans in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.

TITLE OF THE INITIATIVE	EU Chemicals Strategy for Sustainability - Revision of the Cosmetic Products Regulation
LEAD DG (RESPONSIBLE UNIT)	DG GROW F2 - Bioeconomy, Chemicals, Cosmetics
LIKELY TYPE OF INITIATIVE	Legislative proposal
INDICATIVE PLANNING	Q4 2022
ADDITIONAL INFORMATION	*https://ec.europa.eu/growth/sectors/cosmetics_en* *https://ec.europa.eu/environment/strategy/chemicals-strategy_en*

The Inception Impact Assessment is provided for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Inception impact assessment, including its timing, are subject to change.

A. Context, Problem definition and Subsidiarity Check

Context

The European Green Deal sets a high ambition for a toxic-free environment leading to zero pollution. The Chemicals Strategy for Sustainability (CSS) adopted on 14 October 2020 outlines the Commission's strategy for the sustainable and safe use of chemicals. The objectives of the Strategy are to better protect citizens and the environment against hazardous chemicals and encourage innovation for the development of safe and sustainable alternatives. To this end, the CSS includes an institutional commitment of the Commission to present a new legislative proposal to amend the Cosmetic Products Regulation (Regulation (EC) No 1223/2009).

The Cosmetic Products Regulation will be subject to a targeted revision, alongside other chemicals legislation including the REACH Regulation and CLP Regulation**.** The purpose of this impact assessment is to review some of the provisions of the Cosmetic Products Regulation in light of the objectives of the CSS.

Problem the initiative aims to tackle

The Cosmetic Products Regulation applies to all cosmetic products made available on the EU market, in order to ensure the functioning of the internal market and to ensure a high level of protection of human health. Recently, as indicated in the CSS, in order to enable green and digital transitions and to protect the environment and human health, existing EU chemicals legislation, including the Cosmetic Products Regulation, must evolve and respond to the challenges that hamper the sustainable use of chemicals.

Although the Cosmetic Products Regulation prohibits, as a general rule, substances that are carcinogenic, mutagenic or toxic for reproduction (CMRs), with a possibility for exceptions under strict conditions, other most harmful chemicals may pose similar risks to consumers and professional users. The Cosmetics Product Regulation is not yet aligned to the approaches announced under the CSS to implement the **generic approach to risk management** and the **essential uses concept** intended to address those risks. Similarly, other than CMRs, the Cosmetic Products Regulation does not have 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.

Substances in cosmetics undergoing a risk assessment by the Scientific Committee on Consumer Safety (SCCS) are often subject to risk assessments and regulation under other legal frameworks and by other scientific committees. In line with the **"One Substance, One Assessment"** approach of the CSS, effectiveness, efficiency and coherence of the assessments as well as the best use of expertise and resources available in the agencies could be improved by reattributing assessments of substances also used in cosmetics to an EU Agency.

In order to achieve consistency of regulatory outcomes, EU chemicals legislation needs to use coherent terminology as regards the **definition of nanomaterials**. The current definition of nanomaterial in the Cosmetic Products Regulation may need to be aligned with the outcome of the comprehensive review taking place in the context of the CSS.

This initiative will also take into account the simplification and digitalisation of labelling requirements of chemicals to improve the communication of essential information on chemicals. As such, the use of digital tools for product labels should be assessed for cosmetic products.

Basis for EU intervention (legal basis and subsidiarity check)

This initiative will be based on Article 114 of the Treaty on the Functioning of the European Union, under which the EU can take action to ensure the functioning of the internal market. The Cosmetic Products Regulation comprehensively harmonises rules for cosmetic products made available in the EU, in order to ensure the proper functioning of the internal market and a high level of protection of human health.

A revision of this Regulation therefore can only be conducted at EU level, to improve the set of harmonised rules that apply to cosmetic products. The objectives of this initiative cannot be sufficiently achieved by the Member States alone, because of their scale and effects, and can therefore be better achieved at EU level. Therefore, the subsidiarity principle is respected.

B. Objectives and Policy options

In order to achieve the objectives of the CSS, the impact assessment will analyse the following policy options in addition to the baseline scenario of no policy change:

- **Extending the generic approach to risk management to ensure that cosmetics do not contain, firstly, chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative; secondly, chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ:** the impact assessment will analyse various options including the extension of the existing or modified provisions restricting CMRs (Article 15 of CPR) to further hazard classes, review the criteria and processes to decide on exceptions to bring them in line with the essential use concept currently developed under CSS, and introducing provisions to take account of combination effects.

- **To improve effectiveness, efficiency and coherence of safety assessments across EU legislation as well as to ensure the best use of expertise and resources in the Agencies, in line with the "One Substance, One Assessment" approach, tasks of the SCCS on cosmetic ingredients could be reattributed to ECHA**: the impact assessment will examine how the tasks are to be integrated in ECHA, including as a new working group of RAC, or as an independent committee under the auspices of ECHA, or inclusion in the proposal for a founding regulation for ECHA, amongst other options.

- **Reviewing the definition of nanomaterial to ensure coherent terminology across chemicals legislation:** options may include replacing the current definition used in the Cosmetic Products Regulation by the horizontal one laid down in Commission Recommendation 2011/696/EU of 18 October 2011 or with an updated one as announced in the CSS, or modifying it to bring it in line with the new or revised horizontal, broad definition.

- **Changing the way in which specific product label information is provided:** options will include on-pack and digital labelling and/or simplifying certain information.

The above-mentioned options are preliminary and may evolve with the analysis.

C. Preliminary Assessment of Expected Impacts

Likely economic impacts

Some changes to the Cosmetic Products Regulation will probably reduce costs for industry, for instance on nanomaterials and through improvements in the risk assessment and management of harmful substances. Other changes might lead to increased costs for industry, including SMEs, throughout the supply chain. This would be a result of the introduction of stricter rules on the most harmful chemicals such as endocrine disruptors, preparation of exemption dossiers and generation of safety data, and the need for reformulation of cosmetic products. A proportionate transitional period will be discussed to support a smooth transition. The specific impacts on SMEs of the different measures will be assessed in the context of the Impact Assessment.

This targeted revision aims to provide EU industry with a global competitive advantage in terms of economic sustainability and legal clarity, and also increase competitiveness at a global level as new rules will have an impact on cosmetic imports from non-EU countries.

In particular, a modernised regulatory framework aims to help industry efficiently cope, in a timely manner, with the future production and use of sustainable chemicals. Moreover, a set of revised rules for cosmetics, consistent with other EU chemicals legislation, is meant to facilitate economic operators' activities in this sector by improving cost-effectiveness of compliance activities. In particular, digital labelling could increase cost-efficiency for industry,

e.g. through decreased administrative costs and increased ease to quickly adapt information on labels subject to frequent changes.

Also, positive economic impacts may be observed in the future due to the reduction of the economic burden of negative health effects of the most harmful chemicals.

Likely social impacts

A targeted revision of the Cosmetic Products Regulation aims to contribute to the protection of consumers and vulnerable groups by reducing exposure to the most harmful chemicals.

Likely environmental impacts

This initiative is deployed in the context of the CSS, which is part of the EU's growth strategy towards a sustainable climate neutral and circular economy by 2050 (the EU Green Deal). The review of the Cosmetic Products Regulation is, therefore, aimed at supporting the green transition of the chemical industry, by minimising and substituting as far as possible chemicals having a chronic effect for the environment and phasing out the most harmful ones for non-essential societal use.

Likely impacts on fundamental rights

The initiative is unlikely to have any impacts on fundamental rights.

Likely impacts on simplification and/or administrative burden

In the context of the overall modernisation of the EU's regulatory framework for hazard and risk assessment and management of chemicals, the revision of the Cosmetic Products Regulation could have positive effects in terms of predictability for business operators as well as the national authorities as regards the current and future production and use of chemicals. For instance, streamlining scientific advice on substances in cosmetic products may lead to more consistent and efficient use of resources and ensure that assessment methodologies are more coherent and harmonised across different chemical legislations. Potential administrative burden will be assessed via the impact assessment.

Digital labelling could lead to reduced administrative burdens by easing compliance with labelling requirements and lead to simplified processes of compliance checks of products (relevant to market surveillance authorities, e.g. through customised information, quick searches, languages). Its impact on organisation of controls on products entering the EU market may need to be assessed accordingly.

D. Evidence Base, Data collection and Better Regulation Instruments

Impact assessment

An impact assessment will be carried out with the objective to identify and assess, both quantitatively and qualitatively, the economic, social and environmental impacts (positive and negative) of the various options. The impact assessment is planned for the end of 2022 and will be presented together with the Commission's proposal for the revision of the Cosmetic Products Regulation.

Evidence base and data collection

The impact assessment will build on existing reports, reviews and information relating to the implementation of the Cosmetic Products Regulation, notably:

- Commission Communication on the Chemicals Strategy for Sustainability
- Fitness Check of chemicals legislation (excluding REACH)
- Fitness Check on endocrine disruptors
- Review of Regulation (EC) No 1223/2009 with regards to substances with endocrine-disrupting properties
- Review of Recommendation 2011/696/EU on the definition of nanomaterial
- Status report on the use of nanomaterials in cosmetic products and a review of the provisions concerning nanomaterials of the Cosmetic Products Regulation

The impact assessment will also make use of other sources, in particular, guidance documents adopted by the Working Group on Cosmetic Products and will refer to relevant impact assessment supporting studies being carried out in the context of the REACH and CLP revisions as well the existing study on fragrance allergens labelling in cosmetic products.

Consultation of citizens and stakeholders

The Commission will seek feedback on the proposed initiative from the main stakeholders, including competent authorities, businesses and industry representatives including manufacturers of ingredients and cosmetic products, NGOs, academia, individuals/consumers, consumer organisations, and other stakeholders in order to gather evidence on the impacts that it would cause. All industry consultations will pay special attention to SMEs, possibly through a SME panel or a targeted consultation.

In accordance with Better Regulation principles, in addition to the feedback received on the Inception Impact Assessment, a 12-week public consultation accessible via the Commission's "Have Your Say" website in all official EU languages will be carried out. Further targeted stakeholder consultations/interviews and a workshop may take place as part of the supporting impact assessment study. A factual summary report will be published after the public consultation is closed. A synopsis report analysing the consultation results will be added to the impact assessment.
Will an Implementation plan be established?
The initiative concerns the revision of an existing Regulation, which applies directly in all Member States. No implementation plan will be established but, where necessary, existing guidance documents may need to be revised or new ones developed for Member States and other stakeholders.