April 2024

Cosmetics Europe response to ex post Commission's public consultation on the "One Substance, One Assessment" legislative package Proposals for Regulations on a Common Data Platform on Chemicals and on the Re-attribution of scientific and technical tasks to ECHA

Cosmetics Europe[1] is the European trade association for the cosmetics and personal care industry representing the cosmetics and personal care industry in Europe. Ranging from antiperspirants, fragrances, make-up, and shampoos, to soaps, sunscreens and toothpastes, cosmetics and personal care products play an essential role in all stages of our life. European citizens use cosmetic products as part of their daily lives, serving their essential needs and expectations. These needs and expectations drive our industry as well as delivering innovative products that enhance consumers' well-being and quality of life and boost their self-esteem.

COSMETICS EUROPE'S CONSIDERATIONS

Cosmetics Europe would like to express its support to the main objective of the so called **"One Substance, One Assessment" approach** (OSOA) under the Chemicals Strategy for Sustainability (CSS) to **improve the efficiency, effectiveness, coherence, and transparency of issuing safety assessments of chemicals across different pieces of EU legislation**.

We would like to share some considerations on the legislative proposals on the **establishment of a Common Data Platform on Chemicals** and on the **re-attribution of scientific and technical tasks to the European Chemicals Agency** (ECHA).

- **Proposal for a regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals**

We welcome the objectives of the **establishment of a Common Data Platform on Chemicals (CDPC)** to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where required by EU legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the EU citizens' trust in the scientific base for the decisions taken under EU legal acts on chemicals.

[1] For more information on Cosmetics Europe, visit the website Cosmetics Europe - The Personal Care Association :: Home.

In particular, we believe that the proposed system will foster scientific progress and increase the availability of New Approach Methods (NAM) data in the chemical safety and help in gaining and disseminating knowledge on chemical safety assessment. This new system might also contribute to reducing animal testing. Furthermore, collecting all available information in one platform could make safety assessments faster and more robust, and ultimately reinforce citizens' trust in the chemical safety evaluation and in the decision-making process for chemicals.

While we support the measures outlined to reach the objectives of the proposal, we would like to draw the attention on **some elements**, as follows:

1) **Scope (chemicals data)**

In line with Recital (31) of the Proposal which indicates that "*it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts*", we understand, as to cosmetic ingredients, that chemicals data in the scope of the Proposal are those related to cosmetic ingredients referred to in the Annexes of the Cosmetic Products Regulation[2], i.e., those ingredients which must be submitted to the European Commission for an evaluation by the Scientific Committee on Consumers Safety (SCCS).

2) **Definitions**

We consider that some definitions need to be further clarified. As regards the data types, the definition of "environmental sustainability related data" is too broad and it is not clear to which information it refers to. Likewise, the definition of "chemicals data" should be further clarified. In relation to the definitions, a clarification is needed on the delegated power given to the Commission to add new categories of data types. Furthermore, the definitions of "duty holder" and "business operators" should be further clarified to highlight the difference between them. Lastly, a definition of "study" should be included (see hereafter on the study notifications).

3) **Study notifications**

In line with our understanding of the scope, we consider that studies generated as part of the regulatory obligation for those cosmetic ingredients to be reviewed by the SCCS will have to be notified. Additionally, studies to be notified should be limited to those relevant for hazards/risk identification. For clarification, we would recommend defining an exhaustive list of studies to be notified, including for which hazard endpoint of interest. Clear acceptability standards and criteria for the studies should be also indicated, e.g., which guidelines should be followed when conducting a study.

[2] Regulation (EC) n. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (link to the consolidated text).

4) Confidentiality, access, and use of data

We support the protection of confidential information under the originator principle as foreseen by the proposal. We understand that the current practice as regards confidential information submitted to the SCCS would be maintained and guaranteed. Therefore, the public will have access to chemicals data contained in the CDPC when such information has been already disclosed in accordance with EU acts under which the data was submitted. We underline that to continue fostering innovation, particular attention should be given by ECHA to the protection of proprietary data in the CDPC, especially as some data will be made publicly available.

5) Data standardization

We highlight the importance of ensuring that data standardization (format and vocabularies) do not create unnecessary burdens for the industry and is relevant to sectoral specific legislation.

- **Proposal for a directive of the European Parliament and of the Council amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency and improving cooperation between agencies in the area of chemicals**

We would like to reiterate that due to its specific role and expertise, the SCCS needs to continue being a stand-alone committee within ECHA. Whilst we support the CSS objective of improving effectiveness, efficiency, and coherence of safety assessments across EU legislation, we highlight that any re-allocation of the SCCS work to ECHA should uphold the specific and unique cutting-edge expertise that it has built up over more than 40 years with regards to safety of cosmetic ingredients and products. This can only be achieved if the SCCS will remain a stand-alone committee within ECHA.

Although the proposal does not directly impact the Cosmetic Products Regulation, the Commission Staff Working Document[3] (SWD) accompanying the proposal on the re-attribution of tasks to ECHA includes the consideration of the re-allocation of tasks currently under the responsibility of the SCCS. We welcome the suggestion, as noted in the SWD, to maintain the SCCS as a separate committee. However, we believe that the number of opinions, as summarized in Table 16 of the SWD (page 35) is too low as it does not account for future additional workload. This includes changes in the nanomaterial definition resulting in additional reviews, and the extension of GRA to new hazard classes.

As underlined in the SWD, the re-attribution should ensure that valuable expertise gathered by existing entities is preserved. The knowledge of the SCCS to perform risk assessment without animal use must be preserved and cosmetics must continue using only data from non-animal tests.

[3] SWD(2023) 850 final.

Transparent safety assessment evaluation for cosmetics should continue to be underpinned by the use and further development of the current SCCS "Notes of Guidance" (page 58 of the SWD).

Any re-allocation of the SCCS work to ECHA could nevertheless also represents the opportunity to promote risk assessment methodologies based on non-animal data beyond cosmetics. We consider it important to underline that the implementation of an OSOA approach should consider the fact that cosmetics and cosmetic-only ingredients must not undergo testing using animals. Reduction in administrative burden should under no circumstance override the legal requirement to avoid and/or minimise testing using animals.

While it makes sense to harmonize hazard data and move towards a "One Substance, One *hazard* Assessment", risk assessments are critical and most relevant to EU consumers. Risk assessment must continue to be the ultimate decision-making process since it requires consideration of specific and realistic product exposure scenarios. Any harmonization that focuses on making regulatory decisions based solely on a hazard-focused approach should be carefully assessed since it would lead to setting the state of cosmetic risk assessment science back decades and ultimately would not result in a better protection of consumers.