Cosmetics Europe – The Personal Care Association

John Chave
Director General



To whom it may concern

Brussels, January 24th, 2024

<u>Subject: evolution of EU cosmetic allergens labelling requirements in accordance with Commission</u> <u>Regulation (EU) 2023/1545</u>

Cosmetics Europe¹ would like to inform you about the recent evolution of the allergens labelling requirements for EU cosmetic products, following the entry into force of the Commission Regulation (EU) 2023/1545, published on 26 July 2023². With this explanatory letter, we hope to prevent any potential misinterpretation that otherwise might lead to unwarranted barriers or difficulties in bilateral trade between your country and the EU.

Regulation (EU) 2023/1545 extended the list of allergen substances that must be declared on the packaging of cosmetic products sold in the EU, even if they are present as constituent of a complex ingredient whose name is already listed. This refined labelling approach aims at allowing consumers with allergies to make an informed choice when buying products. From 24 allergen substances today required to be labelled if present above specific threshold concentrations (different whether present in a leave-on or a rinse-off product), this list includes now more than 80 substances³.

The need to comply with this new labelling requirement does not imply any modification of the formulation of the products. It merely provides complementary information to those consumers who know they are sensitized to any of these allergens. Rather than having to avoid all products containing a complex ingredient (e.g. 'fragrance'), consumers can make a more informed choice, based on the additional information concerning specific allergens that are contained in the complex ingredient.

Global cosmetics companies placing products on the EU market are diligently working to ensure compliance with the new EU labelling requirements outlined in the regulation, updating the packaging of their cosmetic products. These products will be progressively introduced for sale from 2024 onwards. All relevant products covered by this provision will have to carry the additional information when placed on the European market as from 31st July 2026. An additional transition period for selling out is granted for products that were already in the market before this date. These transition times were carefully chosen to allow the necessary analysis of thousands of ingredients and the assessment of hundreds of thousands of finished product formulations containing them. Also, in order the labelling to be useful for sensitised consumers, dermatologists will need time to implement the newly identified allergens into their daily patch testing practice.

Cosmetics Europe is mindful of the potential questions that may arise with this change of label of product that will also be sold on your market. It must be emphasised that for operational and economic reasons, the cosmetic industry aims to develop labels which are compliant with the requirements of the largest number of countries. Indeed, labelling regulatory discrepancies fragment

¹ Cosmetics Europe is the trade association representing the interests of the European cosmetics, toiletry, and perfumery industry. Our members include cosmetics and personal care manufacturers as well as associations representing our industry at national level, right across Europe: https://cosmeticseurope.eu/about-us/our-members/full-list-members/

² https://eur-lex.europa.eu/eli/reg/2023/1545/oj

³ These substances are listed in the annex III of the EU Cosmetics Products Regulation (EC) 1223/2009



the market, creating supply chain complexities and leading to unnecessary additional costs. Instead, Cosmetics Europe promotes international convergence of cosmetic regulatory requirements, to achieve the highest level of product quality and safety globally.

With this letter, and in addition to any document that could be provided to you to clarify which allergens may now appear on the label of cosmetic products reaching your market, we would like to emphasise that:

- The extension of the <u>allergens list</u> on the product is solely aimed at meeting the new EU labelling requirements for sensitized consumers information, and it does not represent any modification of products formulation.
- In fact, these allergen substances or groups of substances additionally labelled were already
 present in the products, but were labelled only under recognized name of the complex
 ingredient containing them, for example 'PARFUM', 'FRAGRANCE', 'AROMA' or 'FLAVOR',
 and/or the name of a botanical extract or an essential oil.
- All substances and groups of substances included in the extended allergens list are labelled with recognized International Nomenclature of Cosmetic Ingredients (INCI) names, to facilitate their identification by global consumers.

We appreciate your attention to this matter and sincerely hope that the transparency of the regulatory framework outlined in this letter will contribute to a smoother implementation of this evolution. Our aim is to ensure that this regulatory change leads to a minimum administrative burden, both for your authority and cosmetic companies, facilitating swift and uncomplicated product bilateral trade between the EU and your country.

For a seamless import/export process for cosmetic products and to dispel any potential concern, we emphasize that allergen labelling modifications do not signify a change in formula. Thus, this update should not adversely affect existing product registrations and notifications on a global scale. For instance, in the EU, there is no mandatory requirement to update product notifications on the CPNP portal in response to such allergen labelling evolutions.

To help companies exporting cosmetics products from your country to the EU, Cosmetics Europe published a freely accessible guideline, providing technical clarification about the requirements of the regulation (EU) 2023/1545, accessible under the below link:

https://cosmeticseurope.eu/files/7516/9893/4117/FINAL_Fragrance_allergens_guide_02_11 2023.pdf

Cosmetics Europe would like to thank you in advance for the consideration of this topic to ensure the maximum compatibility of the international regulatory frameworks on cosmetics.

We remain at your disposal to answer any questions you may have.

Mary.

Your sincerely,

John Chave

Director General