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f u t u r e c o s m e t i c s

R Dear customers and partners,  
our newsletter No. 5 provides breaking legal changes for **Regulatory Affairs**.

We are very pleased about your interest, your inquiries, suggestions and the professional exchange, your inci-experts

## Amendment to the Cosmetic Regulation for fragrance allergens

### Will the declaration of fragrance allergens dominate the list of ingredients?

More than 80 possible fragrance allergens are to be declared in cosmetics which is confronting EU distributors of cosmetic products. Fragrances, perfume oils, flavors and essential oils have a major effect on the olfactory experience of a cosmetic product and thus define the value of a product.

At the same time, as potential contact allergens, these substances can trigger symptoms of an allergy and cause a problem for certain user groups. The percentage of the population allergic to fragrance allergens in the Union can be estimated to 1-9 %. Different measures aim to protect the whole population from acquiring fragrance allergies and for the purposes of prevention, a restriction of fragrance allergens may be sufficient. Therefore it is important to identify these allergens and provide information on the presence and labelling of individual fragrance allergens in cosmetic products so consumers can avoid contact with the substance to which they are allergic.

On 15 September 2022, the European Commission notified the WTO of a new amendment to the Cosmetic Regulation. The publication is amending Regulation (EC)

**No 1223/2009** of the European Parliament and the Council as regards labelling of fragrance allergens in cosmetic products. A draft version can be found at

[www.members.wto.org/crnattachments/2022/TBT/EEC/22\\_6171\\_01\\_e.pdf](http://www.members.wto.org/crnattachments/2022/TBT/EEC/22_6171_01_e.pdf)

The Cosmetics Regulation specifies that perfume and aromatic compositions are to be referred to in the list of ingredients. Currently, **25 fragrance allergens** listed in entries 67 to 92 of Annex III to Regulation (EC) **No 1223/2009** are to be mentioned in the list of ingredients (individually labelled). The Scientific Committee on Consumer Safety (SCCS) identified **56 additional fragrance allergens**, which have clearly caused allergies in humans and which have currently no requirement of individual labelling. Therefore, an obligation to individually label those fragrance allergens should be introduced in Annex III to **Regulation (EC) No 1223/2009** when their concentration exceeds **0,001 % in leave-on products** and **0,01 % in rinse-off products**.

A complete list of the additional fragrance allergens regarding Annex III can be found in the Annexes to the Amend of **Regulation No 1223/2009** on

[www.members.wto.org/crnattachments/2022/TBT/EEC/22\\_6171\\_00\\_e.pdf](http://www.members.wto.org/crnattachments/2022/TBT/EEC/22_6171_00_e.pdf)

For reasons of completeness and clarity, the list contains updates of certain existing entries for fragrance allergens by adding isomers and by complementing and amending

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the respective CAS and EC numbers and labeling regulations as well as new entries.

The extension of the list affects various **natural** and **essential oils** and **extracts**, especially *citrus oils* such as *bergamot* and *orange oil*, and furthermore *ylang ylang oil* and flower extracts, such as *lavender* and *jasmine extracts*. These oils and extracts are mainly applied in formulations of natural cosmetics.

The review of existing formulations indicates that the list contains ingredients that are particularly common in cosmetic formulations, including *beta-caryophyllenes*, *linalyl acetate*, *pinenes* and *vanillin*.

For reasons of consistency and clarity, an update of certain existing entries is intended by aligning common names of the substances to those of the latest version of the Common Ingredients Glossary referred to in Article 33 of that Regulation, and by grouping similar substances in one entry. This aligning aims the labelling to be streamlined and more consumer-friendly, as well as to facilitate the work of economic operators and national authorities. For example the presence of one of the substances *Lavandula Hybrida oil*, *-intermedia oil*, *-Angustifolia oil* shall be indicated as *,avandula Oil/ Extract'*

Since the updated list covers a broad spectrum of fragrances, the amendment poses a challenge for cosmetics manufacturers, especially in natural cosmetics.

Once the additional fragrance allergens are identified, it is necessary to check the presence and corresponding concentrations of the fragrance allergens in fragrance oils that are applied in formulations. Particularly perfumery

products must be reviewed, since high concentrations of fragrance oils, and thus higher total concentrations of fragrance allergens, are to be expected.

The European Commission will publish the amendment **first quarter of 2023**.

Only compliant cosmetic products shall be placed on the Union market, **3 years** after the entry into force of this Regulation. This will allow companies to make adjustments, to product formulations and containers that are necessary to ensure that only cosmetic products complying with the new requirements are placed on the market.

Only compliant cosmetic products shall be made available on the Union market, **5 years** after the entry into force of this Regulation. This will allow companies to withdraw from the market cosmetic products which do not comply with the new requirements and which were placed on the market before the new labelling provisions become applicable.

Since the amendment regarding the labeling of fragrances to Regulation No **1223/2009** can result in an adjustment of the INCI declaration, measures such as adjustments of the INCI declaration, reformulation if necessary, examination of marketability must be taken accordingly. We will gladly support you in dealing with these measures – please do not hesitate to contact us.

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We support you with our expertise in managing these challenges – please contact us