Council of the European Union

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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	[…](2022) XXX draft - D 088781/1
Subject:	COMMISSION REGULATION (EU) …/… of XXX amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards labelling of fragrance allergens in cosmetic products

Delegations will find attached document […](2022) XXX draft - D 088781/1.

Encl.: […](2022) XXX draft - D 088781/1

EUROPEAN
COMMISSION

Brussels, XXX
[…](2022) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards labelling of fragrance allergens in cosmetic products

(Text with EEA relevance)

D0088781/01

COMMISSION REGULATION (EU) …/… of XXX amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards labelling of fragrance allergens in cosmetic products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products[1], and in particular Article 31(1) thereof,

Whereas:

(1) Fragrance substances are organic compounds with characteristic, usually pleasant, odours. They are widely used in perfumes and other perfumed cosmetic products, but also in many other products such as detergents, fabric softeners and other household products.

(2) Contact allergy is a life-long, altered specific reactivity in the human immune system. Upon re-exposure to a sufficient amount of an allergen, eczema (allergic contact dermatitis) may develop. When a person has already been sensitised to an allergen, a much lower concentration of it is sufficient to trigger symptoms of an allergy. The percentage of the population allergic to fragrance allergens in the Union can be estimated to 1–9 %[2].

(3) Different measures aim to protect the whole population from acquiring fragrance allergies (primary prevention) and to protect sensitised individuals from developing allergy symptoms (secondary prevention).

(4) For the purposes of primary prevention, a restriction of fragrance allergens may be sufficient. However, sensitised persons may develop symptoms when they are exposed to lower concentrations of an allergen than the maximum permitted levels. Therefore, as a measure of secondary prevention, it is important to provide information on the presence of individual fragrance allergens in cosmetic products so that sensitised persons can avoid contact with the substance to which they are allergic.

(5) In accordance with Article 19(1), point (g), of Regulation (EC) No 1223/2009, a cosmetic product is to be made available on the Union market only where a list of ingredients is indicated on its packaging. Furthermore, that Article specifies that perfume and aromatic compositions and their raw material are to be referred to by the terms ‘parfum’ or ‘aroma’ in the list of ingredients and complemented by substances

[1] OJ L 342, 22.12.2009, p. 59.

[2] Impact assessment study on fragrance labelling on cosmetic products - Publications Office of the EU (europa.eu), p. 64.

the mention of which is required under the column 'Other' in Annex III to that Regulation. Currently, 24 fragrance allergens listed in entries 45 and 67 to 92 of Annex III to Regulation (EC) No 1223/2009 are to be mentioned in the list of ingredients (individually labelled).

(6) In response to the request of the Commission for an update of the list of individually labelled fragrance allergens, the Scientific Committee on Consumer Safety (SCCS) adopted an opinion at its plenary meeting of 26-27 June 2012[3]. It confirmed that the fragrance allergens listed in entries 45 and 67–92 of Annex III to Regulation (EC) No 1223/2009 are still relevant. Furthermore, it identified 56 additional fragrance allergens, which have clearly caused allergies in humans and which have currently no requirement of individual labelling.

(7) In light of the SCCS opinion, it can be concluded that there is a potential risk to human health arising from the use of the additional fragrance allergens identified by the SCCS and that it is necessary to inform consumers about the presence of those fragrance allergens. 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. Furthermore, fragrance substances, such as prehaptens and prohaptens, that can be transformed to known contact allergens via air oxidation or bioactivation should be treated as equivalent to fragrance allergens and be subject to the same restrictions and other regulatory requirements.

(8) For reasons of consistency and clarity, it is also necessary to update certain existing entries for fragrance allergens in Annex III to Regulation (EC) No 1223/2009 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. Furthermore, when there are multiple common ingredient names for a substance, it should be set out in the individual labelling requirement which name is to be used in the list of ingredients referred to in Article 19(1), point (g), in order for the labelling to be streamlined and more consumer-friendly, as well as to facilitate the work of economic operators and national authorities.

(9) For reasons of completeness and clarity, it is also necessary to update certain existing entries for fragrance allergens in Annex III to Regulation (EC) No 1223/2009 by adding isomers and by complementing and amending the respective CAS and EC numbers, thus facilitating the work of economic operators and national authorities.

(10) As the updated list of fragrance allergens is likely to result in entries in Annex III to Regulation (EC) 1223/2009 combining existing and new restrictions, it is necessary to provide that the economic operators should, on the one hand, continue to apply existing restrictions, and, on the other hand, be allowed a reasonable period of time to comply with new restrictions.

(11) With regard to the new restrictions, economic operators should be allowed a reasonable period of time to adapt to them by making the adjustments to product formulations and containers that are necessary to ensure that only cosmetic products

[3] SCCS (Scientific Committee on Consumer Safety), opinion on fragrance allergens in cosmetic products (SCCS/1459/11), 26-27 June 2012.

complying with the new requirements are placed on the market. Economic operators should also be allowed a reasonable period of time 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. Considering the relatively low and stable percentage of consumers developing allergic contact dermatitis, the large number of new fragrance allergens to be individually labelled and the significant number of cosmetic products concerned, the transition period should be 3 and 5 years, respectively.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 1223/2009 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula von der Leyen