

Summary

Public consultation on fragrance allergens in the framework of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products

Regulation (EC) No. 1223/2009 on cosmetic products ('Cosmetics Regulation') provides that perfume, aromatic compositions and their raw materials shall be referred to, in the list of ingredients on the packaging, as 'parfum' or 'aroma'. However, 26 fragrance allergens listed in Annex III of the Cosmetic Regulation shall be indicated in the list of ingredients in addition to the term 'parfum' or 'aroma'. Moreover, Annex II lists substances which are prohibited in cosmetic products, including some fragrance allergens.

In June 2012, the Scientific Committee on Consumer Safety adopted a new opinion on fragrance allergens¹ in cosmetic products, in which it:

- 1) Updated the list of fragrance allergens that the consumer should be made aware of when they are present in cosmetic products, while confirming that the 26 fragrance allergens currently regulated for individual labelling are still of concern;
- 2) Identified, among fragrance allergens established in humans, some substances of special concern;
- 3) Indicated that three fragrance allergens (HICC, atranol and chloroatranol) should not be used in cosmetics.

In view of the SCCS opinion, there are several areas in which further scientific work is needed, in particular the refinement of the dermal sensitisation Quantitative Risk Assessment ("QRA") for which work is ongoing. In addition, the Cosmetics Regulation should be amended in order to ensure adequate consumer information and to protect consumers against the strongest allergens.

In view of the above, the services of the European Commission propose to:

¹ SCCS/1459/11; http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf

1) Amend Annex III of the Cosmetics Regulation ('List of substances which cosmetic products must not contain except subject to the restrictions laid down') to submit additional contact allergens to the obligation of individual labelling in the list of ingredients, in addition to the terms 'parfum' or 'aroma', when their concentration exceeds 0.001% in leave-on products and 0.01% in rinse-off products.

The proposed transitional period² for listing fragrance allergens added to Annex III on the packaging of cosmetic products being placed on the market is three years.

2) Amend Annex II of the Cosmetics Regulation ('List of substances prohibited in cosmetic products') so that HICC, atranol and chloroatranol are prohibited in cosmetic products.

The proposed transitional period for making available on the market products containing atranol and chloroatranol is two years. For HICC, the proposed transitional period is two years for placing products containing this substance on the Community market and five years for their withdrawal.

The Commission would like to invite any interested parties, including authorities of the Member States, manufacturers of cosmetic products, producers of the substances concerned and relevant industry and consumers associations, to submit their comments on the proposed measures and on their possible economic impact.

The deadline for the submission of comments is **14th May 2014**.

Any comments should be sent with the reference:

'Fragrance allergens - Public Consultation'

by post or e-mail by **14th May** at the latest to:

European Commission

Directorate General Health and Consumers

Unit B/2, Health Technology and Cosmetics,

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² The transitional periods mentioned in 1) and 2) shall be counted from the moment when the proposed amendments to the Cosmetics Regulation enter into force. The amendments will enter into force on the twentieth day following that of their publication in the Official Journal of the European Union.