



**EFA response to the European Commission 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**

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is a non-profit network of allergy, asthma and chronic obstructive pulmonary diseases (COPD) patients organisations, representing 35 national associations in 22 countries and over 400,000 patients. EFA is dedicated to making Europe a place where people with allergies, asthma and COPD have the right to best quality of care and safe environment, live uncompromised lives and are actively involved in all decisions influencing their health.

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Executive Summary

EFA is representing people with allergy, asthma and COPD at the European level. Asthma and allergy are the most common chronic diseases in children and the leading cause of school absences, emergency department visits and hospitalisations.¹ In Europe almost 30 million of children and adults less than 45 years old have asthma, and around 10% of them have severe asthma, which is difficult to treat and manage. It is estimated that 1/3 of European population will develop asthma, most likely before the age of 20.² COPD is a progressive disease that affects 44 million people in Europe and is expected by the World Health Organisation (WHO) to become the third leading cause of death by 2030.³ Studies predict that 1 in every 2 Europeans will suffer from an allergy by 2015. Among all the different types of allergies, respiratory ones represent the most common allergies and currently affect around 20-30% of the European population.⁴

This response was prepared in consultation with EFA members, and we would like to acknowledge the Belgian Organisation for the Prevention of Allergy (Prévention des Allergies), the Finnish Allergy and Asthma Federation (Allergia- ja Astmaliitto), the French Association for the Prevention of Allergies (Association Française pour la Prévention des Allergies, AFPRAL) and the Norwegian Asthma and Allergy Association (Norges Astma- og Allergiforbund) for their input and comments to the consultation draft.

EFA is particularly concerned by this consultation, as cosmetic products cause a wide range of allergic reactions. Your document mentions that in Europe, allergy to fragrances in cosmetics affects about 1 to 3% of the general population and about 16% of eczema patients. Some people experience itching, burning or stinging within minutes of using a product. Adverse reactions to fragrances in perfumes and cosmetic products include allergic contact dermatitis, irritant contact dermatitis, photosensitivity, immediate contact reactions (contact urticaria), and pigmented contact dermatitis. Airborne and conjugal contact dermatitis occur too. Perfumes and deodorants are the most frequent sources of sensitisation to fragrance ingredients in women, while aftershave products and deodorants are most often responsible in men. Thereafter, eczema may appear or be worsened by contact with other fragranced products, such as cosmetics, toiletries, household products, industrial contacts and flavourings.

We use these products to make us look good and feel clean, but the unintentional effect in some people may be a decrease of quality of life, loss of productivity and worse health outcomes. As a consequence, we welcome the opinion of the Scientific Committee on Consumer Safety (SCCS) and the consequent decision of the European Commission to launch a consultation on this topic, as it provides the opportunity to people with allergy to have a say in a subject that is daily affecting their lives.

¹ Erkka Valovirta, *EFA Book on Respiratory Allergies – Raise Awareness, Relieve the Burden*, 2011, available at: <http://www.efanet.org/documents/EFABookonRespiratoryAllergiesFINAL.pdf>.

² European Respiratory Society (ERS), *The European Lung White Book – Respiratory Health and Disease in Europe*, 2013.

³ Mariadelaide Franchi, *EFA Book on COPD in Europe – Sharing and Caring*, 2009, available at: <http://www.efanet.org/documents/EFACOPDBook.pdf>.

⁴ Erkka Valovirta, *EFA Book on Respiratory Allergies*, cit.

Comments

Opinion of the Scientific Committee on Consumer Safety

Although EFA is generally pleased to see that the Scientific Committee on Consumer Safety has adopted a new opinion on fragrance allergens in cosmetic products, we are disappointed as the text only covers contact allergens, excluding respiratory allergens. The SCCS recognises that fragrances are volatile and therefore, in addition to skin exposure, a perfume also exposes the eyes and naso-respiratory tract and 2–4% of the adult population is affected by respiratory or eye symptoms by such an exposure. It is also known that exposure to fragrances may exacerbate pre-existing asthma. This is crucial as respiratory allergy is, despite the scenario that 113 million European citizens suffer from allergic rhinitis and 68 million from allergic asthma, often underdiagnosed, with approximately 45% of patients having never received a diagnosis.⁵ Therefore, we hope that another decision will be taken soon to fill this gap that could be dangerous for people with allergy and respiratory diseases.

Although the SCCS opinion acknowledges that people experience most of their allergic reactions to fragrances and preservatives, the Committee decides to focus only on fragrances and leave preservatives out of the scope. EFA would like to see a comprehensive approach towards preservatives too to guarantee that the quality of life of people with allergy is taken into account.

We welcome the provision that considers substances known to be transformed into allergens that are more potent than the parent substance as equivalent to these allergens.

We are glad that a maximum limit of concentration in the cosmetic products is proposed for 12 new chemicals and 8 natural extracts of special concerns that could provoke contact sensitisation and that the consumers should be informed of the presence of these substances. The consumers should be able to make informed choices while buying a product and therefore know the names of the allergenic substances present and not only the fact that there are fragrances in the product.

However, we would like to emphasise the importance and need for quality data in the SCCS opinions. Recently, the SCCS published their revised opinion on Methylisothiazolinone (MI) (P94 – SCCS/1521/13). The revised opinion reclassifies MI as a strong allergen and suggest new maximum levels for use in cosmetics. The old classification, as a “moderate allergen”, was erroneous. The previous level was 0.01% (100 ppm), whereas the updated level is 0.0015% (15 ppm) for use in rinse-off products. The SCCS were not able to establish safe levels for use in leave-on products (mainly due to lack of data), compared to the previous levels, which was 0.01%. The number of MI positive patients with contact dermatitis is on the rise, and some MI related reactions to cosmetics may have been prevented years ago if MI had been classified correctly at an earlier stage. A good example is children sensitised to MI in baby wipes. This is a good example of an allergen used by the cosmetics industry up to 0.01% due to erroneous classification.

We welcome the provision that requires that three fragrance allergens (3 and 4-(4-Hydroxy-4-methylpentyl) cyclohex-3-ene-1-carbaldehyde (HICC), atranol and chloroatranol) should not be present in

⁵ Erkka Valovirta, *EFA Book on Respiratory Allergies*, cit.

cosmetics. The phase-out of these fragrances is necessary to protect the health of allergic people. Public health concerns should always come first than any other economic considerations: after all, while cosmetics are part of modern everyday life, they are not essential medicines or nutrients/food. This is especially true as allergy is quite expensive for the European economies. The estimated costs of untreated patients amounted to a reduction in performance at work by 10-30%, which is a monetary loss of 24-72 EUR per day.⁶

Commission's proposed changes to the cosmetics regulation

EFA welcomes the Commission's proposal to amend Annex III to the Cosmetics Regulation to submit additional contact allergens to the obligation of individual labelling, in addition to the 26 allergens already listed there. Consumers, and especially people with allergy, should always be able to make better informed choices. Adding additional allergens to the list of those whose name have to be added to "parfum" or "aroma" in the ingredients' list is paramount as ingredient information is a cornerstone in the prevention of allergic contact dermatitis, as knowledge about the allergens which a patient has been exposed to is crucial for including the right substances in the allergy test, and for subsequent information on avoidance of re-exposure.

Once again, nonetheless, we would like to underline that it is necessary to have quality data and periodical checks and updates on the opinions issued by SCCS to ensure that they are not erroneous and that the levels proposed (levels that exceed 0.001% in leave-on products and 0.01% in rinse-off products) are safe for people.

Labelling is vital, but we would like to think forward and call for a possible ban of these substances in cosmetic products in the short- to medium-term. Perfume is a fragrance at all times, people who are hypersensitive or allergic to perfumes and fragrances do not make a difference between fragrances more or less tolerated by the general population.

We welcome the proposed provision to amend Annex II to the Cosmetics Regulation to ban HICC, atranol and chloroatranol as public health consideration and the safety of Europeans should always come first.

The proposed transitional periods for listing the new fragrance allergens on the packaging of the cosmetic products (three years) and for making available on the market products containing atranol, chloroatranol and HICC (two to five years depending on the fragrance) are too long, as citizens' safety has to come first and overcome any other economic consideration.

For possible future changes to the Cosmetics Regulation, we would like to raise your attention on the fact that for people with allergy the mix of several fragrances is particularly problematic. Therefore, future research should focus not only on studying single fragrances that could provoke allergic reactions, but also on the mix of several of them that can be harmful for people with allergy, even though the fragrances contained are not allergens as such.

⁶ Erkka Valovirta, *EFA Book on Respiratory Allergies*, cit.

People with allergy would appreciate a system for reporting adverse reactions they experienced with cosmetics to their doctors and national authorities that deal with the implementation of the Regulation, as this will ensure constant checks and periodic updates of the most harmful substances. The example of the pharmacovigilance system that is in place for monitoring the safety of medicinal products and take actions to reduce their risks and increase the benefits for patients could be followed and adopted both at the national and EU levels.⁷

Finally, we would like to draw your attention to what many of our member associations are doing: they are granting their logo in their markets for cosmetic products that are “suitable for most people with allergy/asthma”. These products are always 100% perfume/fragrance free, and they do this because people with allergy have so many problems with the current cosmetics market. Changes are needed and as fast as possible to ensure that the quality of life of these people is not further limited.



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⁷ The new pharmacovigilance legislation, adopted in 2010, allows patients to report any adverse reactions they have had with the medicine they take directly to the competent authorities. More information are available here: http://ec.europa.eu/health/human-use/pharmacovigilance/index_en.htm.