



EU Commission Proposals on Fragrance Allergens

Industry Comments 9 May 2014

Overall position on the proposals:

IFRA broadly welcomes the proposed measures. The Commission has devoted a great deal of effort to assess all the aspects of this issue and more specifically the importance of distinguishing the needs to protect un-sensitized consumers from induction and providing adequate information to avoid elicitation in previously sensitized consumers.

On induction prevention, we think that the measures related to the substances will be effective.

However, we are concerned that the extension of the current labelling of allergens may not improve the level of information for consumers already sensitized, nor enable future enhancements. The current proposals, we feel, could be more effective by combining meaningful labelling and additional information through a website.

Nevertheless, consumers can be confident that their health will be protected and that they can continue to enjoy safe, innovative products.

Identification of Allergens:

IFRA agrees with the Commission proposal to focus on the contact allergens established in humans. However, the list proposed by the SCCS still needs further clarification. A recommendation has been drafted by IFRA in agreement with the Cosmetics Industry (Cosmetics Europe and P.C.P.C.)

HICC:

IFRA notes that this material should not be used in products placed on the market two years after the entry into force of the measure and withdrawn from shelves after five years. As foreseen by the European Regulation on Cosmetic Products (Art.31), the decision could be reviewed pending the availability of new scientific evidence.



Inpurities in Mosses (Atranol & Chloroatranol):

IFRA and its membership will ensure that the impurities atranol and chloroatranol will not be present above trace levels in natural materials through the implementation of Good Manufacturing Practices. As the purity levels of the mosses have been established in IFRA standards since 2009, all products on shelves should be compliant two years after the entry into force of the measure.

Information to Consumers:

IFRA Members, with some hard work on an analytical method and investment in processes, will endeavour to provide its value chain partners with the information required on the relevant allergens in their compounds¹. IFRA can confirm the comments made in July 2013 on the draft proposal made by the Commission to the members of the Working Group on Cosmetics products in June 2013. (*“Due to the complexity of the development of the new analytical methods, their implementation through all fragrance materials and the related information to consumers, [...] such a programme needs about five years to be completely implemented.”*) IFRA has already started the programme in mid-2013 in order to meet the shortest possible transitional period. It is also understood that the dissemination of information across the whole Industry, SMEs in particular, would require some flexibility.

IFRA is worried by the proposal to extend the labelling of contact allergens to all the additional ones established on humans. IFRA is of the opinion that keeping the actual approach, indicating the fragrance allergens in the list of ingredients labelled on the product is not the most effective and appropriate means enabling the allergic consumers to make an informed choice as to which fragranced product to use with confidence.

In a nutshell, in mutual understanding with the medical community, the information to consumers must be primarily designed as the key risk management measure for the population already sensitized, therefore allergic. This population's safety must be provided by clear and effective communication enabling adequate choices to be made to avoid further elicitation of allergic symptoms.

¹ From the 82 allergens of table 13.1 in the SCCS opinion, only the 54 **chemically-defined** substances can be quantified. As previously expressed by the CEN Working Group on allergens (TC-347 WG4), **the quantification of a mixture of components in a mixture of other components is inherently impossible**. In other words, a natural extract (which is composed of many constituents) ceases to be dosable from the moment where it is mixed with the other ingredients of fragrance oil or a consumer product. For this reason, the **presence** of natural extracts reported in table 13.1 will be declared by the fragrance supplier but not quantified via analytical methods.

Natural extracts reported in table 13.1 might contain constituents also considered as fragrance allergens and present in table 13.1. These fragrance allergens are part of the 54 chemically-defined and can be quantified.



To be effective, the information to consumers must be relevant to the target audience. It has to be interesting, easy to understand, credible and action oriented.

Experience has shown that substance labelling has not been helpful or effective. It has not helped protect people already sensitized from elicitation while often confusing the vast majority of the other 'un-sensitized' population. This situation will be even more relevant when extending the list of allergens from the current 26 to 82+ established on humans.

The most effective and appropriate means should focus on communication **and enable the allergic consumers to make an informed choice** as to which fragranced product to use with confidence. As such, this information should be provided up-front in order for them to be warned of the possible presence of allergens in the product they are considering to choose. This is entirely consistent with the manner in which other intolerances in affected populations are managed e.g., hair dyes, latex, food allergies.

This information may be conveyed in different ways such as, for example, pictograms, on pack warnings, web based sources and free access to consumer help desks.

To be more specific, we would advise ***the allergens most frequently reported to be labelled with their INCI name (or equivalent)*** in cases where they would be present above the agreed threshold. ***For the other additional allergens*** which may be present, we would recommend, through an 'easy to read mention' (pictogram or short reference), that the sensitized consumer be prompted to ***consult the brand's web site*** (or other freely available sources of meaningful information).

In summary, IFRA believes that the combination of the labelling of allergens most frequently reported in conjunction with a web site for the extended list of allergens and an information campaign is a more effective means to inform sensitized consumers. It allows for the provision of more relevant information, being easy to understand and action oriented. In this way, the information will be proportionate, simple, workable and easy to update/adapt. A web site and its database will also be more useful, accessible and easy to use by dermatologists. To be more specific, should a known allergen be contained in a given product, we would ***advise the sensitized consumer to consult the brand's web site*** (or other freely available sources of meaningful information).

Last but not least, the availability of a web site would create a ***strategic opportunity to address long term needs*** of informing consumers on the sustainable and safe use of cosmetic products.

In any case, the approach used to inform consumers should be proportionate and not discriminatory. Skin allergies are not exclusively linked to fragrance substances. Hence ***consumers must be informed in the same way about any ingredients used in cosmetic products which are also established skin allergens***. Should an alternative to labelling be adopted, this would need to be extended to all kinds of substances with the equivalent human health risks.



The Scientific Workplan: IDEA - International Dialogue on the Evaluation of Allergens:

The fragrance industry will continue delivering on its commitment to the long term scientific program called IDEA – International Dialogue on the Evaluation of Allergens. Launched early last year, it has been designed as an international multi-stakeholder effort involving independent academics, regulators, dermatologists, consumer organisations and industry experts. The proceedings from the IDEA Workshops will be reviewed annually by the EU Commission and the stakeholders. The first annual review took place on December 13th in Luxembourg following the first three Workshops held last year.

The aim of the IDEA program (www.ideaproject.info) is to work together on the science of fragrance allergens and to establish agreed international protocols, methodologies and defined criteria for assessing the potential risk of fragrance allergens. The past years demonstrated that there is a need for better and common understanding, assessment and management of fragrance allergens. This program is designed to significantly improve the risk assessment methodologies and identify appropriate risk management measures.

In this context, the **Quantitative Risk Assessment (QRA)** methodology as clearly outlined in the background to the Commission proposal is fully supported by IFRA and the Industry. They are strongly committed to the IDEA project helping with further refinement of the methodology and giving regular input to a formal progress review organized by the EU Commission in order to ensure transparent and effective implementation of this methodology.