



NATRUE Organization - Statement

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

NATRUE welcomes the Commission's efforts to enhance consumer protection by providing relevant information on fragrances used in cosmetics to consumers whilst ensuring solutions sought are proportionate and workable for industry. Consequently, NATRUE is pleased to have the opportunity to comment on the revised proposal.

NATRUE's main concern is that the planned extended substance declaration on packaging will not serve the affected consumer but rather create a climate of uncertainty.

Regulatory background

The recent Commission proposal banning three fragrances and extending the declaration on the packaging to a total of 90 fragrances is based on the opinion on fragrance allergens in cosmetic products published by the Scientific Committee on Consumer Safety (SCCS) in June 2012.

The actual allergenic potential of a fragrance in the population is not clear.

The SCCS determines the allergic potential of fragrances solely on the number of skin reactions that occur, without taking into account, neither the absolute number of tests and thus the percentage of positive skin reactions, nor the frequency of distribution of the substance.

The Information Network of Departments of Dermatology (IVDK) in Germany expressed its concern regarding the above-mentioned approach and conclusions reached by the SCCS. VDK are of the opinion that most of the fragrances identified are not relevant allergens.

Currently, standardised testing kits for dermatological practices are available for less than 50 of the 90 fragrances and essential oils to be declared according to the proposal. This would mean that packaging may be required to provide information concerning a maximum of 90 fragrances/essential oils, whilst neither consumers nor their dermatologists would be able to determine whether consumers are actually allergic to them in more than 45% of the cases.

Concerning the 26 existing fragrances already declared and for which suitable testing substances exist, only 14 fragrances are tested in the two fragrance mixes and generally without testing for the individual substances in a second step. This disproportion is likely to worsen when three times as many substances are to be tested.

From studies performed on sectors of the population it can be estimated that the frequency of contact allergy to fragrance ingredients in the general population in Europe is 1-3%. Most of these consumers, whilst knowing they have a fragrance allergy, do not know the exact fragrance substances they are allergic to. Thus, for that population, the declaration "fragrance" on the packaging would be sufficient.

Development of analytical methods required

Currently an established routine method does not exist to identify and quantify the other 64 substances that are proposed to be added. Extending the declaration requirement would



NATRUE Organization - Statement

therefore entail enormous efforts to develop analytical methods. This not only represents a challenge for the producers, but also for the chemical supervisory authorities, who currently do not have a suitable method to check the proposed requirements needed by the EU. This said, NATRUE would be happy to contribute towards resolving this situation wherever and whenever possible.

Extended INCI declaration

The objective of the enhanced labelling of fragrance allergens is to ensure better consumer information concerning allergens. If it is now necessary to declare 90 fragrances, we estimate that the number of substances on the INCI declaration of Natural and Organic Cosmetic products would far more than double: On average, five fragrances are currently labelled. If the new labelling requirements are implemented, NATRUE estimates its members would need to declare 20 fragrance allergens on average for each product. It would then become extremely difficult for consumers to identify specific substances at the point of sale. Some of the substances to be declared have long names, e.g. *Jasminum Grandiflorum* Flower Extract or *Pelargonium Graveolens* Flower Oil. This may also make it harder for customers to easily find specific substances.

Furthermore this solution would be impractical due to the lack of space in general on the packaging; the space risks being insufficient for such an extended declaration. Furthermore, an enlarged INCI list would make it difficult to provide additional information on the package, e.g. application instructions or qualities of the product, the labelling in different languages etc. And what about the packaging of small products? Eye cream for example and products designed for “travel size” intended for use in planes – implementation of the proposed regulation presents real problems.

Moreover, as the INCI list would contain more fragrances and would become much longer, it becomes harder for persons that are allergic to substances *other* than fragrances to find those substances on the list.

Article 19 of the EU Cosmetics Regulation states that, whilst labelling is not subject to a specific font size, the information must be in indelible, easily legible and visible lettering. In many cases, this will not leave enough space for approximately 20 additional substances to be added.

Proposed changes

NATRUE proposes to include the possibility to provide internet-based access to information for consumers.

Indeed, the possibility of providing internet-based (dematerialized) information for consumers is a very optimal means of conveying information offering many benefits to consumers. Affected consumers with an average level of information, interest and understanding can not only retrieve a complete list of ingredients, which can be provided in the local language, but can also access an overview of the declarable fragrances in the product, and this without first having to extract them from the ingredient list on the packaging

Also a web-based (dematerialized) declaration would enable the consumer to easily search for substances. It even opens the possibility to offer a search function for products with or without certain substances. Furthermore, changes to the INCI list can be made easily and effectively – something of particular importance when a product is reformulated which happens on a regular basis.



NATRUE Organization - Statement

However, there are people in Europe who do not have access to the internet. To ensure these people have access to the relevant information concerning fragrances from the manufacturer, the phone-number of a dedicated hotline could be provided on the packaging. Including such a hotline on the packaging would also have the added advantage of enabling consumers to obtain direct information about the fragrances contained in the product from the manufacturer.

Conclusion

The proposed changes as they stand would require important financial investment and personnel resources because most cosmetic products are affected. Furthermore, more analysis is required to establish if the additional fragrance products are actually part of the cosmetics products or not. The proposed implementation period of three years is not feasible and urgently needs to be extended to 5 up to 7 years.
