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Re: Response to Public Consultation paper on the simplification of cosmetics directive 76/768/EEC

*The National Allergy Research Centre is an independent academic institution.
This is the response of the National Allergy Research Centre:*

The suggested regulatory frameworks for cosmetic products are diverse and the collective impact of the various proposals is difficult to assess. The National Allergy Research Centre would like the Commission to ensure that safety of cosmetic products is not only maintained but also improved if a simplification procedure is made.

Item 3

It is stated that the Cosmetic Directive leave little room for manoeuvre in transposition by Member States. It is important that health of all citizens in EU is safeguarded. A regulation will be more open for individual decisions and will likely create differences in the safety level of products from different countries. Turning the Directive into one regulation is likely to reduce the safety level and cannot be supported.

If the annexes are turned into a Regulation the lowest concentration limit of an ingredient has to be used no matter the function of the ingredient.

Item 6

Turning the negative list and the positive list into one list would give an extremely long list, which is difficult to use. It would be a better idea only to have a positive list and what is not on the positive list could not go into a cosmetic product.

Item 7

A modernization of the inventory is needed. A more flexible procedure for updating the inventory is fully supported. Further the usability of INCI names for informing the consumer should be assessed. Many consumers would **not** agree that INCI names are easily identifiable e.g. methyl-di-bromo glutaronitrile or hydroxyisohexyl 3-cyclohexene carboxaldehyde. These are just a few examples of important allergens, which have extremely complicated names making it difficult for the consumer with allergies to avoid products, they cannot tolerate. A recent study from our group shows that almost half of the patients with contact allergy to ingredients in cosmetics find it difficult or extremely difficult to read the ingredient label (unpublished results).

Thus apart from a more flexible procedure a more easy way of informing the consumer should be developed.

Item 9

It is important that future safety files contains data on the sensitizing potential of the substances and if it is a well-known allergen data should be present on safe levels of use protecting both the naïve consumer and the already sensitised individual. Such data would be derived from dose-response studies performed in sensitized patients.

Item 10

Presently is very laborious to contact the authorities of other members states and often the result is no response. The suggested action is fully supported. A central register of cosmetic products is needed like for pharmaceuticals (EMA).

It would improve safety for all consumers in Europe and therefore have a beneficial impact on socio-economics.

Item 11

Co-ordination between member states of activities would be an important step forward.

Serious adverse skin reactions to cosmetics are as frequent as occupational skin disease and have some of the same implications. Serious adverse effects are seen also in children leading to intensive care. It is critical that the Commission cannot account for the size of such a problem on a European basis.

The European Commission has an important role in improving the safety of cosmetics. Co-ordination of data collection from different member states will improve the basis for decision making. Member States should be encouraged to establish active surveillance systems on contact allergy and a minimal dataset should be agreed. Aggregated data from different countries should be submitted to the Commission and assessed by the scientific committee on cosmetics or another purely scientific body independent of industry. Such data can be used for decision making or as alerts for further investigations.

A cosmetovigilance system is expected to have a considerable preventive potential, if data is used for improving safety and it will also have a beneficial socio-economic impact, in terms of saved health care expenses, costs of medication, sick leave and impaired quality of life of those with allergic reactions to cosmetic products.

Item 13

The safety of a cosmetic ingredient should not only be based on the product information file made by the industry. It should be based on a review made by the SCCP where the members have not only read the industry file but also taken the scientific literature from the rest of the world into account. The Commission can not rely on stakeholders to go routinely through all cosmetic ingredients suggested by the Commission, since there are no resources for this kind of work. It is a very unreasonable procedure which will create an enormous work load on member states and consumers. The Commission should establish a European Cosmetic Agency, which would be responsible for assessing the files and updating knowledge on adverse effects of ingredients in cosmetics. This is justified by the potentially severe side effects from cosmetics, which are comparable to side effects from pharmaceuticals as well as the considerable size of the population at risk.

Item 14

The elements of the Cosmetic Directive that should be strengthened concerns safety. The safety evaluation should be undertaken by a European Cosmetic Agency or an expanded SCCP with more resources.

Item 15+16

If cosmetics were covered by No data- No market like it is known from pharmaceuticals, there would exist more safe cosmetics on the market and it would be meaningful to have the sentence “without any harm to the consumer”.

Strict criteria for assessing the content of a file need to be developed. Again pharmaceuticals should be used a model. Especially old chemicals should be reassessed.

Item 17

Hair dyes are ingredients that give some of the worst allergic side effects why it is important a positive list for hair dye ingredients is maintained. All the ingredients should be listed as “ only these substances can be used”.

Item 18

The content of the question is unclear.

Sincerely yours

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