



18.12.2015

## NOTICE TO MEMBERS

**Subject: Petition No 0937/2014 by Anthony Marshall (British) requesting that benzyl alcohol be added on the list of allergens**

### 1. Summary of petition

The petitioner calls on the EP to add the Benzyl Alcohol to the list of fourteen allergens which will be subject to new food labelling regulations as of December, 2014. According to him, benzyl alcohol is a known contact allergen which is presently used as an ingredient in foods, whether as a preservative, flavouring or other descriptions. He believes that consumers have the right to be informed about the adverse health effects and role in the allergy sensitization process of benzyl alcohol and have the right to appropriate allergen labelling about fragrance ingredients in their foods. He stresses that consumers have the right to purchase food products which do not contain this harmful ingredient.

### 2. Admissibility

Declared admissible on 18 March 2015. Information requested from Commission under Rule 216(6).

### 3. Commission reply, received on 18 December 2015

The Commission services are aware of health risks associated with benzyl alcohol. On the basis of the scientific data available and the characteristics and use of this substance in the different products mentioned in the petition it has not been deemed that a full ban should be introduced. Certain measures like concentrations limits and labelling requirements are nevertheless considered necessary to prevent adverse effects i.e. contact allergy that benzyl alcohol could produce when it is present in certain products that come into direct contact with the skin as detergents and cosmetics.

a) Use of benzyl alcohol in non-food products:

Examples of opinions dealing, among others, with benzyl alcohol as fragrance allergen are the two opinions of the Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers (SCCNFP/0017/98 Final) and the Scientific Committee on Consumer Goods (SCCS/1459/11), which can be found under the links below:

[http://ec.europa.eu/health/archive/ph\\_risk/committees/sccp/documents/out98\\_en.pdf](http://ec.europa.eu/health/archive/ph_risk/committees/sccp/documents/out98_en.pdf)

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_073.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf)

Below are the EU regulations containing requirements with regard to benzyl alcohol relating to all products that were mentioned in the petition.

**Cosmetic products:** In cosmetic products, the use of benzyl alcohol is governed by Regulation No 1223/2009 ("Cosmetics Regulation"). As many other ingredients of cosmetics, benzyl alcohol must be indicated in the list of ingredients (Article 19 of the Cosmetics Regulation).

More specifically, benzyl alcohol is mentioned in the following Annexes to the Cosmetics Regulation:

- Annex V, entry 34, where benzyl alcohol is authorised as a preservative in cosmetic products at a maximum concentration of 1,0%;
- Annex III, entry 45 (a), where the use of benzyl alcohol is authorised in solvents for purposes other than inhibiting the development of microorganisms in the product. This purpose has to be apparent from the presentation of the product. In such a case, this substance can be used without any concentration limits;
- Annex III, entry 45 (b), according to which the presence benzyl alcohol in fragrance, aromatic compositions and their raw materials in the cosmetic product must be specifically indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on products or 0.01% in rinse-off products. It means that there is a labelling obligation for this ingredient but there is no maximum concentration limit.

**Detergents:** Labelling requirements for detergents are set out in Article 11 and Annex VII of Regulation (EC) No 648/2004 (Detergents Regulation). Annex VII A of the Detergents Regulation stipulates that preservation agents shall be listed on the label, irrespective of their concentration. Furthermore, certain allergenic fragrances, including benzyl alcohol, shall be listed if added at concentrations exceeding 0,01 % by weight.

Finally for further consumer products that might contain benzyl alcohol and not covered by the previous legislation, the general safety provision under the General Product Safety Directive [1] apply.

The General Product Safety Directive does not oblige producers to disclose the list of ingredients, but products still have to be compliant to the definition of "safe product" according to Art. 2 of the Directive which means "any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons". In addition, "producers

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<sup>1</sup> OJ L 11, 15/01/2002, p. 4.

shall provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks" (Art. 5 of the General Product Safety Directive).

Thus, the producer shall be obliged to place only safe products on the market and even in cases when labelling ingredients is not mandatory, it is mandatory to warn consumers of any possible risk related to the use of the products.

#### b) Use of benzyl alcohol in food products:

Annex II of Regulation (EU) No 1169/2011 contains the EU list of foods causing allergens or intolerances. It has been established on the basis of the scientific opinions adopted by the European Food Safety Authority (EFSA)<sup>1</sup>. According to the latter, those substances are considered as part of the most common food allergens and there is ample evidence to support their inclusion in the list. Benzyl alcohol is not included in the Annex in question.

Benzyl alcohol is a natural constituent of a number of plants. However, it is also authorised for use as food additive (E 1519) in accordance with Regulation (EC) No 1333/2008. It can only be used as flavourings for: liqueurs, aromatised wines, aromatised wine-based drinks and aromatised wine-products, cocktails and for confectionery (Annex III to Regulation (EC) No 1333/2008). Benzyl alcohol is not authorised as a preservative in food. Maximum limits are established for it.

Benzyl alcohol is included in the Union list of chemically defined flavourings with number FL No. 02.210. It is included in the Union list of Flavourings (Annex I of Regulation 1334/2008).

Both these uses have been evaluated by EFSA or the SCF (the EFSA predecessor as risk assessment body) in these opinions.

[http://ec.europa.eu/food/fs/sc/scf/out138\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf)

[http://www.efsa.europa.eu/sites/default/files/scientific\\_output/files/main\\_documents/2994.pdf](http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2994.pdf)

#### Conclusion

There is no scientific data justifying a complete ban of this substance in all products, as requested by the petitioner. To protect the consumer, EU law already includes the obligation to inform the consumer about the presence of benzyl alcohol in cosmetics and detergents and imposes restrictions on concentration levels for certain categories of products. With regard to foods, there is no sufficient scientific data to include the substance in the EU allergen list. Nevertheless, the use of benzyl alcohol in the foods is limited by the EU relevant legislation in order to ensure the consumer protection.

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[http://www.efsa.europa.eu/sites/default/files/scientific\\_output/files/main\\_documents/opinion\\_nda\\_04\\_en1%2C2.pdf](http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/opinion_nda_04_en1%2C2.pdf)

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