

**Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies
on a request from the Commission related to a notification from CEPS on
nuts used in distillates for spirits pursuant to Article 6 paragraph 11 of
Directive 2000/13/EC**

(Request N° EFSA-Q-2006-141)

(adopted on 3 May 2007)

SUMMARY

The applicant provided information regarding the addition of almonds, almond oils, and nuts to an alcohol distillation process where they act as natural flavouring agents of the final alcoholic distillate, supplementing information submitted to obtain temporary exemption.

The beverages in question are widely consumed in the European Union. Literature review that includes information up to April 2006 failed to reveal allergic reactions after consumption of distillates where nuts have been used as flavourings before distillation, although underreporting cannot be excluded. Further evidence of the unlikelihood of distillates made mainly from almonds or nuts to elicit allergic reactions stems from additional analytical data on potential residues of protein and their allergenicity in the distillates and the distillation process. The analytical methodology did not address the allergenic activity of residual protein levels in the final products by using appropriate human sera. Neither epidemiological studies nor double blind placebo controlled food challenge studies in clinical settings have been carried out to address possible adverse allergic reactions to distilled spirit drinks due to almond or nut allergens.

Based on the data submitted by the applicant, the Panel notes that proteins and peptides are not carried over into the distillate during a properly controlled distillation process, at least not in amounts above 1 mg/L. Although the analytical evidence is derived from experiments that were performed predominantly with almonds, the Panel considers that distillates made from nuts are unlikely to trigger a severe allergic reaction in susceptible individuals.

KEY WORDS

Allergenicity, distillates, protein content, nut, almond, allergens.

BACKGROUND

In November 2003, the European Parliament and the Council adopted Directive 2003/89/EC¹ amending Directive 2000/13/EC, as regards indication of the ingredients present in foodstuffs.

Annex IIIa of the Directive specifies a list of food ingredients or substances that are known to trigger allergic reactions or intolerances in sensitive individuals for which no labelling exemptions are allowed. Whenever the listed ingredients/substances or their derivatives are used in the production of foodstuffs, they must be labelled.

Article 1, paragraph 11, subparagraph 2 of the Directive establishes a procedure allowing for temporary labelling exemption of derivatives from ingredients listed in Annex IIIa for which it has been scientifically established that it is not possible for them to cause adverse reactions. In accordance with this provision, submissions of requests for temporary labelling exemption were notified to the Commission before 25 August 2004. The Commission, after consultation with the European Food Safety Authority, adopted a list (Directive 2005/26/EC²) of those ingredients which are temporarily excluded from Annex IIIa until 25 November 2007, pending the final results of the notified studies.

Consequently, applicants who submitted a dossier in 2004 on the basis of subparagraph 2, resulting in the inclusion of a product in the list of Directive 2005/26/EC, and who are seeking exclusion of that product from Annex IIIa beyond 25 November 2007 will have to submit a request enclosing the final results of the notified scientific studies. Therefore in the context of the permanent labelling exemption procedure, the European Food Safety Authority is asked to provide scientific opinions on the submissions in accordance with the present terms of reference.

TERMS OF REFERENCE

In accordance with Article 29 (1) (a) of Regulation (EC) N° 178/2002, the European Commission requests the European Food Safety Authority to evaluate the scientific data submitted by European Spirits Organisation (CEPS) in the framework of the procedure laid down in Article 6, paragraph 11 of Directive 2000/13/EC. On the basis of that evaluation, EFSA is requested to issue an opinion on the information provided, and particularly to consider the likelihood of adverse reactions triggered in susceptible individuals by the consumption of the following ingredients/substances used under the conditions specified by the applicant: nuts used in distillates for spirits.

ASSESSMENT

Taking account of the potential allergen content and well documented clinical allergic reaction in individuals sensitive to the stated material (nuts/almonds) (NDA, 2004a), it is appropriate for the Panel to assess the likelihood that the finished product may cause a reaction in a nut

¹ Directive 2003/89/EC of the European Parliament and of the Council amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs. OJ L 308, 25.11.2003, p. 15.

² Commission Directive 2005/26/EC of 21 March 2005 establishing a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council. OJ L 75, 22.03.2005, p. 33-34.

(almond) allergic consumer. The Labelling Directive (Directive 2000/13/EC as amended by Directive 2003/89/EC) defines nuts as follows: Almond (*Amygdalus communis L.*), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinoensis (Wangenh.) K. Koch*), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*) and products thereof. Almonds are botanically member of the Rosaceae family, Amygdaloideae subfamily (NDA, 2004a).

In 2004, the Panel issued an Opinion on a notification submitted by the European Spirits Organisation (CEPS) to the European Commission pursuant to Article 6, paragraph 11 of Directive 2000/13/EC as amended by Directive 2003/89/EC, for temporary exemption from labelling (NDA, 2004b).

Under the framework of permanent exemption from labelling, the present Opinion is based on assessment of an updated dossier from CEPS, which contains additional information and data mainly with regard to literature review and laboratory-based, *in vitro* tests.

1. Manufacturing process

Certain distillates are produced by the addition of nuts or nut oils before the subsequent alcohol distillation process to act as natural flavouring agent to the alcoholic distillate produced. Such spirit drinks include gin and liqueurs.

For certain spirit drinks the process of distillation is not only used to distil the alcohol, but also to extract volatile substances from various botanical ingredients, such as herbs, nuts and spices, to flavour the product. These botanicals are typically added to “neutral spirits” in a pot still and distilled. The production of flavoured distillates from neutral or other spirits is traditionally a batch process that uses copper pot stills and is specific to a particular product or brand. The types of stills may be divided into two categories depending on the placement of the flavouring botanicals with respect to the liquid to be distilled: the nuts are placed (loose or in a bag) in the body of the still with the aqueous alcohol, such that the plant material is in direct contact throughout the distillation process. Distilled almond oils may also be added to the aqueous alcohol in the still. Alternatively, the botanicals may be raised above the liquid or contained in a separate basket, through which the ethanol-water vapours pass. This type of distillation is most commonly used for the production of gin and related spirits. The nature of the manufacturing process makes it unlikely that significant levels of high molecular weight, high boiling point compounds such as proteins and peptides will be carried over into the distillate. No studies presented in the open literature provided evidence that these substances do have a vapour pressure and there is general agreement in the scientific community that they do not distil.

2. Evidence of non-allergenicity

2.1 History of non-allergenicity of the product

The applicant performed a literature survey that includes information up to April 2006 to find links between nut allergies and allergic reactions related to the consumption of spirit drinks, where the nuts have been used as flavourings before distillation. The review was undertaken using the PubMed database of the US National Library of Medicine. The PubMed database includes over 14 million citations for biomedical articles from MEDLINE and additional life

science journals dating back to the 1950s. Titles and abstracts were searched for NUT ALLERGY and this gave 90 literature reports. Linking of these search terms with GIN and with DISTILLED SPIRITS gave no reported literature. Combination of the general term ALCOHOL with NUT ALLERGY yielded no published reports. Searching with the names of specific nuts referred to in Annex IIIa of directive 2003/89/EC (ALMOND or HAZELNUT or WALNUT or CASHEW NUT or PECAN NUT or BRAZIL NUT or PISTACHIO NUT or MACADAMIA or QUEENSLAND NUT) in conjunction with ALLERGY and GIN (or DISTILLED SPIRITS or ALCOHOL) only gave one reference, which relates to allergic reactions to wood dusts and their components.

Combination of ALLERG* and DISTILLED SPIRITS gave one reference to a review of allergic and asthmatic reactions to alcoholic drinks (Vally and Thompson, 2003). From this review most sensitivities to alcoholic drinks do not appear to be immune mediated, but are more frequently pharmacological intolerances to specific chemicals in these drinks. Where allergic and asthmatic reactions to specific non-alcohol components have been reported, these are almost wholly concerned with non-distilled drinks. Only one reported investigation of spirit consumption triggering asthmatic attacks could be found, however the substance causing the reaction was not identified (Breslin *et al.*, 1973). Patients reacted to specific drinks but not to the equivalent amount of ethanol. Skin prick tests for routine common allergens gave no reaction to nuts.

The applicant's literature search did not reveal allergic reactions after consumption of distillates, where almonds or nuts have been used as flavouring substances before distillation. It remains possible that adverse effects due to drinking of distillates where the nuts have been used as flavouring substances before distillation may not be perceived as due to nut allergens but rather be attributed to alcohol, and under-reporting may thus have occurred.

The Panel notes that sales of spirit drinks in the European Union totalled over 260 million cases of 12 bottles of 700 ml each.

2.2. Laboratory-based tests

2.2.1 In vitro studies

The applicant asserts that the physico-chemical properties of the allergenic proteins found in almonds and nuts (hazelnut, walnut, cashew, pecan, Brazil, pistachio, Macadamia and Queensland nut) will result in their complete lack of volatility, and hence their absence from products obtained by distillation. To support this concept, model distillations of proteins were performed with bovine serum albumin (BSA) and with almond, hazelnut and walnut proteins in alcohol-water mixtures. However, the distillation of pure protein solutions in the laboratory, without the presence of additional components typically found in industrial distillation matrices, can result in different foaming, boiling homogeneity, and steam carry over, and is not necessarily representative of the corresponding industrial conditions.

Two analytical methodologies were employed: non-specific total protein determination (Bradford Analysis Microassay) and specific almond and hazelnut protein enzyme-linked immunosorbent assays (ELISA). In order to increase the sensitivity and to remove ethanol, which interferes with the analysis, the samples for the Bradford Microassay were evaporated to dryness and made up with water, thus introducing a concentration step. The Bradford method is an appropriate assay provided the liquid is non-coloured. Thus, it is appropriate for gin and

vodka, but it is not suitable for coloured liqueurs. The method has a detection limit of 0.5 mg/L for BSA, which equated to a limit of detection of approximately 0.7 mg/L for almond, hazelnut and walnut proteins. The applicant took 1.0 mg/L as operational limit of detection (LOD).

The LOD of the ELISA assay for almond in spirit matrices was 1 mg/L. However, by applying a pre-concentration step, the method was validated for a LOD of 0.1 mg/L for both almond and hazelnut. No ELISA kit was available for walnut.

In the model system neither BSA nor nut proteins were detected in the distillates above the LOD, be it with the Bradford Analysis Microassay for total proteins or with the ELISA assay.

The allergen-specific analytical studies undertaken focussed entirely on almonds, because of their use in the production of gin and associated spirits. No industrial distillates flavoured with nuts were tested.

Forty-two industrial samples were analysed: 32 gin samples obtained from 4 different distilleries, 8 separate liqueur samples distilled from almonds, and 2 alcoholic solutions of almond essential oils (distilled). The total protein content was estimated to be less than 0.5 mg/L for vodka/neutral spirits and less than 1.0 mg/L for gin. These LOD correspond to a 10-fold increase in sensitivity when compared with the data previously submitted for temporary exemption. No almond protein above 0.1 mg/L was detected in any of the 42 alcoholic distillates. .

The analytical data presented indicate that almond proteins are not transported into the products of distillation during spirit manufacture, at least not in amounts above 1.0 mg/L. The analytical methodology did not address the allergenic activity of residual protein levels in the final products by using appropriate human sera.

Data regarding hazelnut and walnut are reported only in the model distillation system and not during industrial production. No data were presented for the other nuts mentioned in the application. On the other hand, it was stated by the applicant that no distillates flavoured with other nuts than almonds are commercially available.

2.2.2 Animal studies

No animal studies were provided or referred to in the data submitted.

2.3 Clinical studies

2.3.1 Skin tests

No systematic skin prick testing studies in nut allergic individuals exposed to distillates have been reported, where the nuts have been used as flavourings before distillation. Only one case report of spirit consumption triggering asthmatic attacks could be found. However, the substance causing the reaction was not identified (Breslin *et al.*, 1973). Skin prick tests for routine common allergens gave no reaction to nuts. Hence, this case report does not indicate nut allergen involvement in the responses noted.

2.3.2 *Double blind placebo controlled food challenge (DBPCFC)*

No DBPCFC data in nut-allergic individuals exposed to distillates, where the nuts have been used as flavourings before distillation, have been reported.

2.3.3 *Epidemiological studies*

The applicant has not carried out epidemiological studies in order to investigate possible adverse reactions to distilled spirit drinks due to nut allergens.

CONCLUSIONS

Based on the data submitted by the applicant, the Panel notes that proteins and peptides are not carried over into the distillate during a properly controlled distillation process, at least not in amounts above 1 mg/L. Although the analytical evidence is derived from experiments that were performed predominantly with almonds, the Panel considers that distillates made from nuts are unlikely to trigger a severe allergic reaction in susceptible individuals.

DOCUMENTATION PROVIDED TO EFSA

Dossier submitted by the European Spirits Organisation (CEPS) to the European Commission pursuant to Article 6, paragraph 11 of Directive 2000/13/EC on 25 August 2006.

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