



**Paper for information: Government Updates on Nutrition  
Related Activities  
EFSA**

**Agenda Item: 6**

Please see attached paper for information.

**Scientific activities of the EFSA Panel on  
Dietetic Products, Nutrition and Allergies (NDA Panel)**

(submitted by Dr. Rodríguez Iglesias, scientific co-ordinator of the NDA Panel)

- 1) At its last plenary meeting in December, the NDA Panel adopted three opinions, one of which was on the evaluation of the allergenicity of lupin for labelling purposes. This opinion was in relation to the update of Annex IIIa of Directive 2000/13/EC, as amended by Directive 2003/89/EC, which establishes a list of foods that are known to trigger allergies or intolerances. The other two opinions concerned the novel food applications of two vegetable oils being processed in a specific way in order to increase the content of vitamin E present in the oils, i.e. maize-germ and rapeseed oils high in unsaponifiable matter. In addition, the NDA Panel adopted the minutes' statement replying to the applicant's comment on the Panel's Opinion relating to the evaluation of goats' milk protein as a protein source for infant formulae and follow-on formulae. Details about these evaluations are provided in the Annex.

**Annex. Opinions adopted by the NDA Panel at its last plenary meeting****Opinion on the evaluation of lupin for labeling purposes**

Lupin (genus *Lupinus*, subfamily *Papilionaceae*, family *Leguminosae*) is a legume which includes over 450 species. *Lupinus albus* (white lupin, Mediterranean countries), *Lupinus luteus* (yellow lupin, Central Europe), *Lupinus angustifolius* (blue lupin, Australia) are used for human and animal consumption. Lupin seeds have been part of normal food intake since ancient times and are consumed as snacks in several European countries. Since the introduction of lupin flour as an ingredient in wheat flour in the 1990s for its nutritional and food processing qualities, lupin consumption became more widespread in Europe.

Allergic reactions to lupin have been documented. IgE-binding proteins of lupin flour extracts have been identified and show *in vitro* cross-reactivities with peanut and other legumes, although the most clinically relevant cross-reactions are with peanut proteins. There is no definite indication that technological treatments alter the allergenic potential of lupin, although reduction in allergenicity has been reported after autoclaving lupin seeds at 138°C for 30 minutes.

The frequency of allergic reactions to lupin in the general population is unknown. Most, though not all, allergic reactions have been reported in peanut allergic individuals. The possibility of under-reporting of allergy cases cannot be excluded, as until recently lupin was a hidden ingredient in various bakery and meat products. One controlled study in peanut allergic patients suggests a clinically relevant cross-reactivity rate of about 30%, but higher (68%) rates have been reported. Clinical reactions range from mild local reactions to systemic anaphylaxis. Ingested doses of lupin flour reported to have triggered clinical reactions range from 265 to 1000 mg, but the lowest dose triggering reactions has not been established.

**Opinion on maize-germ oil high in unsaponifiable matter as a novel food ingredient**

“Maize-germ oil high in unsaponifiable matter” is obtained via concentration of the unsaponifiable fraction of refined maize-germ oil by the application of a high vacuum-distillation step (“molecular distillation”). The novel food is considered equivalent to its source as regards fatty acid composition and contaminants. The difference between the novel food and its source arises from the concentration of the unsaponifiable fraction from 1.2 g/100 g to 10 g/100 g (including 7 g/100 g sterols and 2 g/100 g total tocopherols) and the concomitant decrease of triglycerides (from 98.8 g/100g to 90 g/100g). The high-vacuum distillation step also results in the concentration of polycyclic aromatic hydrocarbons and possibly other organic contaminants in the novel food, so that appropriate treatments and strict control measures must be in place to ensure that the levels of these contaminants in the final product comply with current regulations.

As regards toxicology, microbiology and allergenic potential, the novel food is comparable to refined maize oil.

The novel food supplies 70 mg sterols/g and 20 mg total tocopherols/g. According to the proposal of the applicant, the novel food could be used as an ingredient in a wide range of foods. The intended maximum daily intake of the novel food of 2 g results in an intake of 40 mg total tocopherols, corresponding to 11 mg  $\alpha$ -tocopherol equivalents. The Tolerable Upper Intake Level for vitamin E of 300 mg/day for adults (SCF, 2003) is not likely to be exceeded under the specified conditions of use of the novel food. A daily intake of 2 g of “maize-germ oil high in unsaponifiable matter” provides 140 mg of total phytosterols. This amount is less than the intake of 1-3 g per day recognised as being effective in significantly reducing LDL-cholesterol levels in serum (SCF, 2002).

The Panel concludes that the novel food is safe for human consumption under the specified conditions of use.

**Opinion on rapeseed oil high in unsaponifiable matter as a novel food ingredient**

“Rapeseed oil high in unsaponifiable matter” is obtained via concentration of the unsaponifiable fraction of refined rapeseed oil by the application of a high vacuum-distillation step (“molecular distillation”). The novel food is considered equivalent to its source (refined rapeseed oil) as regards fatty acid composition and contaminants. The difference between the novel food and its source arises from the concentration of the unsaponifiable fraction from 1.0 g/100 g to 9 g/100 g (including 7 g/100 g sterols and 1 g/100 g total tocopherols) and the concomitant decrease of triglycerides (from 99.0 g/100g to 91.0 g/100 g). The high-vacuum distillation step also results in the concentration of polycyclic aromatic hydrocarbons and possibly other organic contaminants in the novel food, so that appropriate treatments and strict control measures must be in place to ensure that the levels of these contaminants in the final product comply with current regulations.

As regards toxicology, microbiology and allergenic potential, the novel food is comparable to refined low erucic acid-rapeseed oil.

The novel food supplies 70 mg sterols/g and 10 mg total tocopherols/g. According to the proposal of the applicant, the novel food could be used as an ingredient in a wide range of foods. The intended maximum daily intake of the novel food of 1.5 g results in an intake of 15 mg total tocopherols, corresponding to 7 mg  $\alpha$ -tocopherol equivalents. The Tolerable Upper Intake Level for vitamin E of 300 mg/day for adults (SCF, 2003) is not likely to be exceeded under the specified conditions of use of the novel food. A daily intake of 1.5 g of “rapeseed oil high in unsaponifiable matter” provides 105 mg of total phytosterols. This amount is less than the intake of 1-3 g per day recognised as being effective in significantly reducing LDL-cholesterol levels in serum (SCF, 2002).

The Panel concludes that the novel food is safe for human consumption under the specified conditions of use.

**Extract from**  
**the Minutes' Statement replying to applicant's comment on the Panel's Opinion relating to the evaluation of goats' milk protein as a protein source for infant formulae and follow-on formulae**

(Full Minutes' statement is available on EFSA Website:  
[http://www.efsa.eu.int/science/nda/nda\\_statements/1299\\_en.html](http://www.efsa.eu.int/science/nda/nda_statements/1299_en.html))

On 19 February 2004 the Panel adopted an Opinion on the evaluation of goats' milk protein as a protein source for infant formulae and follow-on formulae<sup>1</sup>. On 4 July 2005 the applicant submitted to the European Commission its comments and additional information in response to the Opinion. Following that, EFSA was asked by the European Commission to assess the submission and to consider whether there is a need to update the aforementioned Opinion of the Panel.

In its Opinion of 2004, the Panel concluded that the data submitted were insufficient to establish the suitability of goats' milk protein as a protein source for infant formula and that unmodified goats' milk protein is not suitable to be used as a protein source in infant formula.

The comments provided by the applicant refer, among other issues, to the following two main issues: 1) Amino acid pattern of the goats' milk protein-based formula; and 2) the clinical study of a goats' milk protein-based formula.

During its 12<sup>th</sup> plenary meeting dated 6 December 2005, the NDA Panel expressed the following conclusion:

According to the amino acid analysis provided now, the goats' milk formula fulfils the requirements of Directive 91/321/EEC with respect to the amino acid pattern.

In agreement with the previous conclusion of the Panel the clinical study of a goats' milk protein-based formula submitted is insufficient due to methodological flaws. Therefore, on the basis of the data submitted, the previous overall conclusion of the Panel that there are insufficient data to establish the suitability of goats' milk protein as a protein source in infant formula remains valid.

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<sup>1</sup> Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission relating to the evaluation of goats' milk protein as a protein source for infant formulae and follow-on formulae. The EFSA Journal 30, 1-15.  
[http://www.efsa.eu.int/science/nda/nda\\_opinions/catindex\\_en.html](http://www.efsa.eu.int/science/nda/nda_opinions/catindex_en.html)