

COMMITTEE PAPER FOR DISCUSSION**ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES****EFSA OPINIONS ON MAIZE-GERM OIL AND RAPESEED OIL HIGH IN UNSAPONIFIABLE MATTER****Issue**

The Committee is invited to consider two opinions from EFSA on vegetable oil products proposed for authorisation as novel food ingredients. The Committee is asked whether the EFSA opinions and the additional information provided by the applicant address the concerns raised when the Committee first reviewed these products in 2002.

Background

1. EFSA's Scientific Panel on Dietetic Products, Nutrition and Allergies has recently published Opinions regarding the safety of two types of oil high in unsaponifiable matter as novel food ingredients. These are derived from maize-germ oil (Annex 1) and rapeseed oil (Annex 2) respectively. These two novel food ingredients were the subject of favourable initial opinions from the French Competent Authority (CA) under the Novel Food Regulation (EC) 258/97.
2. As a result of reasoned objections from Member States, including the UK, both these products were referred to EFSA by the Commission for consideration by the Scientific Panel on Dietetic Products, Nutrition and Allergies. In view of the similarity of the products, the similar nature of the objections from the UK and the EFSA Opinions, these two opinions are considered together in this paper, with particular reference to the objections originally raised by the ACNFP.
3. These two oils, "high in unsaponifiable matter", are obtained by a concentration of the unsaponifiable fraction of a maize-germ oil and a non-erucic rapeseed oil respectively, using a novel processing method of molecular distillation. The effect of the novel manufacturing process on the nutritional and chemical composition of the novel food places it in category (f) in accordance with Article 1(2) of the Novel Food Regulation (EC) 258/97 (Annexes 1 and 2; p3, para 4).

ACNFP concerns

4. At the March 2002 meeting of the ACNFP the Committee considered initial opinions from the French CA regarding the rapeseed oil (ACNFP/54/4; Annex 3) and maize-germ oil (ACNFP/54/5; Annex 4). The Committee entered reasoned objections for both these novel food applications based on similar criticisms of the data provided by the applicant for both products. The main comments were:
 - i. **Product specification:** The Committee agreed with the French CA regarding the ambiguity in the specification of these products. The UK CA was of the

opinion that the applicant needed to provide a more accurate specification that provides at least a maximum and minimum range for each component. For the rapeseed oil product it was recommended that this should include the specific erucic acid content as the UK CA believe the Codex standard for erucic acid is less than 2% rather than less than 5%.

- ii. **Setting intake levels:** The French CA recommended that the applicant should reduce the daily intake of the novel food, from 5g to 1.5g for the rapeseed oil and 8g to 2g for the maize-germ oil. This was based on their safe upper limit for vitamin E (a multiple of its recommended daily intake (RDI)). The Committee expressed doubts about this practice of setting safe upper limits for vitamins based on a multiple of the RDI since Member States have established safe upper limits based on toxicity.
 - iii. **Limiting daily intake:** The Committee was concerned about how the company would limit the intake of these novel food ingredients given the number of foods that could potentially contain them. The UK CA does not consider that the applicant has satisfactorily demonstrated that it can limit consumption to a daily intake of 1.5g for the rapeseed oil and 2g for the maize-germ oil. The intake and likely use of these products needed to be clarified.
 - iv. **Labelling issues:** The UK agreed with the French CA that the applicant should not be allowed to make cholesterol lowering health claims. However, the UK also pointed out that susceptible or high risk members of the population may still be affected by these products, therefore the label should incorporate wording to indicate that the product contains phytosterols.
5. The UK CA did not have any specific safety concerns about these products. However, the UK CA objected to the marketing of these products until the concerns listed above were addressed.

The EFSA Opinions

6. Positive opinions for both these oils were adopted by EFSA on 6 December 2005 and published in January 2006. Information in the opinions relating to the four points previously raised by the ACNFP (4i - 4iv) is detailed below (6i – 6iv).
- i. **Product specification:** The applicant has provided more detailed information on the specification of these products, including maximum, minimum and average values for most components (Annexes 1 and 2, Table 1) as requested by the ACNFP. In addition, the erucic acid content of the rapeseed oil is set at a maximum of 2% (Annex 2; p4, Table 1).
 - ii. **Setting intake levels:** The issue of intake levels derived from multiples of the RDI for vitamin E has not been addressed and the daily intakes requested by the French CA of 1.5g for the rapeseed oil and 2g for the maize-germ oil have been used as the basis for EFSA's risk assessment. Consumption of either of the products in these amounts would provide 40 mg total tocopherols, corresponding to 11 mg a-tocopherol equivalents. The Tolerable Upper Intake Level for vitamin E of 300 mg/day for adults (SCF, 2003) is not likely to be

exceeded. In the UK, the Expert Group on Vitamins and Minerals has set a Safe Upper Level of 540 mg alpha-tocopherol equivalents for supplemental intake of vitamin E.

- iii. **Limiting daily intake:** Concerns over the daily intake of these products have not been directly addressed by EFSA. The Opinions state that these products are not intended to replace any existing food and that the applicant recommends their use as food ingredients: “to restore the nutritional balance in terms of the intake of vitamin E and phytosterols in miscellaneous food products or in functional foods.” Potential areas of use suggested by the applicant are (i) dietary supplements and (ii) any food products for which claims are made concerning the intake of vitamin E and phytosterols (Annexes 1 and 2; p7, paras 1 & 2).
- iv. **Labelling issues:** Labelling of the product is not mentioned by EFSA. However, regarding phytosterols, the opinions confirm that the levels present in both products (105mg/1.5g rapeseed oil; 140mg/2g maize-germ oil) are less than the 1-3g per day necessary to significantly lower serum cholesterol (Annexes 1 and 2; p8, para 6).

Concerns of other Member States

- 7. The EFSA opinions mention two additional concerns raised by MS, namely the possibility of excessive vitamin E intake and the provision of insufficient toxicological information for a safety assessment to be made.
- 8. **Levels of vitamin E:** EFSA has presented arguments to suggest that under the, “specified conditions of use”, the contribution of the products to vitamin E intake is low and the tolerable upper intake level of 300mg/day for adults is unlikely to be exceeded (Annexes 1 and 2; p8, para 3 and p9, para 6).
- 9. **Toxicological information:** No additional information appears to have been provided under this heading. However, as the manufacturing process may result in the concentration of polycyclic aromatic hydrocarbons (PAHs) data was provided on the levels of PAHs before and after treatment with active carbon (Annexes 1 and 2; p5, Table 2). The opinions stipulate that appropriate treatments must be in place to ensure that the levels of PAHs and other organic contaminants in the final products comply with current regulations (Annexes 1 and 2; p5, para 5).

Committee Action Required

- 10. The Committee is asked to consider whether it agrees with the conclusions of the EFSA Scientific Panel on these maize-germ and rapeseed oils high in unsaponifiable matter and, if not, what remaining concerns it has regarding these products.

**Secretariat
March 2006**

Annexes attached:

Annex 1: The EFSA Journal (2005) 303, 1-11: Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to maize-germ oil high in unsaponifiable matter as a novel food ingredient. Available via www.efsa.eu.int

Annex 2: The EFSA Journal (2005) 304, 1-11: Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to rapeseed oil high in unsaponifiable matter as a novel food ingredient. Available via www.efsa.eu.int

Annexes available on request

Annex 3: ACNFP/54/4 and annexes (rapeseed oil).

Annex 4: ACNFP/54/5 and annexes (maize-germ oil).