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

(Request N° EFSA-Q-2004-013)

(adopted on 6 December 2005)

SUMMARY

"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 α-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.

KEY WORDS

Maize-germ oil, unsaponifiable matter, molecular distillation, vitamin E, sterols.

INTRODUCTION

"Maize-germ oil high in unsaponifiable matter" is obtained via concentration of the unsaponifiable fraction of refined maize-germ oil. The "unsaponifiable fraction" of vegetable oils comprises those constituents which, after saponification (i.e. base-catalysed hydrolysis) of the oil exhibit low solubility in water and high solubility in lipophilic solvents.

Typical components are: sterols and methylsterols, tocopherols and tocotrienols, carotenoids, other terpenic compounds (triterpenic alcohols), fatty alcohols and waxes, hydrocarbons and squalene.

The process applied to obtain "maize-germ oil high in unsaponifiable matter" involves molecular distillation (i.e. evaporation under high-vacuum) of maize-germ oil. This physical fractionation results in an enrichment of compounds with lower boiling points in the condensed distillate. Compared with the starting maize-germ oil, the content of triglycerides in the final product is reduced from 98.8 to 90%, whereas the content of "unsaponifiable matter" increases from 1.2 to 10%.

The intake of the novel food requested by the applicant is 2 g per day. This would provide 11 mg of vitamin E and 140 mg of total sterols per day.

BACKGROUND

On 24 October 2001, Expanscience (formerly Pharmascience) submitted a request under Article 4 of the Novel Food Regulation (EC) N° 258/97 to the French competent authorities for placing on the market foods and food ingredients derived from maize germ oil high in unsaponifiable matter.

On 8 January 2002, the French competent authorities forwarded to the Commission its initial assessment report, carried out by the "Agence Française de Sécurité Sanitaire des Aliments" (AFSSA) which had reached the conclusion that the product was safe provided that the daily intake was limited to 2 g/day.

In accordance with Article 6 (4) of the Novel Foods Regulation, the Commission forwarded the initial assessment report to Member States on 18 February 2002. Member States submitted their comments and/or presented reasoned objections within the 60 day period provided for in the authorisation procedure. In consequence, a Community Decision is now required under Article 7, paragraph 1 of Regulation (EC) No 258/97.

The concerns raised by the Competent Authorities of Member States were:

- that there could potentially be an excessive intake of vitamin E;
- that the applicant had provided insufficient toxicological information for a safety assessment to be made.

TERMS OF REFERENCE

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002, the European Food Safety Authority is asked to carry out the additional assessment for maize-germ oil high in unsaponifiable matter in the context of Regulation (EC) N° 258/97.

EFSA is asked to consider the elements of a scientific nature in the comments/objections raised by the other Member States.

ASSESSMENT

The application (Laboratoires Pharmascience 2001; Laboratoires Expanscience 2004 and 2005) was made under the novel foods and novel food ingredients Regulation 258/97/EC.

According to the scope described in Article 1 (2) of the Regulation, the product falls under category f, i.e. "foods and food ingredients to which have been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances."

It belongs to class 6 (foods produced by new process), as defined in the recommendations of the Scientific Committee on Food (SCF) concerning the assessment of novel foods (Commission Recommendation 97/618/EC). Accordingly, information related to the structured schemes I, II, III, IX, X, XI, XII and XIII has been submitted and is considered below.

I. Specification of the novel food (NF)

The source of the novel food is refined maize-germ oil. This should meet the requirements of the Codex Alimentarius for edible maize oil (Codex Alimentarius, 2001). It consists of 98.8% triglycerides and 1.2% unsaponifiables (comprising 1.0% sterols, 0.1% tocopherols and 0.1% miscellaneous compounds).

The specification of "maize-germ oil high in unsaponifiable matter" proposed by the applicant is presented in Table 1. Average and range values listed are based on analysis of samples from three industrial scale batches.

Parameters such as appearance, odour, colour, contents of water, volatile matter and insoluble impurities, meet the quality criteria expected from edible oils.

Oxidative stability

The oxidative stability of the novel food was tested by storing the packaged product (125 mL hermetic, opaque sales-packaging, blanketed with nitrogen) at 40°C and 75% relative humidity (accelerated conditions) and at room temperature under normal storage conditions. Under the conditions of the accelerated test the peroxide value rose only from 0.3 mEq O_2/kg (t=0) to 0.4 mEq O_2/kg (t=1 month) and 0.6 mEq O_2/kg (t=3 months). According to the applicant, ongoing monitoring at room temperature (normal storage conditions) is also showing satisfactory oxidative stability of the novel food.

Table 1. Specifications of "maize-germ oil high in unsaponifiable matter"

	Specification	Average (min; max)
Unsaponifiable matter (g/100g)	> 9.0	12.1 (10.8; 13.7)
Tocopherols (g/100g)	≥ 1.3	2.1 (1.6; 2.4)
α-tocopherol (%)	10-25	18.9 (17.3; 22.0)
β-tocopherol (%)	< 3	0.55 (0.5; 0.6)
γ- tocopherol (%)	68-89	77.9 (75.2; 79.7)
δ- tocopherol (%)	< 7	2.7 (2.3; 3.3)
Sterols, triterpenic alcohols, methylsterols (g/100g)	> 6.5	8.7 (7.3; 9.5)
campesterol (%)	18-28	23.2 (22.6; 23.9)
stigmasterol (%)	4-8	6.4 (6.1; 6.7)
β-sitosterol (%)	54-67	60 (59.0; 60.6)
Δ-5 avenasterol (%)	2-8	5 (4.8; 5.1)
brassicasterol (%)	< 0.2	0.05 (0; 0.1)
Fatty acids in triglycerides (%)		
palmitic acid (C16)	10-20	15.1 (14.4; 15.6)
stearic acid (C18)	< 3.3	1.5 (1.4; 1.7)
oleic acid (C18:1)	20-42.2	28.7 (27.6; 30.0)
linoleic acid (C18:2)	34-65.6	52.1 (49.6; 53.7)
linolenic acid (C18:3)	< 2	0.7 (0.6; 0.8)
Acid value (mg KOH/g)	≤ 6	1.9 (0.3; 2.7)
Peroxide value (mEq O_2/kg)	≤ 10	1.4 (0.5; 3.0)
Fe (μg/kg)	< 1500	45.5 (28.0; 63.0)
Cu (μg/kg)	< 100	58.5 (30.0; 87.0)
Polycyclic aromatic hydrocarbons (PAH)		
benzo[α]pyrene (μg/kg)	< 2	< 0.04[a]

[a] Value from single analysis taken from Table 2.

Contaminants

Analysis of residual solvent demonstrated the level of hexane to be less than 1.0 mg/kg in the maize-germ oil used as source for the novel food as well as in the final "maize-germ oil high in unsaponifiable matter". This is in accordance with the maximum limits set in Directive 97/60/EC.

Analysis of aflatoxins demonstrated the levels of aflatoxin B_1 and of total aflatoxins (B_1+B_2+G_1+G_2) to be below the limits of quantification of 0.03 μg/kg and 0.17 μg/kg, respectively. This is in accordance with the limits set in Regulation (EC) Nº 257/2002.

The contents of the heavy metals lead and arsenic were reported to be below the maximum permissible concentration of 100 μg/kg for vegetable oils (Codex Alimentarius, 2001). Levels of organochlorine and organophosphorus compounds were determined to be below the detection limits of 20 μg/kg and 60 μg/kg, respectively.

Polycyclic aromatic hydrocarbons (PAH)

The applicant demonstrated that concentrating the unsaponifiable matter via molecular distillation is accompanied by an increase in the levels of polycyclic aromatic hydrocarbons (Table 2). The level determined for the marker compound benzo[α]pyrene is above the

maximum level of 2 µg/kg set in Regulation (EC) Nº 208/2005 for oils and fats intended for direct consumption or use as ingredient in foods.

Treatment of the "maize-germ oil high in unsaponifiable matter" with active carbon resulted in a significant reduction of the contents of PAHs. In carbon-treated material the levels of the 8 PAHs listed in Table 2 were drastically reduced; their total level was below 1 µg/kg.

Table 2. Polycyclic aromatic hydrocarbons (PAH)[a]

PAH	Maize-germ oil (µg/kg)	Maize-germ oil high in unsaponifiables (µg/kg)	Maize-germ oil high in unsaponifiables (treated with charcoal) (µg/g)
Benzo[α]pyrene	0.13	2.64	< 0.04
Dibenzo[*a,h*]anthracene	0.02	0.41	< 0.01
Benzo[*a*]anthracene	0.16	4.19	< 0.03
Benzo[*b*]fluoranthene	0.18	3.94	< 0.04
Benzo[*k*]fluoranthene	0.08	1.77	< 0.02
Indeno[1,2,3-*cd*]pyrene	0.11	2.31	< 0.03
Chrysene/Triphenylene	0.40	9.09	< 0.14
Benzo[*ghi*]perylene	0.18	3.12	< 0.07

[a] Determined according to Grimmer *et al*. (1997).

As consequence of these data, the applicant will systematically extend the originally described process to produce "maize-germ oil high in unsaponifiable matter" (Laboratoires Pharmascience, 2001; Laboratoires Expanscience, 2004) by an additional treatment with active carbon.

According to the applicant (Laboratoires Expanscience, 2005), this treatment is conducted in accordance with good manufacturing practice (GMP) in order to preserve the nutritional properties of the novel food, especially unsaturated fatty acids, vitamin E and phytosterols. The first three productions will be checked for their levels of benzo[α]pyrene. Then controls will be made according to a defined sampling plan. Compositional data provided on a batch of "maize-germ oil high in unsaponifiable matter" treated with charcoal were in accordance with the specifications given in Table 1.

The high-vacuum distillation step might also result in the concentration of other organic contaminants, therefore appropriate treatments must be in place to ensure that the levels of these contaminants in the final product comply with current regulations.

II. Effect of the production process applied to the NF

Refined maize-germ oil is subjected to molecular distillation, a fractional evaporation performed under high vacuum (10^{-2}-10^{-3} mm of Hg) and high temperature (200-300 °C). The process as such is not new. It is well established for separation and purification operations in the food industry (e.g., isolation of mono- and diglycerides, vitamin E or flavourings) (Hui, 1996). The application of the procedure to a refined oil has not been described.

The changes resulting from the application of molecular distillation to maize-germ oil are summarized in Table 3.

Table 3. Comparison of the chemical compositions of the novel food ("maize-germ oil high in unsaponifiable matter") and its source ("maize germ oil")

	Maize-germ oil		**Maize-germ oil high in unsaponifiable matter**	
Unsaponifiable matter (g/100g)	1.2		10	
Sterols (g/100g)	1.0		7.0	
Total tocopherols (g/100g)	0.1		2.0	
Miscellaneous (g/100g)	0.1		1.0	
Triglycerides (g/100g)	98.8		90	
Fatty acids	(%)	(g/100 g oil)	(%)	(g/100 g oil)
SFA	14	13.8	15	13.5
MUFA	30	29.7	29.5	26.5
PUFA	56	55.3	55.5	50.0

SFA: Saturated fatty acids; MUFA: Monounsaturated fatty acids; PUFA: Polyunsaturated fatty acids.

The physical fractionation causes an enrichment of components with lower boiling points in the re-condensed distillate. Consequently, the unsaponifiables are concentrated by a factor of approximately 8. The various compound classes in this group behave differently; the highest degree of concentration (factor 20) is being observed for tocopherols.

On the other hand, the proportion of triglycerides is reduced from 98.8% to 90%. Due to the incomplete distillation of the triglyceride fraction and the preferential enrichment of triglycerides with lower boiling points in the distillate, there is a minor reduction of triglycerides containing monounsaturated and polyunsaturated fatty acids. According to the applicant, the content of *trans* fatty acids in the novel food is less than 1% of the total fatty acids. Despite the slight shift in composition, the triglyceride fraction of "maize-germ oil high in unsaponifiable matter" is considered by the Panel as equivalent to that of refined maize germ-oil.

III. History of the organism used as source of the NF

Maize and maize-germ oil have a tradition of safe food use. The crop originating from Central America has been cultivated in Europe since the 1950s. According to data from the applicant, the area on which maize is grown in Europe (4 million hectares in 1996/97) is mainly located in France (42%) and Italy (24%). Maize is primarily used for animal feed (65%), followed by human consumption (27%) and industrial purposes (8%).

According to the applicant, 228,000 tonnes of maize-germ oil were produced in Europe in 1997. 31,000 tonnes were consumed in France (9.5% of European consumption); this corresponds to an average consumption of 0.5 kg/person /year or 1.4 g/person/day.

Regarding its composition (Codex Alimentarius, 2001) maize-germ oil is especially characterised by its high contents of linoleic acid (34-66% of total fatty acids) and tocopherols (330-3720 mg/kg).

IX. Anticipated intake/extent of use of the NF

"Maize-germ oil high in unsaponifiable matter" is not intended to replace any existing food. The applicant recommends "its use as a food ingredient 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 are (i) dietary supplements and (ii) any food products for which claims are made concerning the intake of vitamin E and phytosterols (e.g., margarines, mixtures of food grade oils, milk and dairy products, dressings and sauces, cakes, pastries and breads, ready-made meals sterilised in a hermetic container, cooked pork meats, etc.).

The novel food supplies 70 mg sterols/g and 20 mg total tocopherols/g. The applicant suggests a maximum daily intake of the novel food of 2 g per person and day. In terms of sterol intake (140 mg), this approximately corresponds to a consumption of one tablespoon (13 g) of maize-germ oil (Table 4). The intake of total tocopherols (40 mg) is three times higher than from 13 g of maize-germ oil.

Table 4. Comparison of triglyceride, sterol and tocopherol amounts in portions of maize-germ oil and "maize-germ oil high in unsaponifiable matter"

	One tablespoon (13 g) of maize-germ oil	**2 g of "maize-germ oil high in unsaponifiable matter"**
Triglycerides (g)	12.8	1.8
Unsaponifiables (mg)	156	200
Sterols (mg)	130	140
Tocopherols (mg) (80% γ-tocopherol; 20% α-tocopherol)	13	40

X. Information from previous human exposure to the NF or its source

According to the applicant maize-germ oil (the source of the novel food) is widely and commonly used in all European countries and by all groups of the population.

In terms of total content of unsaponifiables, the novel food is similar to other edible oils of plant origin, e.g. wheat germ oil (3-4 g unsaponifiables/100 g oil) or avocado oil (1-12 g unsaponifiables/100 g oil).

XI. Nutritional information on the NF

The nutritional properties of "maize-germ oil high in unsaponifiable matter" are determined by its content of fatty acids, vitamin E and phytosterols.

Fatty acids
Maize-germ oil is a prime source of linoleic acid and oleic acid (Codex Alimentarius, 2001). Despite a slight reduction of the amounts of these unsaturated fatty acids resulting from the enrichment of components with lower boiling points in the distillate in the course of the

molecular distillation step, there is no significant change in their preponderance in the "maize-germ oil high in unsaponifiable matter".

A 2 g dose of "maize-germ oil high in unsaponifiable matter" provides 0.3 g of oleic acid and 0.5 g of linoleic acid. This amount of linoleic acid corresponds to 5% of the average recommended daily intake (10 g).

Vitamin E
On the basis of a Recommended Daily Allowance (RDA) of vitamin E of 12 mg, i.e. 12 mg α-tocopherol equivalents (α-TE), the applicant calculated that a daily intake of 2 g of "maize-germ oil high in unsaponifiable matter" would provide 11 mg α-TE, i.e. 92% of the RDA. The calculation was derived as follows: A daily intake of 2 g of "maize-germ oil high in unsaponifiable matter" provides 40 mg of total tocopherols comprising 80% γ-tocopherol (32 mg) and 20% α-tocopherol (8 mg). Taking into account that the vitamin E activity of γ-tocopherol is 10 times lower than that of α-tocopherol, 40 mg of total tocopherols correspond to 11.2 mg α -TE (8 mg α-tocopherol + 3.2 mg from γ-tocopherol).

The SCF considered a ratio of 0.4 mg α-TE/g total PUFA to be adequate both for adults and infants (SCF, 1993). This corresponds to an intake of 2 and 3 mg α-TE/day for women and men, respectively, taking into account the Population Reference Intake (PRI) for essential PUFA.

The SCF established the Tolerable Upper Intake Level of vitamin E as 300 mg/day for adults (SCF, 2003). Bjelakovic *et al*. (2004) analysed results of cancer prevention studies with vitamin A, β-carotene, vitamin E and selenium. In this study supplemental intake of vitamin E and β-carotene combined was associated with an increased risk of mortality. In another meta-analysis of intervention studies with vitamin E supplementation only, Miller *et al*. (2005) reported a significantly increased mortality at supplemental intakes above 270 mg/day (400 IU), although there was a dose-response relationship indicating a trend for increasing mortality at intakes above 100 mg/day (160 IU).

Phytosterols
The hypocholesterolaemic effect of phytosterols is well-known. However, 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 in serum by about 5-15% (SCF, 2002).

XII. Microbiological information on the NF

Taking into account the lipophilic nature of the novel food, the lack of water and the microbial purity of the source, the risk of bacterial proliferation is considered unlikely. Moreover, the temperature at which the novel food is processed eliminates any risk of viable microorganisms being present. The packed product is stored under inert conditions protected from light.

XIII. Toxicological information on the NF

Acute oral toxicity was tested in accordance with OECD Guideline 401 in mice and rats (in each case 5 males and 5 females). LD_{50} values were higher than 20 mL/kg body weight (mice) and 5000 mg/kg body weight (rats) (EViC-CEBA, 1999 a and b).

The Ames test was carried out in accordance with OECD Guideline 471 with five strains of *Salmonella enterica var.* Typhimurium. Up to 5000 µg/plate showed no mutagenic activity with and without metabolic activation (Marzin, 2000).

The material used for the toxicity studies exhibited a content of unsaponifiable matter of 9.6 g/100 g (sterols: 7.3 g/100 g; tocopherols: 1.6 g/100 g; squalene 0.5 g/100 g). The proportions of fatty acids in triglycerides, the acid value and the peroxide value were in agreement with the specifications given in Table 1.

CONCLUSIONS AND RECOMMENDATIONS

"Maize-germ oil high in unsaponifiable matter" is considered equivalent to its source (refined maize-germ oil) as regards fatty acid composition and contaminants (e.g. solvent residues, heavy metals, aflatoxins, organochlorine and organophosphorus compounds). 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/100 g) due to the application of a high vacuum-distillation step ("molecular distillation").

This manufacturing 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 the quality and the safety of the final product.

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 α-tocopherol equivalents. Under the specified conditions of use, the contribution to vitamin E intake by the novel food is low and the Tolerable Upper Intake Level for vitamin E of 300 mg/day for adults (SCF, 2003) is not likely to be exceeded.

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.

DOCUMENTATION PROVIDED TO EFSA

Dossier on maize-germ oil high in unsaponifiable matter as a novel food ingredient in the European Union. Application pursuant to Regulation (EC) N° 258/97 submitted by Laboratoires Pharmascience, Epernon (France), November 2001.

Supplementary information submitted by Laboratoires Expanscience (formerly Pharmascience) on request of EFSA, March 2004.

Complementary data to the 2004 submission submitted by Laboratoires Expanscience (formerly Pharmascience), June 2005.

EViC-CEBA (1999a). Evaluation de la toxicité aigue après administration par voie orale chez la souris – Epreuve limité- Concentrat de mais –Rapport d'éssai (Tf 822/99-3437). EVic-CEBA Laboratoire de Recherche et d'Expérimentation, Blanquefort (France).

EViC-CEBA (1999b). Evaluation de la toxicité aigue après administration par voie orale chez le rat – Epreuve limité- Concentrat de mais –Rapport d'éssai (Tf 823/99-3437). EVic-CEBA Laboratoire de Recherche et d'Expérimentation, Blanquefort (France).

Marzin D (2000). Recherche de mutagénicité sur Salmonella typhimurium his$^-$ selon la methode de B.N. Ames sur le produit concentrat de mais (NIPL-R 000108/Concentrat de mais, Pharmascience, 29.02.2000). Institut Pasteur de Lille, Lille (France).

REFERENCES

Bjelakovic G, Nikolova D, Simonetti RG, Gluud C (2004). Antioxidant supplements for prevention of gastrointestinal cancers: a systematic review and meta-analysis. Lancet 364: 1219-1228.

Codex Alimentarius (2001). Codex standard for named vegetable oils CX-STAN 210-1999. Codex Alimentarius Vol. 8, 11-25.

Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) N° 258/97 of the European Parliament and of the Council. Official Journal of the European Communities, 16.9.97, L 253/1.

Commission Regulation (EC) No 257/2002 of 12 February 2002 amending Regulation (EC) No 194/97 setting maximum levels for certain contaminants in foodstuffs and Regulation.

Commission Regulation (EC) No 208/2005 of 4 February 2005 amending Regulation (EC) No 466/2001 as regards polycyclic aromatic hydrocarbons. Official Journal of the European Communities L 34/3, 8.2.2005.

Directive 97/60/EC of the European Parliament and of the Council of 27 October 1997 amending for the third time Directive 88/344/EEC on the approximation of the laws of the

Member States on extraction solvents used in the production of foodstuffs and food ingredients. Official Journal of the European Communities L 331, 3.12.1997.

Grimmer G, Jacob J, Naujack KW (1997). Atmospheric emission of polycyclic aromatic hydrocarbons in sampling areas of the German environmental specimen bank. Method for the precise measurement of gaseous and particle-associated polycyclic aromatic hydrocarbons in the sub-nanogram range using deuterated internal standards. Chemosphere 34: 2213-2226.

Hui YH (1996). Edible oil and fat products: Processing technology (Vol. 4). In: Bailey's industrial oil and fat products (5th Edition). Wiley-Interscience Publication, John Wiley & Sons, Inc.

Miller ER 3rd, Pastor-Barriuso R, Dalal D, Riemersma RA, Appel LJ, Guallar E (2005). Meta-analysis: high-dosage vitamin E supplementation may increase all cause mortality. Ann Intern Med 142: 37-46.

Regulation (EC) N° 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. Official Journal of the European Communities, 14.02.97, L 43/1.

SCF (Scientific Committee on Food) (1993). Reports of the Scientific Committee on Food (31st series). Commission of the European Community, Luxembourg, pp. 177-189.

SCF (Scientific Committee on Food) (2002). General view of the Scientific Committee on Food on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources, with particular attention to the effects on β-carotene (expressed on 26 September 2002). European Communities, Luxembourg.

SCF (Scientific Committee on Food) (2003). Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of vitamin E (expressed on 4 April 2003). European Communities, Luxembourg.

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