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EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to flaxseed oil and vitamin E and maintenance of the skin permeability barrier function pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to a combination of flaxseed oil and vitamin E and maintenance of the skin permeability barrier function pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to a combination of flaxseed oil and vitamin E and maintenance of the skin permeability barrier function. The food constituent that is the subject of the health claim is a combination of flaxseed oil and vitamin E. The Panel considers that the combination of flaxseed oil and vitamin E is sufficiently characterised. The claimed effect is “contributes to maintain skin permeability barrier function”. The target population proposed by the applicant is healthy adults with dry and sensitive skin. Maintenance of the permeability barrier function of the skin is a beneficial physiological effect. The applicant identified two published human intervention studies as being pertinent to the health claim. Owing to the very limited information provided regarding key methodological aspects, and to the important limitations of the statistical analysis performed, the Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim. The Panel concludes that a cause and effect relationship has not been established between the consumption of a combination of flaxseed oil and vitamin E and maintenance of the skin permeability barrier function. © European Food Safety Authority, 2012

KEY WORDS

Flaxseed oil, vitamin E, skin permeability barrier, health claims

¹ On request from the Competent Authority of Belgium following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00337, adopted on 4 July 2012.

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³ The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen for the preparatory work on this scientific opinion.

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SUMMARY

Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to a combination of flaxseed oil and vitamin E and maintenance of the skin permeability barrier function.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.

The food constituent that is the subject of the health claim is a combination of flaxseed oil and vitamin E. The Panel considers that the combination of flaxseed oil and vitamin E is sufficiently characterised.

The claimed effect is “contributes to maintain skin permeability barrier function”. The target population proposed by the applicant is healthy adults with dry and sensitive skin. The Panel considers that maintenance of the permeability barrier function of the skin is a beneficial physiological effect.

The applicant identified two published human intervention studies as being pertinent to the health claim.

Owing to the very limited information provided regarding key methodological aspects (i.e. baseline characteristics of the study groups, background diet, skin site tested, use of cosmetics, randomisation, sample size estimate, primary outcome, methods used for data analysis), and to the important limitations of the statistical analysis performed (repeated measures and multiple testing not taken into account), the Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

The Panel considers that no human studies have been provided from which conclusions can be drawn for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of a combination of flaxseed oil and vitamin E and maintenance of the skin permeability barrier function.

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BACKGROUND

Regulation (EC) No 1924/2006⁴ harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 24/02/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- On 15/03/2012, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- The applicant provided the missing information on 19/04/2012.
- The scientific evaluation procedure started on 23/04/2012.
- On 31/05/2012, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application, and the clock was stopped on 04/06/2012, in compliance with Art. 18(3) of Regulation (EC) No 1924/2006.
- On 19/06/2012, EFSA received the requested information as submitted by the applicant and the clock was restarted.
- During its meeting on 04/07/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to a combination of flaxseed oil and vitamin E and maintenance of the skin permeability barrier function.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: a combination of flaxseed oil and vitamin E and maintenance of the skin permeability barrier function.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of a combination of flaxseed oil and vitamin E, a positive assessment of its safety, nor a

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

decision on whether a combination of flaxseed oil and vitamin E is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Nutrilinks Sarl - Chemin de Beau-rivage 7 - Case postale 96 CH-1000 Lausanne 21 - Switzerland.

Food/constituent as stated by the applicant

According to the applicant, flaxseed oil (1.11 g/day of α -linolenic acid) and vitamin E (10 mg/day) in a food supplement.

Health relationship as claimed by the applicant

According to the applicant, the claimed effect is “contributes to maintain skin permeability barrier function”.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “contributes to maintain skin permeability barrier function”.

Alternative wordings proposed by the applicant: “contributes to skin hydration”, “helps to protect skin from dryness”, “helps to limit skin drying”, “helps to prevent skin drying”, “helps to increase skin hydration”, “helps to increase skin hydration of dry skin”, “helps to reduce skin irritation”, “contributes to reduce skin redness”, “helps to reduce skin sensitivity”.

Specific conditions of use as proposed by the applicant

According to the applicant, the target population is healthy adults with dry and sensitive skin. The applicant has proposed an intake of four capsules per day during 12 consecutive weeks.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is a combination of flaxseed oil and vitamin E. The food constituent is available in the form of soft gel capsules. Each capsule consists of flaxseed oil (555 mg), vitamin E (d- α -tocopherol) (2.5 mg), and other ingredients (gelatine, glycerol, rosemary extract and titanium dioxide).

The fatty acid composition of flaxseed oil together with its complete specifications have been provided by the applicant: 2-8 % palmitic acid (C16:0), 2-6 % stearic acid (C18:0), 12-25 % oleic acid (C18:1, n-9), 10-20 % linoleic acid (C18:2, n-6), 45-64 % α -linolenic acid (C18:3, n-3) and 0-2 % erucic acid (C22:1, n-9). These fatty acids can be analysed in foods by established methods.

The specifications of vitamin E, which is derived from sunflower oil, have been provided by the applicant. Vitamin E can be analysed in foods by established methods.

Information pertaining to the manufacturing process and control specifications of the finished product, to batch-to-batch variability and to stability data has been provided by the applicant.

The Panel considers that the food constituent, a combination of flaxseed oil and vitamin E, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect is “contributes to maintain skin permeability barrier function”. The target population proposed by the applicant is healthy adults with dry and sensitive skin.

Skin is the outer barrier of the body and provides protection from exposure to harmful irritants and potentially pathogenic microorganisms. An impairment of the permeability barrier function of the skin leads to water loss from the *stratum corneum* and to skin dehydration. The associated symptoms include roughness of the skin with visible scaling and flaking, itching, and reduced resistance to shearing forces. Maintenance (i.e. reduced loss) of the permeability barrier function of the skin protects the skin against dehydration.

The Panel considers that maintenance of the permeability barrier function of the skin is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed, ScienceDirect, Blackwell Synergy, Wiley InterScience, Mary Ann Liebert, Scirus, IBIDS, SciFinder Scholar, Pascal and SCOPUS. The time period considered was from January 2008 to May 2011.

The following key words were used alone or in combination: [“flaxseed oil” OR “omega 3 fatty acids” OR “ α -linolenic acid” AND “vitamin E”] AND [“skin” OR “hydration” OR “moisturization” OR “epidermis” OR “fibroblast” OR “keratinocyte” OR “TEWL” OR “dry skin” OR “barrier functions” OR “sensitivity” OR “irritation”]. The inclusion criteria for selecting pertinent publications were studies performed with a combination of α -linolenic acid from flaxseed oil and vitamin E. No exclusion criteria were applied.

The applicant identified two published human intervention studies as being pertinent to the health claim.

In a randomised, double-blind, placebo-controlled study, De Spirt et al. (2009) investigated the effect of 2.2 g/day of flaxseed oil plus 10 mg/day of vitamin E vs. 2.2 g of borage oil plus 10 mg/day of vitamin E vs. 2.2 g/day of placebo (~60 % medium chain fatty acids and ~40 % non-identified fatty acids) for 12 weeks in 45 (n=15 subjects per group) healthy, non-smoking females (age 18-65 years; BMI 18-25 kg/m²) with dry skin defined as a corneometer value of <40 arbitrary units. The exclusion criteria were pregnancy and breast-feeding, history of fat malabsorption, liver diseases, diseases presenting with lipid metabolism, photosensitising disorders, and intake of lipid or vitamin supplements or any other medication. The flaxseed oil used in the study had a similar fatty acid composition as the flaxseed oil which is the subject of the health claim. Following EFSA’s request for information on the demographic characteristics for each of the study groups at baseline, and on the background diet of the study participants, the applicant acknowledged that this information was not available. Water-holding capacity (measured by corneometry), transepidermal water loss (measured by TEWA-Meter TM 300[®]), reddening (measured by chromametry), capillary blood flow (measured by Laser-Doppler-Flowmetry), evaluation of the skin surface (i.e. roughness, scaling, smoothness, wrinkles) and blood fatty acid composition were assessed at day 0, week 6 and week 12. Reddening and capillary blood flow were assessed after exposure to an irritant (nicotinate). Following EFSA’s request for information on the skin area tested and on whether cosmetics or ointments were allowed to be used on the tested area during the study, the applicant acknowledged that this information was not available. No information was provided in the publication regarding the method used for randomisation. It was also unclear how sample size was estimated or which outcome was the primary outcome of the study. In addition, the statistical methods used for data analysis were poorly described and results for direct comparisons of the study groups with respect to changes in the outcome variables of interest were not reported. Upon EFSA’s request for clarification, the applicant

acknowledged that no additional information was available on these points. Owing to the very limited information provided regarding key methodological aspects (i.e. baseline characteristics of the study groups, background diet, skin site tested, use of cosmetics, randomisation, sample size estimate, primary outcome, methods used for data analysis), the Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

Neukam et al. (2011) conducted a 12-week double-blind study in 26 non-smoking females (age 18-65 years; BMI 18-25 kg/m²) who received daily either four capsules of flaxseed oil (2.2 g/day) plus vitamin E (15.4 mg/day) or four capsules of safflowerseed oil (2.2 g/day) (n=13 subjects per group). The exclusion criteria were history of malabsorption, liver diseases or disorders of lipid metabolism, pregnancy or lactation. Subjects were requested not to take any medication, vitamins or other nutritional supplements and to refrain from using any cosmetic treatment in the test area (inner forearm) or from extensively sunbathing in the month before and during the study. The flaxseed oil used in the study had a similar fatty acid composition to the flaxseed oil which is the subject of the health claim. Following EFSA's request for information on the demographic characteristics for each of the study groups at baseline, and on the background diet of the study participants, the applicant acknowledged that this information was not available. Erythema formation (measured by chromametry), capillary blood flow (measured by Laser-Doppler-Flowmetry), skin surface structure (i.e. roughness, scaling, smoothness, wrinkles), water-holding capacity (measured by corneometry), transepidermal water loss (measured by TEWA-Meter TM 300[®]) and blood fatty acid composition were assessed at baseline and weeks 6 and 12. Erythema formation and capillary blood flow were assessed after exposure to an irritant (nicotinate). No information was provided in the publication regarding the method used for randomisation. It was also unclear how sample size was estimated or which outcome was the primary outcome of the study. Upon EFSA's request for clarification, the applicant acknowledged that no additional information was available on these points. Within group comparisons between baseline and each time point were performed using the non-parametric Wilcoxon signed-rank test. Between-group comparisons of changes from baseline at each time point were performed using the Wilcoxon rank sum test. The Panel notes that the statistical methods used for the data analysis did not take into account repeated measures or multiple testing. Upon EFSA's request for clarification, the applicant acknowledged that no additional information was available on these points. Owing to the very limited information provided regarding key methodological aspects (i.e. baseline characteristics of the study groups, background diet, randomisation, sample size estimate, primary outcome), and to the important limitations of the statistical analysis performed (repeated measures or multiple testing not taken into account), the Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel considers that no human studies have been provided from which conclusions can be drawn for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of a combination of flaxseed oil and vitamin E and maintenance of the skin permeability barrier function.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, a combination of flaxseed oil and vitamin E, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is “contributes to maintain skin permeability barrier function”. The target population as proposed by the applicant is healthy adults with sensitive and dry skin. Maintenance of the permeability barrier function of the skin is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of a combination of flaxseed oil and vitamin E and maintenance of the skin permeability barrier function.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on a combination of flaxseed oil and vitamin E and maintenance of the skin permeability barrier function pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0332_BE). February 2012. Submitted by Nutrilinks Sarl.

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Neukam K, De Spirt S, Stahl W, Bejot M, Maurette JM, Tronnier H and Heinrich U, 2011. Supplementation of flaxseed oil diminishes skin sensitivity and improves skin barrier function and condition. *Skin Pharmacology and Physiology*, 24, 67-74.

GLOSSARY/ABBREVIATIONS

TEWL Transepidermal water loss