SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to *Eff*$_{EXT}$™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein" pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2]

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 *Eff*$_{EXT}$™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein". The Panel considers that *Eff*$_{EXT}$™, which is standardised pure krill oil, is sufficiently characterised. The claimed effect is "helps to support joint function by maintaining low levels of plasma C-reactive protein". The Panel notes that the claim refers to a reduction of inflammation indicated by a lowered concentration of plasma C-reactive protein. Whether or not reduction of inflammatory markers is considered beneficial depends on the context in which a claim is made. In the context of the study provided, the Panel notes that the claim refers to diseases such as osteoarthritis or rheumatoid arthritis, in which a reduction of inflammation would be a therapeutic target for the treatment of the disease. The Panel considers that the reduction of inflammation in the context of diseases such as osteoarthritis or rheumatoid arthritis is a therapeutic target for the treatment of the disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006. © European Food Safety Authority, 2012

KEY WORDS

Eff$_{EXT}$™, krill oil, joints, inflammation, health claims

[1] On request from the Competent Authority of Belgium following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00386, adopted on 13 September 2012.

[2] Panel members: Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean (J.J.) Strain, Inge Tetens, Daniel Tomé, Dominique Turck and Hans Verhagen. Correspondence: nda@efsa.europa.eu

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to *Eff*$_{EXT}$™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein" pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2012;10(9):2889. [6 pp.]. doi:10.2903/j.efsa.2012.2889. Available online: www.efsa.europa.eu/efsajournal

© European Food Safety Authority, 2012

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 *Eff*$_{EXT}$™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein".

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

The food that is the subject of the health claim is *Eff*$_{EXT}$™, which is standardised pure krill oil. The Panel considers that *Eff*$_{EXT}$™ is sufficiently characterised.

The claimed effect is "helps to support joint function by maintaining low levels of plasma C-reactive protein". The target population as proposed by the applicant is adults presenting with sensitive joints.

The Panel notes that the claim refers to a reduction of inflammation indicated by a lowered concentration of plasma C-reactive protein. Whether or not reduction of inflammatory markers is considered beneficial depends on the context in which a claim is made. In the context of the study provided by the applicant, the Panel notes that the claim refers to diseases such as osteoarthritis or rheumatoid arthritis, in which a reduction of inflammation would be a therapeutic target for the treatment of the disease.

The Panel considers that the reduction of inflammation in the context of diseases such as osteoarthritis or rheumatoid arthritis is a therapeutic target for the treatment of the disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

TABLE OF CONTENTS

Abstract 1
Summary 2
Table of contents 3
Background 4
Terms of reference 4
EFSA Disclaimer 4
Information provided by the applicant 5
Assessment 5
1. Characterisation of the food/constituent 5
2. Relevance of the claimed effect to human health 6
Conclusions 6
Documentation provided to EFSA 6
References 6

BACKGROUND

Regulation (EC) No 1924/2006[3] 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 06/03/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- On 04/04/2012, 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 17/04/2012.
- The scientific evaluation procedure started on 30/04/2012.
- During its meeting on 13/09/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to *Eff*$_{EXT}$™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein".

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: *Eff*$_{EXT}$™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein".

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of *Eff*$_{EXT}$™, a positive assessment of its safety, nor a decision on whether *Eff*$_{EXT}$™ 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.

[3] 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.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Nutrilinks Sarl, Chemin de Beau-rivage 7, P.O. Box 96, CH-1000 Lausanne 21, Switzerland.

Food/constituent as stated by the applicant

According to the applicant, *Eff*$_{EXT}$™, which is a standardised pure krill oil extract.

Health relationship as claimed by the applicant

According to the applicant, the claim relates to the improvement of joint flexibility, joint comfort and function, brought about by a reduction of systemic inflammation as indicated by a reduction of C-reactive protein.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "helps to support joint function by maintaining low levels of plasma C-reactive protein".

The following alternative wordings were proposed: "supports joint health", "is fast-acting and clinically proven to improve joint comfort and function", "C-reactive protein is a key marker of inflammation and joint health", "beneficial to help maintain normal (joint) inflammation and improve (joint) function and comfort", "active (by reducing the levels of plasma C-reactive protein) after only 7 days of daily consumption", "active (by reducing the levels of plasma C-reactive protein up to 30 %) after only 14 days of daily consumption".

Specific conditions of use as proposed by the applicant

The applicant has proposed an intake of 300 mg *Eff*$_{EXT}$™ per day, preferably in the morning, for 30 consecutive days. The target population is adults presenting with sensitive joints.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is *Eff*$_{EXT}$™, which is standardised pure krill oil.

Krill oil is extracted from the crustacean *Euphausia superba* (Antarctic Krill). It has been authorised as a novel food ingredient[4]. The krill oil which is the subject of the claim complies with Commission Decision 2009/752/EC. The main constituents contained in the krill oil which is the subject of the claim are phospholipids (≥42.0 g/100 g), omega-3 fatty acids (≥26.5 g/100 g), comprising eicosa-pentaenoic acid (EPA, C20:5, ≥14.2 g/100 g) and docosahexaenoic acid (DHA, C22:6, ≥8.5 g/100 g), and saturated fatty acids (25.0±5 g/100 g). The content of esterified astaxanthin amounts to around 1,000 to 1,500 mg/kg. Phospholipids, fatty acids and astaxanthin can be measured in foods by established methods. Information on the stability and the batch-to-batch variability of the product has been provided.

[4] 2009/752/EC: Commission Decision of 12 October 2009 authorising the placing on the market of a lipid extract from Antarctic Krill *Euphausia superba* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document C(2009) 7647), OJ L 268, 13.10.2009, p. 33–34.

The Panel considers that the food, *Eff*$_{EXT}$™, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect is "helps to support joint function by maintaining low levels of plasma C-reactive protein". The target population proposed by the applicant is adults presenting with sensitive joints.

The Panel notes that the claim refers to a reduction of inflammation indicated by a lowered concentration of plasma C-reactive protein.

Inflammation is a non-specific physiological response to tissue damage that is mediated by the immune system. Adequate inflammatory responses are of primary importance for the defence against injury of any origin. Whether or not reduction of inflammatory markers is considered beneficial depends on the context in which a claim is made. The one study (Deutsch, 2007) which was provided in support of the claim was carried out in patients with confirmed inflammatory diseases (i.e. osteo-arthritis and rheumatoid arthritis). In the context of the study provided, the Panel notes that the claim refers to diseases such as osteoarthritis or rheumatoid arthritis, in which a reduction of inflammation would be a therapeutic target for the treatment of the disease.

The Panel considers that the reduction of inflammation in the context of diseases such as osteoarthritis or rheumatoid arthritis is a therapeutic target for the treatment of the disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

CONCLUSIONS

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

- The food, *Eff*$_{EXT}$™, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is "helps to support joint function by maintaining low levels of plasma C-reactive protein". The target population as proposed by the applicant is adults presenting with sensitive joints.
- A reduction of inflammation in the context of diseases such as osteoarthritis or rheumatoid arthritis is a therapeutic target for the treatment of the disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on *Eff*$_{EXT}$™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein" pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0341_BE). March 2012. Submitted by Nutrilinks Sarl.

REFERENCES

Deutsch L, 2007. Evaluation of the effect of Neptune Krill Oil on chronic inflammation and arthritic symptoms. Journal of the American College of Nutrition, 26, 39-48.