



## **EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to EffEXT™ and maintenance of normal joint mobility 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 *Eff<sub>EXT</sub>*<sup>TM</sup> and maintenance of normal joint mobility pursuant to Article 13(5) of Regulation (EC) No 1924/2006<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>

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#### 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<sub>EXT</sub>*<sup>TM</sup> and maintenance of normal joint mobility. The Panel considers that *Eff<sub>EXT</sub>*<sup>TM</sup>, which is standardised pure krill oil, is sufficiently characterised. The claimed effect proposed by the applicant is “contributes to support joint flexibility”. The Panel considers that maintenance of normal joint mobility is a beneficial physiological effect. The applicant identified one human intervention study as being pertinent to the health claim. The Panel notes that chronic inflammation was an inclusion criterion of the study, that a significant number of the patients recruited were reported to have confirmed diagnosis of osteoarthritis, rheumatoid arthritis, or of both cardiovascular disease and osteoarthritis, and that the WOMAC osteoarthritis questionnaire was administered only to patients with arthritic disease (osteoarthritis or rheumatoid arthritis). The Panel also notes that no evidence which could justify the extrapolation of the results, obtained in patients with joint diseases characterised by chronic inflammation, to the target population, subjects without chronic joint diseases, was provided by the applicant. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim. The Panel concludes that a cause and effect relationship has not been established between the consumption of *Eff<sub>EXT</sub>*<sup>TM</sup> and maintenance of normal joint mobility.

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#### KEY WORDS

*Eff<sub>EXT</sub>*<sup>TM</sup>, krill oil, joints, osteoarthritis, chronic inflammation, health claims

<sup>1</sup> On request from the Competent Authority of Belgium following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00384, adopted on 28 November 2012.

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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 *Eff*<sub>EXT</sub><sup>TM</sup> and maintenance of normal joint mobility.

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*<sub>EXT</sub><sup>TM</sup>, which is standardised pure krill oil. The Panel considers that *Eff*<sub>EXT</sub><sup>TM</sup> is sufficiently characterised.

The claimed effect proposed by the applicant is “contributes to support joint flexibility”. The target population proposed by the applicant is adults with “sensitive joints”. The Panel considers that the health claim refers to the maintenance of joint mobility in subjects without chronic joint diseases, and does not include the treatment of chronic joint diseases. The Panel considers that maintenance of normal joint mobility is a beneficial physiological effect.

The applicant identified one human intervention study as being pertinent to the health claim.

The study was a randomised, double-blind, placebo-controlled 30-day trial in 90 patients who had confirmed diagnosis of at least one chronic inflammatory disease (i.e. cardiovascular disease, rheumatoid arthritis (RA), osteoarthritis (OA)) and steadily (i.e. for three consecutive weeks) increased plasma concentrations of C-reactive protein (CRP  $\geq 10.0$  mg/l). Patients were randomised to consume daily 300 mg Neptune Krill Oil<sup>TM</sup> (n=45) or a placebo (n=45). The primary outcome of the study was blood concentration of CRP. As a secondary outcome, patients with arthritic disease (having either RA or OA) were asked to complete the Western Ontario and McMaster Universities (WOMAC) osteoarthritis questionnaire.

The Panel notes that chronic inflammation was an inclusion criterion of the study, that a significant number of the patients recruited were reported to have confirmed diagnosis of OA, RA, or of both cardiovascular disease and OA, and that the WOMAC osteoarthritis questionnaire was administered only to patients with arthritic disease (OA or RA). In addition, the Panel considers that although the criteria used for the diagnosis of OA or RA were not specified in the publication, a chronic inflammatory disease of the joints is likely in patients with chronically elevated CRP concentrations of  $\geq 10$  mg/l and mean WOMAC scores for pain, stiffness and functional impairment ranging from 2.85 to 3.45 (the worst score being 4) at baseline. The Panel also notes that no evidence which could justify the extrapolation of the results, obtained in patients with joint diseases characterised by chronic inflammation, to the target population, subjects without chronic joint diseases, was provided by the applicant. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

The Panel concludes that a cause and effect relationship has not been established between the consumption of *Eff*<sub>EXT</sub><sup>TM</sup> and maintenance of normal joint mobility.

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## BACKGROUND

Regulation (EC) No 1924/2006<sup>4</sup> 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.
- On 13/09/2012, the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application. The clock was stopped on 21/09/2012 and restarted on 06/10/2012, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 17/10/2012, EFSA received the requested information (which was made available to EFSA in electronic format on 08/10/2012).
- During its meeting on 28/11/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to *Eff*<sub>EXT</sub><sup>TM</sup> and maintenance of normal joint mobility.

## 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*<sub>EXT</sub><sup>TM</sup> and maintenance of normal joint mobility.

## EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of *Eff*<sub>EXT</sub><sup>TM</sup>, a positive assessment of its safety, nor a decision on whether *Eff*<sub>EXT</sub><sup>TM</sup> is, or is

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<sup>4</sup> 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.

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, P.O. Box 96, CH-1000 Lausanne 21, Switzerland.

### Food/constituent as stated by the applicant

According to the applicant, *Eff*<sub>EXT</sub><sup>TM</sup>, 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.

### Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “contributes to support joint flexibility”.

The following alternative wordings were proposed: “supports joint health”, “is fast-acting and clinically proven to improve joint flexibility”, “is fast-acting and clinically proven to reduce joint stiffness”, “is beneficial to help maintain normal (joint) inflammation and improve (joint) function and comfort”, “is active (by improving joint flexibility/reducing joint stiffness) after only 7 days of daily consumption”, “active from 7 days”.

### Specific conditions of use as proposed by the applicant

The applicant has proposed an intake of 300 mg *Eff*<sub>EXT</sub><sup>TM</sup> 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*<sub>EXT</sub><sup>TM</sup>, which is standardised pure krill oil.

Krill oil is extracted from the crustacean *Euphausia superba* (Antarctic Krill) and has been authorised as a novel food ingredient<sup>5</sup>. 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 are phospholipids ( $\geq 42.0$  g/100 g), omega-3 fatty acids ( $\geq 26.5$  g/100 g), comprising eicosapentaenoic acid (EPA, C20:5,  $\geq 14.2$  g/100 g) and docosahexaenoic acid (DHA, C22:6,  $\geq 8.5$  g/100 g), and saturated fatty acids ( $25.0 \pm 5$  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 batch-to-batch variability of the product has been provided.

The Panel considers that the food, *Eff*<sub>EXT</sub><sup>TM</sup>, which is the subject of the health claim, is sufficiently characterised.

<sup>5</sup> 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.

## 2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is “contributes to support joint flexibility”. The target population proposed by the applicant is adults with “sensitive joints”. A definition for “sensitive joints” was not provided.

The Panel considers that the health claim refers to the maintenance of joint mobility in subjects without chronic joint diseases, and does not include the treatment of chronic joint diseases.

The Panel considers that maintenance of normal joint mobility 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, Google and SCOPUS using the search terms [“Neptune Krill Oil”] AND [“arthritic symptoms” OR “joint”] for publications between January 2000 and May 2011, as well as hand searches in specialised libraries and general web research, to identify human intervention studies conducted with Neptune Krill Oil™ in volunteers presenting with “sensitive joints”. Exclusion criteria and the meaning of “sensitive joints” were not specified. The Panel notes the limited scope of the literature search performed.

The applicant identified one human intervention study as being pertinent to the health claim (Deutsch, 2007).

The study (Deutsch, 2007) was a randomised, double-blind, placebo-controlled 30-day trial in 90 patients who had confirmed diagnosis of at least one chronic inflammatory disease (i.e. cardiovascular disease, rheumatoid arthritis (RA), osteoarthritis (OA)) and steadily (i.e. for three consecutive weeks) increased plasma concentrations of C-reactive protein (CRP  $\geq 10.0$  mg/l), and who were recruited from the practices of primary care physicians. In order to avoid the inclusion of patients with acute inflammation, CRP was measured weekly for three consecutive weeks (i.e. screening period). Patients who maintained a CRP of at least 10 mg/l, without fluctuations higher than 0.5 mg/l, were included in the study and randomised to consume daily 300 mg Neptune Krill Oil™ (NKO™; n=45, 20 women, mean age 54.6 years) or a placebo (microcrystalline cellulose; n=45, 23 women, mean age 55.3 years). Patients were allowed to take acetaminophen (paracetamol) as a rescue analgesic medication for severe pain throughout the trial. The primary outcome of the study was blood concentration of CRP. As a secondary outcome, patients with arthritic disease (having either RA or OA) were asked to complete the Western Ontario and McMaster Universities (WOMAC) osteoarthritis questionnaire, which has been validated to evaluate joint pain, stiffness and loss of function related to osteoarthritis of the knee and hip and has been used for the evaluation of the effect of different interventions on the treatment of osteoarthritis. The WOMAC osteoarthritis score has 3 subscales with 24 items; 5 items assessing pain, 2 items for stiffness, and 17 items measuring physical function. The WOMAC can be scored both separately for each subscale and together to give a composite score. The scale employed in this study to quantify patient global assessment of disease activity was the Likert scale, a 5-point scale in which 0 represents the best outcome and 4 the worst.

The applicant was requested to provide evidence on whether results obtained in patients with chronic inflammatory joint diseases (RA or OA) could be extrapolated to the target population, subjects without chronic inflammatory diseases of the joints. In reply, the applicant acknowledged that the primary outcome of the study was changes in plasma concentrations of CRP in a study population with chronically elevated CRP concentrations ( $\geq 10$  mg/l). However, the applicant claims that the publication did not specify symptomatic or radiologic criteria for the diagnosis of RA or OA, that patients were only taking acetaminophen or acetylsalicylic acid at recruitment and did not use any rescue medication for severe pain during the study except acetaminophen, and that patient withdrawal



rate from the study was very low, which, according to the applicant, would indicate that only subjects having mild to moderate “arthritic-like” symptoms had been recruited.

The Panel notes that the publication (Deutsch, 2007) clearly specifies that chronic inflammation defined as plasma concentrations of CRP  $\geq 10$  mg/l for three consecutive weeks was an inclusion criterion of the study, that a significant number of the patients recruited were reported to have confirmed diagnosis of OA (18 and 16 in the intervention and control groups, respectively), of RA (10 and 12 patients in the intervention and control groups, respectively), or of both cardiovascular disease and OA (12 and 10 patients in the intervention and control groups, respectively), and that the WOMAC questionnaire was administered only to patients with arthritic disease (OA or RA). In addition, the Panel considers that although the criteria used for the diagnosis of OA or RA were not specified in the publication, a chronic inflammatory disease of the joints is likely in patients with chronically elevated CRP concentrations of  $\geq 10$  mg/l and mean WOMAC scores for pain, stiffness and functional impairment ranging from 2.85 to 3.45 (the worst score being 4) at baseline. The Panel also notes that no evidence which could justify the extrapolation of the results, obtained in patients with joint diseases characterised by chronic inflammation, to the target population, subjects without chronic joint diseases, was provided by the applicant. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

The Panel concludes that a cause and effect relationship has not been established between the consumption of *Eff<sub>EXT</sub>*<sup>TM</sup> and maintenance of normal joint mobility.

## CONCLUSIONS

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

- The food, *Eff<sub>EXT</sub>*<sup>TM</sup>, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is “contributes to support joint flexibility”. The target population proposed by the applicant is adults with “sensitive joints”. The health claim refers to the maintenance of joint mobility in subjects without chronic joint diseases, and does not include the treatment of chronic joint diseases. Maintenance of normal joint mobility is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of *Eff<sub>EXT</sub>*<sup>TM</sup> and maintenance of normal joint mobility.

## DOCUMENTATION PROVIDED TO EFSA

Health claim application on *Eff<sub>EXT</sub>*<sup>TM</sup> and maintenance of normal joint mobility pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0339\_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.

## **GLOSSARY/ABBREVIATIONS**

|       |   |
|-------|---|
| CRP   | C-reactive protein                        |
| OA    | Osteoarthritis                            |
| RA    | Rheumatoid arthritis                      |
| WOMAC | Western Ontario and McMaster Universities |