



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to Vitis vinifera L. seeds extract and “helps to decrease swollen legs” 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 *Vitis vinifera* L. seeds extract and “helps to decrease swollen legs” 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 *Vitis vinifera* L. seeds extract and “helps to decrease swollen legs”. The Panel considers that the food constituent which is the subject of the health claim is sufficiently characterised. Upon EFSA’s request for clarification, the applicant stated that the claimed effect was “helps to decrease swollen legs”, and that the beneficial physiological effect could be related to “helps to refine legs”. In the context of the references provided for the scientific substantiation of the claim, and in particular of the human intervention study which was conducted with the food constituent that is the subject of the health claim, the Panel notes that the claim refers to the reduction of peripheral oedema in the context of chronic clinical conditions (e.g. chronic venous insufficiency) where the reduction of peripheral oedema is a therapeutic target for the treatment of the condition. The Panel considers that the reduction of peripheral oedema in the context of chronic clinical conditions is a therapeutic target for the treatment of the condition and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

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KEY WORDS

Vitis vinifera, swollen legs, health claims

¹ On request from the Competent Authority of Belgium following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00388, 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 *Vitis vinifera* L. seeds extract and “helps to decrease swollen legs”.

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 an extract of *Vitis vinifera* L. seeds which is standardised by its content of polyphenols. The Panel considers that *Vitis vinifera* L. seeds extract is sufficiently characterised.

The claimed effect proposed by the applicant is “helps to decrease swollen legs”. The target population proposed by the applicant is healthy adults in the general population. During the validation and evaluation processes, EFSA requested the applicant to identify the specific physiological function of the body that is the subject of the claim, together with the outcome measures which may be used for the scientific evaluation of that function. The applicant stated that the claimed effect was “helps to decrease swollen legs”, and that the beneficial physiological effect could be related to “helps to refine legs”.

In the context of the references provided for the scientific substantiation of the claim, and in particular the human intervention study which was conducted with the food constituent that is the subject of the health claim, the Panel notes that the claim refers to the reduction of peripheral oedema in the context of chronic clinical conditions (e.g. chronic venous insufficiency) where the reduction of peripheral oedema is a therapeutic target for the treatment of the condition.

The Panel considers that the reduction of peripheral oedema in the context of chronic clinical conditions is a therapeutic target for the treatment of the condition and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

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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 06/03/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- On 30/03/2012, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 21/05/2012, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 31/05/2012.
- On 12/09/2012, 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 05/10/2012).
- 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 *Vitis vinifera* L. seeds extract and “helps to decrease swollen legs”.

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: *Vitis vinifera* L. seeds extract and “helps to decrease swollen legs”.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of *Vitis vinifera* L. seeds extract, a positive assessment of its safety, nor a decision on whether *Vitis*

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.

vinifera L. seeds extract 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, Post code 96 CH-1000 Lausanne 21, Switzerland.

Food/constituent as stated by the applicant

According to the applicant, the food constituent that is the subject of the health claim is grape seed extract.

Health relationship as claimed by the applicant

According to the applicant, the claimed effect is “helps to decrease swollen legs”. The applicant claims that swelling in lower limbs of women is accompanied by different signs such as heaviness of legs, swollen legs or painful legs sensations which are having a high impact on quality of life. In addition, the applicant claims that swollen leg is associated with an increase of fluid leakage due to an impairment of venous vein walls, and thus a decrease of swollen legs due to an improvement of venous vein walls function and an increase of capillary resistance is a beneficial physiological effect.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “helps to decrease swollen legs”.

Alternative wordings: “helps to refine and lighten the legs”, “helps to reduce swollen legs sensation”, “helps to decrease excess water responsible for swollen legs sensation”.

Specific conditions of use as proposed by the applicant

According to the applicant, 120 to 150 mg per day of grape seed extract should be consumed during a meal. The applicant has proposed healthy adults in the general population as the target population.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is an extract of *Vitis vinifera* L. seeds.

Vitis vinifera L. (grape vine) is a perennial plant, originating from North and South Africa or South West Europe, which belongs to the *Vitaceae* family. The dry powder extract is obtained by extraction of seeds of *Vitis vinifera* L. with ethanol and ethyl acetate, and subsequent evaporation, filtration, concentration and spray-drying. The extract of *Vitis vinifera* L. seeds is standardised by its content of specific polyphenols: at least 35 % of gallic acid, catechins, epicatechins and procyanidin dimers B1, B2, B3 and B4. Procyanidin dimers account for at least 7% of the extract. These constituents can be analysed in foods by established methods.

Upon EFSA’s request for additional information, the applicant clarified that the range given for the plant/extract ratio depended on the amount of polyphenols in the plant used to obtain the extract.

Information pertaining to the manufacturing process, control specifications and batch-to-batch variability has been provided by the applicant.

The dry powder extract of *Vitis vinifera* L. seeds is proposed to be used in food supplements, with no reference to any specific formulation, in a quantity of 120-150 mg of extract per serving.

The Panel considers that the food constituent, *Vitis vinifera* L. seeds extract, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is “helps to decrease swollen legs”. The target population proposed by the applicant is healthy adults in the general population.

During the validation process, EFSA requested the applicant to identify the specific physiological function of the body that is the subject of the claim, together with the outcome measures which may be used for the scientific evaluation of that function. The applicant stated that swollen legs were associated with an increase of fluid leakage due to an impairment of vein walls, that a decrease of swollen legs due to an improvement of venous wall function and an increase of capillary resistance was a beneficial physiological effect, and that the changes in swollen legs could be assessed by measuring the thickness of oedema by ultrasound.

During the evaluation process, the Panel communicated to the applicant that “venous vein walls function” or “capillary resistance” had not been defined in the application, that “swollen legs measured as the thickness of oedema” was not a physiological function of the body but rather a non-specific clinical symptom related to diseases of various aetiology, and that thickness of oedema was neither a direct measure of “venous wall function” nor of “capillary resistance”. The Panel also requested the applicant to clarify and identify the specific physiological function that is the subject of the health claim, together with the outcome measure(s) which may be used for the scientific evaluation of that function. The applicant replied that the claimed effect was “helps to decrease swollen legs” and that the beneficial physiological effect could be related to “helps to refine legs”.

In the context of the references provided for the scientific substantiation of the claim (Allaert, 2009, unpublished; Djian et al., 2006), and in particular the human intervention study which was conducted with the food constituent that is the subject of the health claim (Allaert, 2009, unpublished), the Panel notes that the claim refers to the reduction of peripheral oedema in the context of chronic clinical conditions (e.g. chronic venous insufficiency) where the reduction of peripheral oedema is a therapeutic target for the treatment of the condition (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2012).

The Panel considers that the reduction of peripheral oedema in the context of chronic clinical conditions is a therapeutic target for the treatment of the condition 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 constituent, *Vitis vinifera* L. seeds extract, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is “helps to decrease swollen legs”. The target population proposed by the applicant is healthy adults in the general population.
- The claimed effect does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on *Vitis vinifera* L. seeds extract and “helps to decrease swollen legs” pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0343_BE). March 2012. Submitted by Nutrilinks Sarl.

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