

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to *Vitis vinifera* L. seeds extract and “helps to drain the body in case of water accumulation” pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

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

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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 *Vitis vinifera* L. seeds extract and “helps to drain the body in case of water accumulation”. The Panel considers that the food constituent which is the subject of the health claim is sufficiently characterised. The claimed effect proposed by the applicant is “helps to drain the body in case of water accumulation”. Upon EFSA’s request for clarification on the specific physiological function that is the subject of the health claim, together with the outcome measures which could be used for the scientific evaluation of that function, the applicant indicated that “increase of body drainage” was a beneficial physiological effect in the context of “a normal venous circulation in the legs”. The applicant acknowledged that this claim referred to the same physiological function of the body as another health claim application on *Vitis vinifera* L. seeds extract and maintenance of normal venous blood flow. The Panel considers that maintenance of normal venous blood flow is a beneficial physiological effect. A claim on *Vitis vinifera* L. seeds extract and maintenance of normal venous blood flow has already been assessed by the Panel with an unfavourable outcome. The reference provided by the applicant for the scientific substantiation of this claim was already considered in the previous submission.

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KEY WORDS

Vitis vinifera, water accumulation, health claims

¹ On request from the Competent Authority of Belgium following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00574, 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 drain the body in case of water accumulation”.

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 seeds of *Vitis vinifera* L., 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 drain the body in case of water accumulation”. The target population proposed by the applicant is healthy adults in the general population. Upon EFSA’s request for clarification on the specific physiological function that is the subject of the health claim, together with the outcome measures which could be used for the scientific evaluation of that function, the applicant indicated that “increase of body drainage” was a beneficial physiological effect in the context of “a normal venous circulation in the legs”. The applicant acknowledged that this claim referred to the same physiological function of the body as another health claim application on *Vitis vinifera* L. seeds extract and maintenance of normal venous blood flow. The Panel considers that maintenance of normal venous blood flow is a beneficial physiological effect.

A claim on *Vitis vinifera* L. seeds extract and maintenance of normal venous blood flow has already been assessed by the Panel with an unfavourable outcome. The reference provided by the applicant for the scientific substantiation of this claim was already considered in the previous submission.

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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 04/05/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- 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 drain the body in case of water accumulation”.

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 drain the body in case of water accumulation”.

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 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.

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.

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 health claim is “helps to drain the body in case of water accumulation”. The applicant claims that an increase of body drainage is associated with a decrease of oedema due to an improvement of capillary vein walls. The applicant also claims that a normal body fluid homeostasis by decreasing interstitial fluid accumulation (body drainage) and improving capillary vein wall functions is relevant to human health.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “helps to drain the body in case of water accumulation”.

Alternative wordings: “helps to reduce bloating caused by excess water”, “helps to fight against excess water”, “helps to eliminate excess water responsible for sensations of swelling”, “helps to activate the elimination of water and to reduce swelling sensation”.

Specific conditions of use as proposed by the applicant

According to the applicant, 120 mg per day of grape seed extract (including around 45 mg/day of polyphenols) 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 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 drain the body in case of water accumulation”. The target population proposed by the applicant is healthy adults in the general population.

Upon EFSA’s request for clarification on the specific physiological function that is the subject of the health claim, together with the outcome measures which could be used for the scientific evaluation of that function, the applicant indicated that “increase of body drainage” was a beneficial physiological effect in the context of “a normal venous circulation in the legs”. The applicant acknowledged that this claim referred to the same physiological function of the body as another health claim application on *Vitis vinifera* L. seeds extract and maintenance of normal venous blood flow.

The Panel considers that maintenance of normal venous blood flow is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

A claim on *Vitis vinifera* L. seeds extract and maintenance of normal venous blood flow has already been assessed by the Panel with an unfavourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2012).

The reference (Djian et al., 2006) provided by the applicant for the scientific substantiation of this claim was already considered in the previous submission which was assessed by the Panel with an unfavourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2012).

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 drain the body in case of water accumulation” in the context of “normal venous circulation in the legs”, which refers to the maintenance of normal venous blood flow. The target population proposed by the applicant is healthy adults in the general population. Maintenance of normal venous blood flow is a beneficial physiological effect.
- A claim on *Vitis vinifera* L. seeds extract and maintenance of normal venous blood flow has already been assessed with an unfavourable outcome. The reference provided by the applicant for the scientific substantiation of this claim was already considered in the previous submission.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on *Vitis vinifera* L. seeds extract and “helps to drain the body in case of water accumulation” pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0347_BE). May 2012. Submitted by Nutrilinks Sarl.

REFERENCES

- EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA), 2012. Scientific Opinion on the substantiation of a health claim related to *Vitis vinifera* L. seeds extract and maintenance of normal venous blood flow pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal, 10(12):2996, 12 pp.
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