



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil and maintenance of normal hair pursuant to Article 13(5) of Regulation (EC) No 1924/2006

EFSA Publication

Link to article, DOI:
[10.2903/j.efsa.2012.2807](https://doi.org/10.2903/j.efsa.2012.2807)

Publication date:
2012

Document Version
Publisher's PDF, also known as Version of record

[Link back to DTU Orbit](#)

Citation (APA):
EFSA Publication (2012). *EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil and maintenance of normal hair pursuant to Article 13(5) of Regulation (EC) No 1924/2006*. Parma, Italy: European Food Safety Authority. the EFSA Journal, No. 2807, Vol.. 10(7) <https://doi.org/10.2903/j.efsa.2012.2807>

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil and maintenance of normal hair 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 two applications 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 thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.) and maintenance of normal hair. The Panel considers that the specified combination is sufficiently characterised. The claimed effects are “contributes to reduce hair loss” and “increases the number of hair”. The target population proposed by the applicant is healthy adults in the general population. The Panel considers that maintenance of normal hair is a beneficial physiological effect. The applicant identified one publication as being pertinent to the health claim. This study did not use the food which is the subject of the claim. 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 a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.) and maintenance of normal hair. © European Food Safety Authority, 2012

KEY WORDS

Thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin, pumpkin seed oil, hair, health claims

¹ On request from the Competent Authority of Belgium following two applications by Nutrilinks Sarl, Question No EFSA-Q-2012-00334 and EFSA-Q-2012-00335, adopted on 27 June 2012.

² Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

³ Acknowledgement: 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.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil and maintenance of normal hair pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2012;10(7):2807. [8 pp.]. doi:10.2903/j.efsa.2012.2807. Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Following two applications 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 thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.) and maintenance of normal hair.

The scope of the applications 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 a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.). The Panel considers that the specified combination is sufficiently characterised.

The claimed effects are “contributes to reduce hair loss” and “increases the number of hair”. The target population proposed by the applicant is healthy adults in the general population. The Panel considers that maintenance of normal hair is a beneficial physiological effect.

The applicant identified one publication as being pertinent to the health claim. This study did not use the food which is the subject of the claim but rather another commercial product. The information provided on the composition was insufficient to establish that the product used in the study complied with the specifications of the food which is the subject of the claim. 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 were provided from which conclusions could 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 thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.) and maintenance of normal hair.

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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 applications were received on 24/02/2012.
- The scope of the applications was proposed to fall under a health claim based on newly developed scientific evidence.
- On 26/03/2012, during the validation process of the applications, EFSA sent a request to the applicant to provide missing information.
- The applicant provided the missing information on 06/04/2012.
- The scientific evaluation procedure started on 16/04/2012.
- During its meeting on 27/06/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.) and maintenance of normal hair.

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 thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.) and maintenance of normal hair.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of a combination of group B vitamins and pumpkin seed oil, a positive assessment of its safety, nor a decision on whether a combination of group B vitamins and pumpkin seed oil 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, Case postale 96, CH-1000 Lausanne 21, Switzerland.

Food/constituent as stated by the applicant

According to the applicant, a combination of vitamins B1, B2, B3, B5, B6, B8 and pumpkin seed oil (*Cucurbita pepo* L.), contained in a food supplement.

Health relationship as claimed by the applicant

According to the applicant, the dietary vitamins help to reinforce hair strength and normal hair function and contribute to reduce hair loss. In addition, the pumpkin seed oil is claimed to increase the number of hairs by curbing the activity of 5-alpha-reductase.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wordings for the health claim: "helps to increase hair number" (0329_BE) and "helps to slow down hair loss" (0330_BE).

The following alternative wordings were proposed: "helps to increase hair density", "helps to stimulate hair growth", "helps to increase hair volume" (0329_BE); "helps to slow down hair loss for 78 % of subjects", "helps to slow down hair loss for 78 % of subjects from the 9th week", "helps to slow down hair loss from the 9th week" (0330_BE).

Specific conditions of use as proposed by the applicant

The applicant has proposed an intake of two capsules of the food per day, providing a daily amount of 1.4 mg thiamin, 1.6 mg riboflavin, 18 mg niacin, 6 mg pantothenic acid, 2 mg pyridoxine, 150 µg D-biotin and 540 mg pumpkin seed oil. The target population proposed by the applicant is healthy adults in the general population.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.).

The amounts contained in one capsule are: 0.70 mg thiamin, 0.80 mg riboflavin, 9 mg niacin, 3 mg pantothenic acid, 1 mg pyridoxine, 75 µg D-biotin and 270 mg pumpkin seed oil. Thiamin, riboflavin, niacin, pantothenic acid, pyridoxine and D-biotin are well-characterised components and can be analysed in foods by established methods.

The pumpkin seed oil is described as being obtained by cold-pressing the seeds of pumpkin (*Cucurbita pepo* L.), followed by filtration. The main constituents of the pumpkin seed oil are linoleic acid (40-62 %), oleic acid (18-38 %), palmitic acid (10-16 %), stearic acid (3-7 %) and alpha-linolenic acid (max. 3 %). These fatty acids can be analysed in foods by established methods.

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

The Panel considers that the food, a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.), which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effects are “contributes to reduce hair loss” and “increases the number of hair”. The target population proposed by the applicant is healthy adults in the general population.

The Panel considers that maintenance of normal hair is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

According to the applicant, the “association of group B vitamins and pumpkin seed oil [in the food supplement] is unique” and “the matrix of the product and ingredients’ interactivity are important factors influencing the food supplement’s activity”. Therefore, the applicant decided “not to consider studies in which the food supplement assessed has not exactly the same composition, in the same concentrations and consumed in the same daily doses”. For these reasons, it did not appear pertinent to the applicant to perform a systematic literature search. No exclusion or inclusion criteria were defined.

The applicant identified one publication as being pertinent to the health claim.

This publication (Weltert et al., 2003) did not use the food which is the subject of the claim but rather another commercial product. The applicant was invited to provide a rationale on how this study could be pertinent for a product-specific claim on a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.). In reply, the applicant indicated that both products have similar characteristics with regards to the amounts of group B vitamins and of pumpkin seed oil. The Panel notes that the information provided on the composition was insufficient to establish that the product used in the study complied with the specifications of the food which is the subject of the claim. 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 were provided from which conclusions could 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 thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.) and maintenance of normal hair.

CONCLUSIONS

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

- The food, a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.), which is the subject of the health claim, is sufficiently characterised.
- The claimed effects are “contributes to reduce hair loss” and “increases the number of hair”. The target population proposed by the applicant is healthy adults in the general population. Maintenance of normal hair is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.) and maintenance of normal hair.

DOCUMENTATION PROVIDED TO EFSA

Two health claim applications on a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.) and maintenance of normal hair pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0329_BE and 0330_BE). February 2012. Submitted by Nutrilinks Sarl.

REFERENCES

Weltert Y, Berry N, Garcia-Mercier C and Chesne C, 2003. Évaluation de l'efficacité d'Oenobiol Capillaire Anti-Chute et du 5 alpha-réductolTM sur la chute de cheveux. Dermatologie Pratique.