

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to hyaluronic acid and protection of the skin against dehydration 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 for authorisation of a health claim 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 hyaluronic acid and protection of the skin against dehydration. The food constituent that is the subject of the health claim, hyaluronic acid, is sufficiently characterised. The claimed effect, protection of the skin against dehydration, is a beneficial physiological effect. The target population proposed by the applicant is the general population. No human studies have been provided from which conclusions could be drawn for the scientific substantiation of the claim. A cause and effect relationship has not been established between the consumption of hyaluronic acid and protection of the skin against dehydration.

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KEY WORDS

Hyaluronic acid, skin, dehydration, health claims.

¹ On request from the Competent Authority of Belgium following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00382, adopted on 27 June 2012.

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SUMMARY

Following an application from Nutrilinks Sarl, submitted for authorisation of a health claim 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 hyaluronic acid and protection of the skin against dehydration.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and/or a health claim including a request for the protection of proprietary data.

The food constituent that is the subject of the health claim is hyaluronic acid. The Panel considers that hyaluronic acid is sufficiently characterised.

The claimed effect is protection of the skin against dehydration. The target population proposed by the applicant is the general population. The Panel considers that protection of the skin against dehydration is a beneficial physiological effect.

The only study identified by the applicant as pertinent to the claim was a single-arm study with no control group. The Panel notes that this study was uncontrolled and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no human studies have been 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 hyaluronic acid and protection of the skin against dehydration.

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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 in 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 Art 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 applications was proposed to fall under a health based on newly developed scientific evidence and/or including a request for the protection of proprietary data.
- 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 hyaluronic acid and protection of the skin against dehydration.

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 hyaluronic acid and protection of the skin against dehydration.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of hyaluronic acid, a positive assessment of its safety, nor a decision on whether hyaluronic acid 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.

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.

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.

The application includes a request for the protection of proprietary data in accordance with Article 21 of Regulation (EC) No 1924/2006.

Food/constituent as stated by the applicant

According to the applicant, the food, which is the subject of the claim, is a dietary supplement capsule, HA2BL150, which contains hyaluronic acid.

Health relationship as claimed by the applicant

According to the applicant, the claimed effect relates to preventing some of the biochemical consequences of skin aging related to a decrease of hydration such as laxity of tone, skin elasticity and roughness and skin wrinkles.

Wording of the health claim as proposed by the applicant

The following wordings are proposed by the applicant: "Helps to maintain good skin hydration", "Contributes to maintain skin elasticity".

Specific conditions of use as proposed by the applicant

The applicant proposes the target population to be the general population and conditions of use of 150 mg of hyaluronic acid per day.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is hyaluronic acid.

Hyaluronic acid is a high molecular weight polysaccharide (glycosaminoglycan) produced mainly by fibroblasts and other specialised connective tissue cells and is chemically well defined. Hyaluronic acid consists of an alternating sequence of D-glucuronate and N-acetyl-D-glucosamine residues linked through alternating bonds. The disaccharide units are joined to one another by a β 1-4 linkage. The residues are joined by a β 1-3 linkage. Hyaluronic acid can be measured in foods by established methods.

The Panel considers that the food constituent, hyaluronic acid, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect is protection of the skin against dehydration. The target population proposed by the applicant is the general population.

The skin is the outer barrier of the body and provides protection from exposure to harmful irritants and potentially pathogenic organisms. An impaired permeability barrier function of the skin leads to water loss from the *stratum corneum* and to skin dehydration. The associated symptoms include roughness of the skin with visible scaling and flaking, itching, and reduced resistance to shearing forces. Maintenance (i.e. reduced loss) of the permeability barrier function of the skin protects the skin against dehydration.

The Panel considers that protection of the skin against dehydration is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed, Science Direct, Google Scholar, INIDS, Scopus, Scirus and Google with the search terms [(“hyaluronic acid” AND ”dietary”) AND (“skin hydration” OR “skin elasticity” OR “corneometry” OR “tewametry”)]. The time span which was covered by the search was not indicated. No published human intervention studies were identified by the applicant through this literature search.

The applicant provided one unpublished study (claimed as proprietary) (Marzatico, 2009) as pertinent to the claim, which was a single-arm intervention study (no control group) in 20 healthy female volunteers in which changes in transepidermal water loss and the water holding capacity of the skin, assessed by corneometry, in response to 30-day hyaluronic acid supplementation were examined. The Panel notes that this study was uncontrolled and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no human studies have been 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 hyaluronic acid and protection of the skin against dehydration.

CONCLUSIONS

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

- The food constituent, hyaluronic acid, which is the subject of the claim is sufficiently characterised.
- Protection of the skin against dehydration is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of hyaluronic acid and protection of the skin against dehydration.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on hyaluronic acid and protection of the skin against dehydration pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0337_BE). March 2012. Submitted by Nutrilinks Sarl.

REFERENCES

Marzatico, F, 2009, unpublished. Evaluation of the moisturizing and anti-wrinkle efficacy of a dietary supplement.