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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to a combination of lycopene, vitamin E, lutein and selenium and "helps to prepare and activate tanning" pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

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 Cyprus, 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 lycopene, vitamin E, lutein and selenium and "helps to prepare and activate tanning". The Panel considers that the combination of lycopene, vitamin E, lutein and selenium is sufficiently characterised. The claimed effect proposed by the applicant is "helps to prepare and activate tanning". Tanning (i.e. increasing the pigmentation of the skin) may contribute to the protection of the skin against UV-induced damage. The Panel considers that protection of the skin from UV-induced (including photo-oxidative) damage is a beneficial physiological effect. A claim on a combination of lycopene, vitamin E, lutein and selenium and protection of the skin from UV-induced (including photo-oxidative) damage 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 the same as in the previous submission.

KEY WORDS

Lycopene, vitamin E, lutein, selenium, skin, tanning, health claims

[1] On request from the Competent Authority of Cyprus following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00593, adopted on 28 November 2012.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Sean (J.J.) Strain, Inge Tetens, Dominique Turck, Hendrik van Loveren, Hans Verhagen and Peter Willats for the preparatory work on this scientific opinion.

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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 Cyprus, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to a combination of lycopene, vitamin E, lutein and selenium and "helps to prepare and activate tanning".

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 a combination of lycopene, vitamin E, lutein and selenium. These constituents are well-characterised and can be analysed in foods by established methods. The Panel considers that the combination of lycopene, vitamin E, lutein and selenium is sufficiently characterised.

The claimed effect proposed by the applicant is "helps to prepare and activate tanning". The target population proposed by the applicant is healthy adults in the general population. Tanning (i.e. increasing the pigmentation of the skin) may contribute to the protection of the skin against UV-induced damage. However, pigmentation of the skin is not a direct measure of UV-induced damage. The Panel considers that protection of the skin from UV-induced (including photo-oxidative) damage is a beneficial physiological effect.

A claim on a combination of lycopene, vitamin E, lutein and selenium and protection of the skin from UV-induced (including photo-oxidative) damage 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 the same as in the previous submission.

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BACKGROUND

Regulation (EC) No 1924/2006[4] 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 21/05/2012.
- 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 30/06/2012.
- 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 25/09/2012 and restarted on 10/10/2012, 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 09/10/2012).
- 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 a combination of lycopene, vitamin E, lutein and selenium and protection of the skin from UV-induced (including photo-oxidative) damage.

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 lycopene, vitamin E, lutein and selenium and protection of the skin from UV-induced (including photo-oxidative) damage.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of a combination of lycopene, vitamin E, lutein and selenium, a positive assessment of its safety, nor a decision on whether a combination of lycopene, vitamin E, lutein and selenium is, or is

[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.

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, a food supplement containing lycopene (8 mg), vitamin E (10 mg), lutein (1 mg) and selenium (50 µg).

Health relationship as claimed by the applicant

According to the applicant, the health claim refers to an enhanced pigmentation of the skin, especially in tanned areas, which have been exposed to UV-radiation.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "helps to prepare and activate tanning."

The following alternative wordings were proposed: "helps to prepare, activate and prolong the tan", "helps to prepare the skin from the inside and to stimulate melanin synthesis", "helps to prepare the skin from the inside to get a better tan".

Specific conditions of use as proposed by the applicant

The applicant has proposed a daily intake of 8 mg lycopene, 10 mg vitamin E, 1 mg lutein and 50 µg selenium in a food supplement during a meal. The supplementation should start at least one month before sun exposure and continue during and after sun exposure. The target population 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 lycopene, vitamin E, lutein and selenium.

The amounts contained in one capsule are: 8 mg lycopene (extracted from tomato), 10 mg vitamin E (as d-alpha-tocopherol), 1 mg lutein (extracted from *Tagetes erecta* L.) and 50 µg selenium (as sodium selenite). Lycopene, vitamin E, lutein and selenium are well-characterised constituents and can be analysed in foods by established methods.

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

The Panel considers that the food, a combination of lycopene, vitamin E, lutein and selenium, 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 prepare and activate tanning" and refers to enhanced pigmentation of the skin, especially in tanned areas which have been exposed to UV-radiation. The target population proposed by the applicant is healthy adults in the general population.

The Panel considers that increasing the pigmentation of the skin during UV-radiation exposure may not be a beneficial physiological effect in all circumstances. The applicant was requested to clarify the beneficial physiological effect, as well as the appropriate outcome measures which could be used for its assessment. In reply, the applicant stated that "the objective of the present application was to communicate on tanning", and that "tanning is an increase of skin pigmentation and thus related to skin appearance and aspect". The applicant acknowledged that in the application reference was made to "cell/skin protection against UV-damage but that it was only an extrapolation". No further clarification on the claimed effect was provided by the applicant.

The Panel notes that the proposed health claim refers to increasing the pigmentation of the skin (i.e. tanning) when exposed to UV-radiation. Tanning may contribute to the protection of the skin against UV-induced damage; protection of the skin against UV-induced damage is considered to be a beneficial physiological effect. However, the Panel considers that pigmentation of the skin is not a direct measure of UV-induced damage.

The Panel considers that protection of the skin from UV-induced (including photo-oxidative) damage is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in Pubmed, ScienceDirect, Google, Google Scholar, IBIDS, Scopus and Scirus using the search terms [("lutein" AND "lycopene" AND "selenium") AND ("vitamin E" OR "tocopherol")] AND ("skin tolerance" OR "dermal tolerance" OR "cutaneous tolerance"). Studies were included if they were performed with a combination of ingredients identical to the food which is the subject of the health claim. No exclusion criteria were 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 (Béjot et al., 2008).

A claim on a combination of lycopene, vitamin E, lutein and selenium and protection of the skin from UV-induced (including photo-oxidative) damage has already been assessed by the Panel with an unfavourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2012).

The reference (Béjot et al., 2008) provided by the applicant as being pertinent to the scientific substantiation of this claim was the same as 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, a combination of lycopene, vitamin E, lutein and selenium, which is the subject of the health claim, is sufficiently characterised.

- The claimed effect proposed by the applicant is "helps to prepare and activate tanning". The proposed target population is healthy adults in the general population. Protection of the skin from UV-induced (including photo-oxidative) damage is a beneficial physiological effect.

- A claim on a combination of lycopene, vitamin E, lutein and selenium and protection of the skin from UV-induced (including photo-oxidative) damage has already been assessed with an unfavourable outcome. The reference provided by the applicant for the scientific substantiation of this claim was the same as in the previous submission.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on a combination of lycopene, vitamin E, lutein and selenium and "helps to prepare and activate tanning" pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0356_CY). May 2012. Submitted by Nutrilinks Sarl.

REFERENCES

Béjot M, Le Révérend B and Maurette JM, 2008. Study of the sun protection efficacy of an antioxidant food supplement in relation to UV aggression (erythema). Laboratoire Oenobiol, Paris, France.

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2012. Scientific Opinion on the substantiation of a health claim related to a combination of lycopene, vitamin E, lutein and selenium and protection of the skin from UV-induced (including photo-oxidative) damage pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal, 10(9):2890, 7 pp.