

SCIENTIFIC OPINION

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 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)²

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 protection of the skin from UV-induced (including photo-oxidative) damage. The Panel considers that the combination of lycopene, vitamin E, lutein and selenium is sufficiently characterised. The claimed effect refers to the photo-protective activity of the food, delaying the appearance of UV-induced erythema and decreasing its intensity. The target population proposed by the applicant is healthy adults in the general population, and in particular people with sensitive skin. The Panel considers that protection of the skin from UV-induced (including photo-oxidative) damage is a beneficial physiological effect. The applicant identified one bioequivalence study as being pertinent to the health claim. The Panel notes that this study did not assess direct measures of UV-induced (including photo-oxidative) skin damage. Therefore, no conclusions could 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 lycopene, vitamin E, lutein and selenium and protection of the skin from UV-induced (including photo-oxidative) damage. © European Food Safety Authority, 2012

KEY WORDS

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

¹ On request from the Competent Authority of Cyprus following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00592, adopted on 13 September 2012.

² Panel members: Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean (J.J.) Strain, Inge Tetens, Daniel Tomé, Dominique Turck and Hans Verhagen. Correspondence: nda@efsa.europa.eu

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 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 2012;10(9):2890. [7 pp.]. doi:10.2903/j.efsa.2012.2890. Available online: www.efsa.europa.eu/efsajournal

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 (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 protection of the skin from UV-induced (including photo-oxidative) damage.

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 components 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 refers to the photo-protective activity of the food, delaying the appearance of UV-induced erythema and decreasing its intensity. The target population proposed by the applicant is healthy adults in the general population, and in particular people with sensitive skin. The Panel considers that protection of the skin from UV-induced (including photo-oxidative) damage is a beneficial physiological effect.

The applicant identified one human intervention study as being pertinent to the health claim.

This double-blind, parallel, 10-week study was a bioequivalence study of two oral “antioxidant formulas” and their purported protective effects against UV radiation. Fifty Caucasian men and women took a placebo for three weeks (i.e. run-in period) and were then randomised to receive for seven further weeks either a supplement designated as “current formula” (6 mg lycopene, 6 mg beta-carotene, 10 mg vitamin E and 75 µg selenium), or the food which is the subject of the health claim (“new formula”). Outcome measures of the study were minimal erythema dose, Individual Typology Angle (i.e. colorimetric measurements), melanin content (i.e. percentage of epidermis occupied by melanin) and “capping” (i.e. assembling of melanosomes at keratinocytes’ upper poles).

The Panel notes that erythema is an inflammatory response of the skin to UV-induced molecular and cellular damage. A reduction in UV-induced erythema (e.g. measured as change in minimal erythema dose or erythema grade) may indicate less UV-induced damage to the skin, but it can also reflect a reduction in the capacity of the skin to react to molecular and cellular damage. Therefore, UV-induced erythema cannot be used alone as an outcome measure for the substantiation of the claim. The other outcomes (i.e. Individual Typology Angle, melanin content and “capping”) used in the study did not provide any information on UV-induced skin damage.

The Panel notes that the submitted study was a bioequivalence study that did not assess direct measures of UV-induced (including photo-oxidative) skin damage. 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 lycopene, vitamin E, lutein and selenium and protection of the skin from UV-induced (including photo-oxidative) damage.

TABLE OF CONTENTS

Abstract	1
Summary	2
Table of contents	3
Background	4
Terms of reference	4
EFSA Disclaimer.....	4
Information provided by the applicant	5
Assessment	5
1. Characterisation of the food/constituent	5
2. Relevance of the claimed effect to human health.....	5
3. Scientific substantiation of the claimed effect	6
Conclusions	6
Documentation provided to EFSA	7
References	7
Glossary / Abbreviations.....	7

BACKGROUND

Regulation (EC) No 1924/2006³ 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.
- During its meeting on 13/09/2012, 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 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.

³ 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.

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 the photo-protective activity of the food supplement, delaying the appearance of UV-induced erythema damages and decreasing its intensity.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "helps to prepare sensitive skin from the inside to improve their tolerance to the sun".

The following alternative wording was proposed: "helps to improve skin tolerance to the sun".

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, and in particular people with sensitive skin.

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 components 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 refers to the photo-protective activity of the food, delaying the appearance of UV-induced erythema and decreasing its intensity. The target population proposed by the applicant is healthy adults in the general population, and in particular people with sensitive skin.

From the information provided, the Panel notes that the claimed effect refers to protection of the skin from UV-induced damage, including photo-oxidative 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 supplement which is the subject of the health claim. No exclusion criteria were specified. The Panel notes the limitations of the literature search performed.

The applicant identified one human intervention study as being pertinent to the health claim.

This double-blind, parallel, 10-week study (Béjot et al., 2008) was a bioequivalence study of two oral “antioxidant formulas” and their purported protective effects against UV radiation. Fifty Caucasian men and women of phototype II or III (sex ratio not specified; age range 18-55 years) took a placebo (not specified) for three weeks (i.e. run-in period) and were then randomised to receive for seven further weeks either a supplement designated as “current formula” (6 mg lycopene, 6 mg beta-carotene, 10 mg vitamin E and 75 µg selenium; n=25), or the food which is the subject of the health claim (“new formula”, n=25). Outcome measures of the study were minimal erythema dose (MED), Individual Typology Angle (i.e. colorimetric measurements), melanin content (i.e. percentage of epidermis occupied by melanin) and “capping” (i.e. assembling of melanosomes at keratinocytes’ upper poles).

The Panel notes that erythema is an inflammatory response of the skin to UV-induced molecular and cellular damage. A reduction in UV-induced erythema (e.g. measured as change in MED or erythema grade (reddening)) may indicate less UV-induced damage to the skin, but it can also reflect a reduction in the capacity of the skin to react to molecular and cellular damage. Therefore, UV-induced erythema cannot be used alone as an outcome measure for the substantiation of the claim. The other outcomes (i.e. Individual Typology Angle, melanin content and “capping”) used in the study did not provide any information on UV-induced skin damage.

The Panel notes that the submitted study was a bioequivalence study that did not assess direct measures of UV-induced (including photo-oxidative) skin damage. 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 lycopene, vitamin E, lutein and selenium and protection of the skin from UV-induced (including photo-oxidative) damage.

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 refers to the photo-protective activity of the food, delaying the appearance of UV-induced erythema and decreasing its intensity. The target population proposed by the applicant is healthy adults in the general population, and in particular people with sensitive skin. Protection of the skin from UV-induced (including photo-oxidative) damage is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of a combination of lycopene, vitamin E, lutein and selenium and protection of the skin from UV-induced (including photo-oxidative) damage.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on 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 (Claim serial No: 0355_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.

GLOSSARY / ABBREVIATIONS

MED minimal erythemal dose