SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to beta-carotene and physiological immune responses of the skin in relation to UV-radiation (sun exposure) (ID 198, 1463) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

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

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to beta-carotene and physiological immune responses of the skin in relation to ultraviolet (UV)-radiation (sun exposure). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claim is beta-carotene, which is a well recognised dietary constituent and is measurable in foods by established methods. The Panel considers that beta-carotene is sufficiently characterised.

The claimed effect is "immune health in relation to UV-radiation". In the context of the proposed wordings, the Panel notes that the claimed effect relates to "helps to maintain physiological immune responses of the skin upon UV-radiation (sun exposure)". The Panel considers that maintaining normal physiological immune responses of the skin in relation to UV-radiation (sun exposure) is beneficial to human health.

Three double-blind, placebo-controlled, randomised trials in healthy subjects exposed to sun or UV light receiving 30 mg beta-carotene per day or placebo, were provided. UV exposure caused a decrease in blood beta-carotene concentrations and suppressed delayed-type hypersensitivity (DTH) in groups without beta-carotene supplementation. However, the Panel notes that restoration of suppressed delayed-type hypersensitivity (DTH) and associated parameters by beta-carotene supplementation as compared to placebo was inconsistent. The Panel also notes that these

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intervention studies were performed with limited numbers of individuals at doses that were 4-fold higher than indicated in the conditions of use.

On the basis of the data available, the Panel concludes that a cause and effect relationship has not been established between the consumption of beta-carotene and maintaining normal physiological immune responses of the skin in relation to UV-radiation (sun exposure).

KEY WORDS

Beta-carotene, immune response, skin, UV, sun exposure, health claims

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The members of the Working Group on Claims: Jean-Louis Bresson, Albert Flynn, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Sean (J.J.) Strain, Inge Tetens, Henk van den Berg, Hendrik van Loveren and Hans Verhagen.

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation 1924/2006[3] submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims. The information provided in the consolidated list for the health claims that are the subject of this opinion is given in Table 1.

Table 1. Main entry health claims related to beta-carotene, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
198	Beta-Carotene	Immune health in relation to UV-radiation	Beta-carotene helps to support immunity upon UV-radiation (sun exposure) Helps to maintain healthy immune responses upon UV-radiation (sun exposure) Helps to maintain physiological immune responses of the skin upon UV radiation (sun exposure)/
	Conditions of use - Max 7,5 mg per day - Up to 10 mg per day (for 4 - 10 weeks) Agency guidance for supplements is that products containing beta-carotene should carry the advisory statement '[Beta-carotene]* should not be taken by heavy smokers. Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.		
	Food or Food constituent	**Health Relationship**	**Proposed wording**
1463	Beta-Carotene	Immune health in relation to UV-radiation	Beta-carotene helps to support immunity upon UV-radiation (sun exposure) Helps to maintain healthy immune responses upon UV-radiation (sun exposure) Helps to maintain physiological immune responses of the skin upon UV radiation (sun exposure)
	Conditions of use - Food supplement with 6mg of beta-carotene in the daily dose - Up to 10 mg per day (for 4 - 10 weeks) Agency guidance for supplements is that products containing beta-carotene should carry the advisory statement '[Beta-carotene]* should not be taken by heavy smokers. Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006. - Max 7,5 mg per day		

[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.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is beta-carotene (β,β-carotene, hereafter beta-carotene), which is a well recognised dietary constituent and it is measurable in foods by established methods. The compound is naturally available from a great variety of fruits and vegetables. Beta-carotene has been authorised for addition to foods and for use in food supplements (Annex II of the Regulation (EC) No 1925/2006[4] and Annex II of Directive 2002/46/EC[5]). This evaluation applies to beta-carotene naturally present in foods and those forms authorised for addition to foods and for use in food supplements (Annex II of the Regulation (EC) No 1925/2006 and Annex II of Directive 2002/46/EC).

The Panel considers that the food constituent, beta-carotene, which is the subject of the health claim is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect is "immune health in relation to UV-radiation". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that the claimed effect relates to "helps to maintain physiological immune responses of the skin upon UV-radiation (sun exposure)".

It is known that ultraviolet (UV)-radiation may result in local as well as systemic immunosuppression, resulting in altered resistance to infections and neoplasm.

The Panel considers that maintaining normal physiological immune responses of the skin in relation to UV-radiation (sun exposure) is beneficial to human health.

3. Scientific substantiation of the claimed effect

The references cited to substantiate the claimed effect include three double-blind, randomised, placebo-controlled intervention trials in healthy subjects exposed to sun or UV light receiving either 30 mg beta-carotene per day or placebo (Fuller et al., 1992; Herraiz et al., 1998; Gollnick et al., 1996).

Fuller et al. (1992) performed a parallel designed, double blind, placebo controlled intervention study in 24 males (aged 19-39), in which capsules with 30 mg beta-carotene per day or placebo were given, while on a low-carotenoid diet. After 28 days, all subjects received 12 exposures to a UV-A/B light source over a 16-day period. The total UV-A dose received ranged from 15.9 to 19.3 J/cm^2. The total shorter-wave ultraviolet-light (UV-B) dose varied from 1.59 to 1.96 J/cm^2. Blood concentrations of carotenoids and delayed-type hypersensitivity (DTH) tests were assessed at baseline, pre-UV, post-UV, and after follow-up. The DTH-test responses were significantly suppressed in the placebo group after UV treatments; the suppression was inversely related to blood beta-carotene concentrations in this group. There was no significant suppression of DTH test responses in the beta-carotene group. The Panel notes that the difference between the beta-carotene and placebo groups was not statistically significant.

[4] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38.
[5] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57.

Herraiz et al. (1998) performed a placebo-controlled, randomised trial in 14 healthy older men (mean age 65.5 years). They received 30 mg beta-carotene or placebo daily for 47 days while on a low carotenoid diet. After 28 days, half of each group received 12 suberythaemic exposures to UV over a 16-day period. DTH tests and plasma carotenoid concentrations were assessed at baseline, pre-UV and post-UV time points, with DTH testing performed on an area of skin protected from UV exposure. UV exposure resulted in significantly suppressed DTH response in the placebo group but not in the beta-carotene group. Higher blood beta-carotene concentrations were significantly associated with maintenance of DTH response. The Panel notes that the difference between the beta-carotene and placebo groups after UV-exposure was not statistically significant.

Gollnick et al. (1996) conducted a randomised, placebo-controlled, double-blind study in 20 healthy young female students to evaluate the effect of beta-carotene (30 mg/day) after 10 weeks of supplementation and over 13 days of sunlight exposure at sea level (30° latitude, Red Sea, Israel). Development of erythema in selected skin areas exposed to natural sunlight was lower in the group supplemented with beta-carotene. Blood concentrations of beta-carotene did not fall during sun exposure in the beta-carotene group, whereas in the placebo group beta-carotene concentrations decreased significantly to sub-physiological levels. Langerhans cells increased significantly in density per square millimetre/epidermis after pre-supplementation with beta-carotene. After UV-exposure, Langerhans cell density decreased in both groups; however, compared to baseline levels, this was significant in the temporary exposed skin region only for the placebo group. The lymphocyte counts did not change significantly in both groups. In contrast to the study by Fuller et al. (1992), the responses to the different recall antigens did not show any significant changes in both groups compared to baseline.

Some other studies included concerned natural killer cell activity in the elderly and its' restoration by beta-carotene supplementation (Moriguchi et al., 1996; Santos et al., 1996, 1998; Wood et al., 2000); these studies did not involve immunosuppression by UV exposure. A study by Prabhala et al. (1991) evaluated effects of beta-carotene on oral leukoplakia or Barrett's esophagus and on immune cell subpopulations, but did not involve UV exposure. Other studies addressed pathological effects of UV on the skin (Albers et al., 2005), blood concentrations of beta-carotene after repeated ultraviolet radiation exposure (White et al., 1988; Biesalski et al., 1996), protection against photooxidative stress (Biesalski and Obermueller-Jevic, 2001; Stahl and Sies, 2004, 2005), antioxidant activity of beta-carotene (Bendich, 2004; Clydesdale et al., 2001) and effects of cutaneous ultraviolet (UV) exposure (Granstein and Matsui, 2004), or effects of fruit and vegetable extracts on immune function in the elderly (Inserra et al., 1999; Watzl et al., 2003, 2005). The Panel notes that these studies cited provided no scientific data that could be used to substantiate the claimed effect.

UV exposure caused a decrease in blood beta-carotene concentrations and suppressed delayed-type hypersensitivity (DTH) in groups without beta-carotene supplementation. However, the Panel notes that restoration of suppressed DTH and associated parameters by beta-carotene supplementation as compared to placebo was inconsistent (Fuller et al., 1992; Herraiz et al., 1998; Gollnick et al., 1996). The Panel also notes that the intervention studies provided were performed with limited numbers of individuals at doses that were 4-fold higher than indicated in the conditions of use.

The Panel concludes that a cause and effect relationship has not been established between the consumption of beta-carotene and maintaining normal physiological immune responses of the skin in relation to UV-radiation (sun exposure).

CONCLUSIONS

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

- The food constituent, beta-carotene, which is the subject of the health claim is sufficiently characterised.

- The claimed effect is "immune health in relation to UV-radiation". The target population is assumed to be the general population. Maintaining normal physiological immune responses of the skin in relation to UV-radiation (sun exposure) is beneficial to human health.
- A cause and effect relationship has not been established between the consumption of beta-carotene and maintaining normal physiological immune responses of the skin in relation to UV-radiation (sun exposure).

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No EFSA-Q-2008-985, EFSA-Q-2008-2200). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[6] (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

a) the role of a nutrient or other substance in growth, development and the functions of the body; or

b) psychological and behavioural functions; or

c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13(1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[7]

Foods are commonly involved in many different functions[8] of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

[6] OJ L12, 18/01/2007
[7] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[8] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

(a) the claimed effect of the food is beneficial for human health,

(b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

(c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. 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 wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

GLOSSARY AND ABBREVIATIONS

UV	Ultraviolet
DTH	Delayed-type hypersensitivity