Vitamin E and protection of DNA, proteins and lipids from oxidative damage: Evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 - EFSA

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- **Requestor:** Competent Authority of France following an application by Specialised Nutrition Europe (SNE, formerly IDACE)
- **Question number:** EFSA-Q-2008-179
- **Panel members:** Jean-Louis Bresson, Barbara Burlingame, Tara Dean, Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf, Harry McArdle, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Kristina Pentieva, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Daniel Tomé, Dominique Turck, Hendrik Van Loveren, Marco Vinceti and Peter Willatts
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. **Abstract**

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to vitamin E and protection of DNA, proteins and lipids from oxidative damage. The Panel considers that vitamin E is sufficiently characterised and that protection of DNA, proteins and lipids from oxidative damage is a beneficial physiological effect. The target population proposed by the applicant is infants (from birth) and young children up to 3 years of age. The Panel has previously assessed a claim on vitamin E and protection of DNA, proteins and lipids from oxidative damage with a favourable outcome. The target population was the general population. The Panel considers that the role of vitamin E in protection of DNA, proteins and lipids from oxidative damage applies to all ages, including infants and young children up to 3 years of age. The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin E and protection of DNA, proteins and lipids from oxidative damage.

Summary

Following an application from Specialised Nutrition Europe (SNE, formerly IDACE), submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to vitamin E and protection of DNA, proteins and lipids from oxidative damage.

The scope of the application was proposed to fall under a health claim referring to children's development and health.

The general approach of the NDA Panel for the evaluation of health claims applications is outlined in the European Food Safety Authority (EFSA) general guidance for stakeholders on health claim applications.

The food constituent that is the subject of the health claim is vitamin E, which is an essential nutrient and can be measured in foods by established methods. The Panel considers that vitamin E is sufficiently characterised.

The claimed effect proposed by the applicant is 'protection of cells against oxidative damage'. The target population proposed by the

applicant is infants (from birth) and young children up to 3 years of age. The Panel considers that protection of DNA, proteins and lipids from oxidative damage is a beneficial physiological effect.

The Panel has previously assessed a claim on vitamin E and protection of DNA, proteins and lipids from oxidative damage with a favourable outcome. The target population was the general population. The Panel considers that the role of vitamin E in protection of DNA, proteins and lipids from oxidative damage applies to all ages, including infants and young children up to 3 years of age.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin E and protection of DNA, proteins and lipids from oxidative damage.

The following wording reflects the scientific evidence: 'Vitamin E contributes to the protection of cell constituents from oxidative damage'.

1 Introduction

1.1 Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1924/2006[1] 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, Articles 14–17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction in disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to this Regulation, an application 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).

1.2 Interpretation of the Terms of Reference

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 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: vitamin E and protection of DNA, proteins and lipids from oxidative damage.

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of vitamin E, a positive assessment of its safety, nor a decision on whether vitamin E 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 17 of Regulation (EC)No 1924/2006.

1.3 Additional information

A health claim on vitamin E and protection of DNA, proteins and lipids from oxidative damage has already been assessed by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) with a favourable outcome (EFSA NDA Panel, 2010).

2 Data and methodologies

2.1 Data

2.1.1 Information provided by the applicant

2.1.1.1 Food/constituent as stated by the applicant

According to the applicant, the food constituent that is the subject of the claim is vitamin E.

2.1.1.2 Health relationship as claimed by the applicant

According to the applicant, vitamin E 'is needed for the immune system of infants and young children'.

The applicant stated that vitamin E is an essential nutrient and a key element for the metabolism of almost all living organisms. It plays an important role for the proper functioning of all cells of the immune system.

2.1.1.3 Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: 'Vitamin E for protection of cells against oxidative damage'. The alternative wordings are 'Vitamin E is involved in protection of cells' or 'Vitamin E participates in protection of cells', etc.…'.

2.1.1.4 Specific conditions of use as proposed by the applicant

The target population proposed by the applicant is infants and young children from birth to 3 years of age.

According to the applicant, the quantities needed to achieve the claimed effects are as follows:

- For follow-on formulae, the content of vitamin E should be within the range set in Directive 2006/141/EC.
- For foods for special medical purposes, the content of vitamin E should be within the range set in Directive 1999/21/EC, except if this is contrary to the intended use of the product.
- For processed cereal-based foods and other foods regulated by Directive 2006/125/EU (as amended), a maximum vitamin E content should not exceed 3 mg/100 kcal.
- For the other foods intended for infants and young children, the content in vitamin E should not exceed 3 mg/100 kcal.

2.1.2 Data provided by the applicant

Health claim application on vitamin E and protection of cells from oxidative damage pursuant to Article 14 of Regulation 1924/2006 is presented in a common and structured format as outlined in the scientific and technical guidance for the preparation and presentation of applications for authorisation of health claims (EFSA NDA Panel, 2011).

As outlined in the general guidance for stakeholders on health claim applications, it is the responsibility of the applicant to provide the totality of the available evidence (EFSA NDA Panel, 2016).

2.2 Methodologies

The general approach of the NDA Panel for the evaluation of health claim applications is outlined in the EFSA general guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016).

The scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health are outlined in a specific EFSA guidance (EFSA NDA Panel, 2011).

3 Assessment

3.1 Characterisation of the food/constituent

The food constituent that is the subject of the health claims is vitamin E, which is an essential nutrient and can be measured in foods by established methods.

Vitamin E is authorised for addition to foods (Annex I of Regulation (EC) No 1925/2006, Annex I of Directive 2002/46/EC, Annex III of Directive 2006/141/EC, Annex IV of Directive 2006/125/EC, Directive 2001/15/EC). This evaluation applies to vitamin E naturally present in foods and those forms authorised for addition to foods (Annex II of Regulation (EC) No 1925/2006, Annex II of Directive 2002/46/EC, Annex III of Directive 2006/141/EC, Annex IV of Directive 2006/125/EC, Directive 2001/15/EC).

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

3.2 Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is 'protection of cells against oxidative damage'. The target population proposed by the applicant is infants (from birth) and young children up to 3 years of age.

From the information provided, the Panel notes that the claimed effect refers to protection of DNA, proteins and lipids from oxidative damage.

The Panel considers that protection of DNA, proteins and lipids from oxidative damage is a beneficial physiological effect.

3.3 Scientific substantiation of the claimed effect

The Panel has previously assessed a claim on vitamin E and protection of DNA, proteins and lipids from oxidative damage with a favourable outcome (EFSA NDA Panel, 2010). The target population was the general population. The Panel considered that vitamin E plays a role in protection of DNA, proteins and lipids from oxidative damage.

Vitamin E functions physiologically as a chain-breaking antioxidant that prevents the propagation of lipid peroxidation (IoM, 2000; Shils et al., 2006). Vitamin E is part of the antioxidant defence system, which is a complex network including both endogenous and dietary antioxidant

enzymes and repair mechanisms, with mutual interactions and synergic effects among the various components.

The Panel considers that the role of vitamin E in protection of DNA, proteins and lipids from oxidative damage applies to all ages, including infants and young children (from birth to 3 years of age).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin E and protection of DNA, proteins and lipids from oxidative damage.

3.4 Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: 'Vitamin E contributes to the protection of cell constituents from oxidative damage'.

3.5 Conditions and restrictions of use

The Panel considers that in order to bear the claim:

- Follow-on formulae should comply with the criteria for the composition of follow-on formulae as laid down in Directive 2006/141/EC.
- Nutritionally complete foods for special medical purposes intended for use by infants and nutritionally complete foods for special medical purposes other than those intended for use by infants should comply with the criteria for the composition of these foods as laid down in Directive 1999/21/EC.
- Processed cereal-based foods for infants and young children should comply with the criteria for the composition of these foods as laid down in Directive 2006/125/EC.
- Other foodstuffs intended for infants and young children should provide at least 15% of the reference values for the nutritional labelling of foods intended for infants and young children as laid down in Directive 2006/141/EC. Such amounts can easily be consumed as part of a balanced diet.
- The target population is infants and young children up to 3 years of age. Dietary Reference Values for vitamin E have been set for infants and young children (EFSA NDA Panel, 2015). The SCF 2003 set a Tolerable Upper Intake Level for vitamin E for children 1–3 years of 100 mg α-TE/day.

4 Conclusions

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

- The food/constituent, vitamin E, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is 'protection of cells against oxidative damage'. The target population proposed by the applicant is infants and young children from birth to 3 years of age. Protection of DNA, proteins and lipids from oxidative damage is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of vitamin E and protection of DNA, proteins and lipids from oxidative damage.
- The following wording reflects the scientific evidence: 'Vitamin E contributes to the protection of cell constituents from oxidative damage'.
- In order to bear the claim, follow-on formulae should comply with the criteria for the composition of follow-on formulae as laid down in Directive 2006/141/EC; nutritionally complete foods for special medical purposes intended for use by infants and nutritionally complete foods for special medical purposes other than those intended for use by infants should comply with the criteria for the composition of these foods as laid down in Directive 1999/21/EC; processed cereal-based foods for infants and young children should comply with the criteria for the composition of these foods as laid down in Directive 2006/125/EC; and other foodstuffs intended for infants and young children should provide at least 15% of the reference values for the nutritional labelling of foods intended for infants and young children as laid down in Directive 2006/141/EC. Such amounts can easily be consumed as part of a balanced diet. The target population is infants and young children up to 3 years of age. A Tolerable Upper Intake Level for vitamin E is 100 mg α-TE/day for children in the age of 1–3 years.

Steps taken by EFSA

1. Health claim application on vitamin E and protection of DNA, proteins and lipids from oxidative damage pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0099_FR). Submitted by Specialised Nutrition Europe (SNE, formerly IDACE), 9-31 Avenue des Nerviens, 1040 Brussels, Belgium.
2. This application was received by EFSA on 14/02/2008.
3. The scope of the application was proposed to fall under a health claim referring to children's development and health.
4. On 26/03/2008, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.

5. On 10/07/2016, EFSA received the missing information as submitted by the applicant.
6. The scientific evaluation procedure started on 07/09/2016.
7. During its meeting on 21/09/2016, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to vitamin E and protection of DNA, proteins and lipids from oxidative damage.

Note

1. 1

   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.