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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to selenium and protection of DNA, proteins and lipids from oxidative damage pursuant to Article 14 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 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 selenium and protection of DNA, proteins and lipids from oxidative damage. The Panel considers that selenium is sufficiently characterised. Protection of body cells and molecules such as DNA, proteins and lipids from oxidative damage is a beneficial physiological effect. The Panel has previously assessed a claim on selenium 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 selenium in the protection of DNA, proteins and lipids from oxidative damage applies to all ages, including infants and young children (from birth to three years of age). The Panel concludes that a cause and effect relationship has been established between the dietary intake of selenium and protection of DNA, proteins and lipids from oxidative damage. The following wording reflects the scientific evidence: "Selenium contributes to the protection of DNA, proteins and lipids from oxidative damage". The target population is infants and children up to three years of age.

KEY WORDS

selenium, antioxidant, oxidative damage, children, health claims

[1] On request from the Competent Authority of France following an application by Specialised Nutrition Europe (formerly IDACE), Question No EFSA-Q-2008-159, adopted on 30 October 2014.

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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, Hendrik Van Loveren, Hans Verhagen and Peter Willatts for the preparatory work on this scientific opinion.

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SUMMARY

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 selenium 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 food constituent that is the subject of the health claim is selenium, which is an essential nutrient and is measurable in foods by established methods. Selenium occurs naturally in foods and is authorised for addition to foods and for use in food supplements. The Panel considers that selenium is sufficiently characterised.

The claimed effect proposed by the applicant is "acts as an antioxidant to protect cells and tissues from oxidative damage". The target population proposed by the applicant is infants and young children from birth to three years of age. The Panel considers that the protection of body cells and molecules such as DNA, proteins and lipids from oxidative damage is a beneficial physiological effect.

The Panel has previously assessed a claim on selenium and protection of DNA, proteins and lipids from oxidative damage with a favourable outcome. The target population was the general population. The Panel considered that the role of selenium as an indirect component of the antioxidant network was well established.

The Panel considers that the role of selenium in the protection of DNA, proteins and lipids from oxidative damage applies to all ages, including infants and young children (from birth to three years of age). Dietary Reference Values for selenium have been set for infants and young children.

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

The following wording reflects the scientific evidence: "Selenium contributes to the protection of DNA, proteins and lipids from oxidative damage".

In order to bear the claim, follow-on formulae should comply with the criteria of 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 of 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 of 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 nutrition labelling for 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 children up to three years of age.

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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, Articles 14 to 17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to Article 15 of this Regulation, an application for authorisation 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 14/02/2008.
- The scope of the application was proposed to fall under a health claim referring to children's development and health.
- On 26/03/2008, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 20/06/2014, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 01/08/2014.
- During its meeting on 30/10/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to selenium and protection of DNA, proteins and lipids from oxidative damage.

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: selenium and protection of DNA, proteins and lipids from oxidative damage.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of selenium, a positive assessment of its safety, nor a decision on whether 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 17 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: Specialised Nutrition Europe (formerly IDACE), 9-31 Avenue des Nerviens, 1040 Brussels, Belgium.

Food/constituent as stated by the applicant

According to the applicant, the food constituent for which the claim is made is selenium.

Health relationship as claimed by the applicant

According to the applicant, selenium acts as an antioxidant to protect cells and tissues from oxidative damage.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "Selenium has an antioxidant functionality that helps maintain and protect healthy cells".

As equivalent alternative wordings, the applicant has proposed: "Selenium contributes to/helps in/protects/supports/is necessary for/is needed for the maintenance of/protection of/function of/normal function of cells/anti-oxidative capacity". "Selenium is an anti-oxidant." "Selenium helps scavenging free radicals."

Specific conditions of use as proposed by the applicant

According to the applicant, the target population is infants and young children from birth to three years of age. The claim should be used on foods that are exclusively intended for the category of infants and young children, and in line with the composition laid down in the specific directives (Directive 2006/141/EC; Directive 2006/125/EC; Directive 1999/21/EC).

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

- For follow-on formulae, the content of selenium should be within the range set in Directive 2006/141/EC;
- For dietary foods for special medical purposes, the content of selenium should be within the range set in Directive 1999/21/EC;
- For processed cereal-based foods and baby foods, the content of selenium should reach at least 15 % of the Nutrient Reference Values set in Directive 2006/125/EC, i.e. 15 % of 10 µg per 100 g or 100 ml or per serving, as reconstituted;
- For foods intended for infants and young children other than follow-on formulae, processed cereal-based foods and baby foods, the content of selenium should reach at least 15 % of the Nutrient Reference Values set in Directive 2006/141/EC (replacing Directive 91/321/EC), i.e. 15 % of 20 µg per 100 ml of product ready for use.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is selenium, which is an essential nutrient and is measurable in foods by established methods.

Selenium occurs naturally in foods and is authorised for addition to foods and for use in food supplements (Annex I of Regulation (EC) No 1925/2006[5] and Annex I of Directive 2002/46/EC[6]). This evaluation applies to selenium naturally present in foods and to those forms authorised for addition to foods and for use in food supplements (Annex II of Regulation (EC) No 1925/2006 and Annex II of Directive 2002/46/EC).

The Panel considers that the food constituent, 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 "acts as an antioxidant to protect cells and tissues from oxidative damage". The target population proposed by the applicant is infants and young children from birth to three years of age.

Reactive oxygen species (ROS), including several kinds of radicals, are generated in biochemical processes (e.g. respiratory chain) and as a consequence of exposure to exogenous factors (e.g. radiation, pollutants). These reactive intermediates damage biologically relevant molecules such as DNA, proteins and lipids if they are not intercepted by the antioxidant network, which includes free radical scavengers such as antioxidant nutrients.

The Panel considers that the protection of body cells and molecules such as DNA, proteins and lipids from oxidative damage is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The Panel has previously assessed a claim on selenium 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 the role of selenium as an indirect component of the antioxidant network is well established (EFSA NDA Panel, 2010). The antioxidant defence system comprises low molecular weight antioxidants and antioxidant enzymes, such as glutathione peroxidases, which catalyse the reduction of hydrogen peroxide or organic hydroperoxides using reduced glutathione as a co-substrate (Papp et al., 2007). These enzymes and other selenoenzymes, such as the thioredoxin reductases, which are also involved in antioxidant defence, are selenium dependent and can respond to selenium supplementation (EFSA NDA Panel, 2010).

The Panel considers that the role of selenium in the protection of DNA, proteins and lipids from oxidative damage applies to all ages, including infants and young children (from birth to three years of age). Dietary Reference Values for selenium have been set for infants and young children (EFSA NDA Panel, 2014).

[5] 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.

[6] 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.

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

4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: "Selenium contributes to the protection of DNA, proteins and lipids from oxidative damage".

5. Conditions and restrictions of use

The Panel considers that, in order to bear the claim:

- follow-on formulae should comply with the criteria of composition of follow-on formulae as laid down in Directive 2006/141/EC[7];
- 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 of composition of these foods as laid down in Directive 1999/21/EC[8];
- processed cereal-based foods for infants and young children should comply with the criteria of composition of these foods as laid down in Directive 2006/125/EC[9];
- other foodstuffs intended for infants and young children should provide at least 15 % of the reference values for nutrition labelling for 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 children up to three years of age. Tolerable Upper Intake Levels (UL) have been established as 60 µg/day for children of 1-3 years (SCF, 2000).

CONCLUSIONS

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

- The food constituent, selenium, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is "acts as an antioxidant to protect cells and tissues from oxidative damage". The target population proposed by the applicant is infants and young children from birth to three years of age. Protection of body cells and molecules such as 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 selenium and protection of DNA, proteins and lipids from oxidative damage.

[7] Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC Text with EEA relevance. OJ L 401, 30.12.2006, p. 1–33.
[8] Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes. OJ L 91, 7.4.1999, p. 29–36.
[9] Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children. OJ L 339, 6.12.2006, p. 16–35.

- The following wording reflects the scientific evidence: "Selenium contributes to the protection of DNA, proteins and lipids from oxidative damage".

- In order to bear the claim, follow-on formulae should comply with the criteria of 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 of 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 of 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 nutrition labelling for 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 children up to three years of age.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on selenium and protection of DNA, proteins and lipids from oxidative damage pursuant to Article 14 of Regulation (EC) No 1924/2006 (EFSA-Q-2008-159, Claim serial No: 0079_FR). February 2008. Submitted by Specialised Nutrition Europe (formerly IDACE).

REFERENCES

SCF (Scientific Committee on Food), 2000. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of selenium. SCF/CS/NUT/UPPLEV/25 Final, 18 pp.

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2010. Scientific Opinion on the substantiation of health claims related to selenium and maintenance of normal hair (ID 281), maintenance of normal nails (ID 281), protection against heavy metals (ID 383), maintenance of normal joints (ID 409), maintenance of normal thyroid function (ID 410, 1292), protection of DNA, proteins and lipids from oxidative damage (ID 1292), and maintenance of the normal function of the immune system (ID 1750) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(10):1727, 18 pp. doi:10.2903/j.efsa.2010.1727

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on Dietary Reference Values for selenium. EFSA Journal 2014;12(10):3846, 67 pp. doi:10.2903/j.efsa.2014.3846

Papp LV, Lu J, Holmgren A and Khanna KK, 2007. From selenium to selenoproteins: synthesis, identity, and their role in human health. Antioxidants and Redox Signaling, 9, 775-806.