SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 29 June 2015

PUBLISHED: 17 July 2015

doi:10.2903/j.efsa.2015.4182

Vitamin D and contribution to the normal function of the immune system: evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006

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

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 D and its contribution to the normal function of the immune system. The Panel considers that vitamin D is sufficiently characterised. A contribution to the normal function of the immune system is a beneficial physiological effect. The Panel has previously assessed claims on vitamin D and its contribution to the normal function of the immune system with favourable outcomes. The target populations were the general population and children aged 3 to 18 years. The Panel considers that the role of vitamin D in the functioning of the immune system 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 vitamin D and contribution to the normal function of the immune system. The following wording reflects the scientific evidence: 'Vitamin D contributes to the normal function of the immune system.' The target population is infants and young children up to three years of age.

Keywords: vitamin D, infants, children, immune system, health claims

Requestor: Competent Authority of France following an application by Specialised Nutrition Europe (SNE, formerly IDACE)

Question number: EFSA-Q-2008-182

Correspondence: nda@efsa.europa.eu

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.

Acknowledgements: 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 output.

Suggested citation: EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Scientific opinion on vitamin D and contribution to the normal function of the immune system: evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2015;13(7):4182, 9 pp. doi:10.2903/j.efsa.2015.4182

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

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 European Food Safety Authority (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 D and its contribution to the normal function of the immune system.

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 claim applications is outlined in the EFSA general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims.

The food constituent that is the subject of the health claim is vitamin D, which is an essential nutrient and can be measured in foods by established methods. Vitamin D occurs naturally in foods and is authorised for addition to foods and for use in food supplements. The Panel considers that vitamin D is sufficiently characterised.

The claimed effect proposed by the applicant is that vitamin D 'contributes to the normal function of the natural defences'. The target population proposed by the applicant is infants and young children from birth to three years of age. From the information provided, the Panel notes that the claimed effect refers to the normal function of the immune system. The Panel considers that a contribution to the normal function of the immune system is a beneficial physiological effect.

The Panel has previously assessed claims on vitamin D and its contribution to the normal function of the immune system with favourable outcomes. The target populations were the general population and children aged 3 to 18 years. The Panel considered that vitamin D plays a role in the functioning of the immune system.

The Panel considers that the role of vitamin D in the functioning of the immune system applies to all ages, including infants and young children (from birth to three years).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin D and contribution to the normal function of the immune system.

The following wording reflects the scientific evidence: 'Vitamin D contributes to the normal function of the immune system.'

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 three years of age. Tolerable Upper Intake Levels have been set at 25 µg/day for infants and 50 µg/day for children aged 1–10 years.

Table of contents

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 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).

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 D and its contribution to the normal function of the immune system.

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of vitamin D, a positive assessment of its safety or a decision on whether vitamin D 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

Health claims on vitamin D and its contribution to the normal function of the immune system have already been assessed by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) with favourable outcomes (EFSA NDA Panel, 2010, 2015).

2. Data and Methodologies

2.1. Data

2.1.1. Information provided by the applicant

Food/constituent as stated by the applicant:

- According to the applicant, the food which is the subject of the claim is vitamin D.

Health relationship as claimed by the applicant:

- According to the applicant, vitamin D contributes to the normal function of the 'natural defences'.
- The applicant states that vitamin D has been shown to have numerous biochemical functions which impact upon the capacity of the immune system to function optimally. The applicant also claims that vitamin D acts as a transcription factor which regulates a number of genes that are involved in immune responses.

[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.

Wording of the health claim as proposed by the applicant:

- The applicant has proposed the following wording for the health claim: 'Vitamin D contributes to the normal function of the natural defences'.
- The following alternative wordings were proposed: 'Vitamin D contributes to the function of the natural defences'; 'Vitamin D contributes to the (normal) development of the natural defences'; 'Vitamin D plays an important role in the (normal) function of the natural defences'; 'Vitamin D contributes to the normal function of the immune system'; and 'Vitamin D contributes to the normal development of the immune system'.

Specific conditions of use as proposed by the applicant:

- The target population proposed by the applicant is infants and young children from birth to three 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 D should be within the range set in Directive 2006/141/EC.
  - For dietary foods for special medical purposes, the content of vitamin D should be within the range set in Directive 1999/21/EC.
  - For processed cereal-based foods and baby foods, the content of vitamin D should be within the range set in Directive 2006/125/EC.
  - For processed cereal-based foods and baby foods, the content of vitamin D 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 vitamin D should reach at least 15 % of the Nutrient Reference Values set in Directive 2006/141/EC, i.e. 15 % of 7 µg per 100 mL product ready for use.

2.1.2. Data provided by the applicant

The applicant provided a health claim application on vitamin D and contribution to the normal function of the immune system pursuant to Article 14 of Regulation 1924/2006. The application was 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, 2011a).

As outlined in the EFSA general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims (EFSA NDA Panel, 2011b), it is the responsibility of the applicant to provide all the available evidence.

2.2. Methodologies

The general approach of the NDA Panel to the evaluation of health claim applications is outlined in the EFSA general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims (EFSA NDA Panel, 2011b).

3. Assessment

3.1. Characterisation of the food/constituent

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

Vitamin D occurs naturally in foods as vitamin D_2 (ergocalciferol) and vitamin D_3 (cholecalciferol). Different forms of vitamin D are authorised for addition to foods and for use in food supplements

(Annex II of Regulation (EC) No 1925/2006,[2] Annex II of Directive 2002/46/EC,[3] Annex III of Directive 2006/141/EC,[4] Annex IV of Directive 2006/125/EC[5] and Directive 2001/15/EC[6]). This evaluation applies to vitamin D 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 D, 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 that vitamin D 'contributes to the normal function of the natural defences'. The target population proposed by the applicant is infants and young children from birth to three years of age.

From the information provided, the Panel notes that the claimed effect refers to the normal function of the immune system.

The Panel considers that a contribution to the normal function of the immune system is a beneficial physiological effect.

3.3. Scientific substantiation of the claimed effect

The Panel has previously assessed a claim on vitamin D and its contribution to the normal function of the immune system with a favourable outcome (EFSA NDA Panel, 2010). The target population was the general population. The Panel considered that vitamin D plays a role in the functioning of the immune system (EFSA NDA Panel, 2010).

The Panel has also assessed a claim on vitamin D and its contribution to the normal function of the immune system, with a favourable outcome, for the target population children aged 3 to 18 years (EFSA NDA Panel, 2015).

The Panel considers that the role of vitamin D in the functioning of the immune system 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 vitamin D and contribution to the normal function of the immune system.

3.4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: 'Vitamin D contributes to the normal function of the immune system.'

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.

[2] 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.
[3] 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.
[4] 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.
[5] 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.
[6] Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses. OJ L 52, 22.2.2001, p. 19–25.

- 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 three years of age. Tolerable Upper Intake Levels have been established for vitamin D in this age group, and have been set at 25 µg/day for infants and 50 µg/day for children aged 1–10 years (EFSA NDA Panel, 2012).

4. Conclusions

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

- The food constituent, vitamin D, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is that vitamin D 'contributes to the normal function of the natural defences'. The target population proposed by the applicant is infants and young children from birth to three years of age. A contribution to the normal function of the immune system is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of vitamin D and contribution to the normal function of the immune system.
- The following wording reflects the scientific evidence: 'Vitamin D contributes to the normal function of the immune system.'
- 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 three years of age. Tolerable Upper Intake Levels have been set at 25 µg/day for infants and 50 µg/day for children aged 1–10 years.

Documentation provided to EFSA

1. Health claim application on vitamin D and contributes to the normal function of the immune system pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0102_FR). Submitted by Specialised Nutrition Europe (SNE; formerly IDACE), 9-31 Avenue des Nerviens, 1040 Brussels, Belgium.

2. The application was received by EFSA on 14 February 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 March 2008, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.

5. On 28 April 2015, EFSA received the missing information as submitted by the applicant.

6. The scientific evaluation procedure started on 3 June 2015.

7. During its meeting on 29 June 2015, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to vitamin D and contribution to the normal function of the immune system.

References

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2010. Scientific Opinion on the substantiation of health claims related to vitamin D and normal function of the immune system and inflammatory response (ID 154, 159), maintenance of normal muscle function (ID 155) and maintenance of normal cardiovascular function (ID 159) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(2):1468, 17 pp. doi:10.2903/j.efsa.2010.1468

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2011a. Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (revision 1). EFSA Journal 2011;9(5):2170, 36 pp. doi:10.2903/j.efsa.2011.2170

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2011b. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal 2011;9(4):2135, 24 pp. doi:10.2903/j.efsa.2011.2135

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2012. Scientific Opinion on the Tolerable Upper Intake Level of vitamin D. EFSA Journal 2012;10(7):2813, 45 pp. doi:10.2903/j.efsa.2012.2813

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Scientific Opinion on the substantiation of a health claim related to vitamin D and contribution to the normal function of the immune system pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2015;13(5):4096, 7 pp. doi:10.2903/j.efsa.2015.4096