

**EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014 .
Scientific Opinion on the substantiation of a health claim related to vitamin D and
contribution to normal bone and tooth development pursuant to Article 14 of
Regulation (EC) No 1924/2006**

EFSA Publication; Tetens, Inge

Link to article, DOI:
[10.2903/j.efsa.2014.3579](https://doi.org/10.2903/j.efsa.2014.3579)

Publication date:
2014

Document Version
Publisher's PDF, also known as Version of record

[Link back to DTU Orbit](#)

Citation (APA):
EFSA Publication (2014). EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014 .
Scientific Opinion on the substantiation of a health claim related to vitamin D and contribution to normal bone
and tooth development pursuant to Article 14 of Regulation (EC) No 1924/2006. Parma, Italy: European Food
Safety Authority. (The EFSA Journal; No. 3579, Vol. 12(2)). DOI: 10.2903/j.efsa.2014.3579

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to vitamin D and contribution to normal bone and tooth development pursuant to Article 14 of Regulation (EC) No 1924/2006¹

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 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 contribution to normal development of bones and teeth. The food constituent, vitamin D, which is the subject of the health claim, is sufficiently characterised. Contribution to normal development of bones and teeth is a beneficial physiological effect for infants and young children. A claim on vitamin D and maintenance of normal bones and teeth in the general population has already been assessed with a favourable outcome. The Panel considers that the role of vitamin D in bone and tooth mineralisation and homeostasis 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 normal development of bones and teeth.

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KEY WORDS

vitamin D, infants, children, bones, teeth, health claims

¹ On request from the Competent Authority of France following an application by Specialised Nutrition Europe (formerly IDACE), Question No EFSA-Q-2008-178, adopted on 5 February 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.

Suggested citation: EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to vitamin D and contribution to normal bone and tooth development pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2014;12(2):3579, 12 pp. doi:10.2903/j.efsa.2014.3579

Available online: www.efsa.europa.eu/efsajournal

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 vitamin D and contribution to normal development of bones and teeth.

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 vitamin D, which is an essential nutrient and is measurable in foods by established methods. The Panel considers that vitamin D is sufficiently characterised.

The claimed effect proposed by the applicant is "vitamin D is essential for the absorption and utilization of calcium and phosphorus in building strong teeth and bones". The target population proposed by the applicant is infants and young children from birth to three years of age. The Panel considers that contribution to normal development of bones and teeth is a beneficial physiological effect for infants and young children.

A claim on vitamin D and maintenance of normal bones and teeth in the general population has already been assessed with a favourable outcome. The conclusion of the Panel was based on the well established role of vitamin D in bone and tooth metabolism as shown by the evidence provided by consensus opinions/reports from authoritative bodies and reviews.

The Panel considers that the role of vitamin D on bone and tooth mineralisation and homeostasis 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 normal development of bones and teeth.

The following wording reflects the scientific evidence: "Vitamin D contributes to normal development of bones and teeth".

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; 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 be easily consumed as part of a balanced diet. The target population is infants and children up to three years. A Tolerable Upper Intake Level has been established for vitamin D in this age group.

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BACKGROUND

Regulation (EC) No 1924/2006⁴ 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 22/07/2013, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 03/12/2013.
- During its meeting on 05/02/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to vitamin D and contribution to normal bone and tooth development.

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 contribution to normal development of bones and teeth.

EFSA DISCLAIMER

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.

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 vitamin D.

Health relationship as claimed by the applicant

According to the applicant, vitamin D is essential for the absorption and utilization of calcium and phosphorus in building strong teeth and bones.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "vitamin D is essential for the absorption and utilization of calcium and phosphorus in building strong teeth and bones".

As equivalent alternative wordings, the applicant has also proposed: "vitamin D is essential for the structure of bones/healthy bones"; "vitamin D helps to build and maintain strong/healthy bones"; "vitamin D is necessary for adequate bone density"; "vitamin D helps build strong bones"; "vitamin D is needed for the development of healthy bones"; "vitamin D is necessary for the absorption and utilisation of calcium and phosphorus"; "vitamin D is essential for the absorption and utilization of calcium and phosphorus in building strong bones"; "vitamin D promotes the absorption of calcium for healthy bones"; "vitamin D is necessary for calcium uptake in bones".

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.

According to the applicant, the quantity needed to achieve the claimed effect is:

- For follow-on formulae, the content in vitamin D should be within the range set in Directive 2006/141/EC.
- For dietary foods for special medical purposes, the content in vitamin D should be within the range set in Directive 1999/21/EC.
- For processed cereal-based foods and baby foods, the content in vitamin D should be within the range set in Directive 2006/125/EC.
- For processed cereal-based foods and baby foods, the content in 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 in 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.

ASSESSMENT

1. Characterisation of the constituent

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

Vitamin D occurs naturally in foods as vitamin D₂ (ergocalciferol) and vitamin D₃ (cholecalciferol). Different forms of vitamin D are authorised for addition to foods and for use in food supplements (Annex II of Regulation (EC) No 1925/2006⁵, Annex II of Directive 2002/46/EC⁶, Annex III of Directive 2006/141/EC⁷, Annex IV of Directive 2006/125/EC⁸, Directive 2001/15/EC⁹). 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.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is “vitamin D is essential for the absorption and utilization of calcium and phosphorus in building strong teeth and bones” and refers to the importance of vitamin D for a normal bone and tooth development. The target population proposed by the applicant is infants and young children from birth to three years of age.

The Panel considers that contribution to normal development of bones and teeth is a beneficial physiological effect for infants and young children.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed and Google Scholar, using the search terms: “vitamin D”, “bone mineral density”, “bone mineral content” and “bone mass accretion” and with the following limits: “humans”, “randomized controlled trial”, published in English with no time limitations, for age “birth – 23 months” and “2-5 years”.

The applicant identified seven human intervention studies (Greer et al., 1981; Chan et al., 1982; Greer et al., 1982; Greer et al., 1989; Koo et al., 1995; Backström et al., 1999a; Backström et al., 1999b), 11 authoritative bodies opinions/recommendations (FoSIM, 1985; CEDAP, 1997; CFIA, 2003; JHCI, 2003; FNFC/FOSHU, 2001; NHPD, 2004; SNF, 2004; OFSP, 2006; EFSA 2008a, EFSA 2008b; EFSA 2008c), 13 reviews (Southard et al., 1991; Tomassi et al., 1996; Cioffia et al., 1997; Namgung and Tsang, 2000; Liu et al., 2001; Mølgard and Michaelsen, 2003; Ruff, 2003; Cranney et al., 2007; Rigo et al., 2007; Cranney et al., 2008; Greer et al., 2008; Holick et al., 2008; Holick et al., 2009), and seven “other” references (Emmett et al., 1996; Brunwald and Brunvatne, 2001; Noble et al., 2001; Pal and Shaw, 2001; Sichert-Hellert et al., 2006; Huybrechts and De Henauw, 2007; Fantino et al., 2008) as relevant for the claim.

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.

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 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.

⁹ 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.

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is a consensus on the role of vitamin D in growth, development and maintenance of bones and teeth. It is well established that an adequate status for vitamin D is required for efficient calcium absorption and for the maintenance of normal blood concentrations of calcium and phosphate that are in turn needed for the normal mineralisation of bones and teeth. An adequate intake of vitamin D is needed to achieve a vitamin D status that is sufficient for normal bone and tooth mineralisation throughout childhood and adolescence and for bone maintenance in adults and the elderly. Low vitamin D status has been shown to reduce bone mineral accretion in children and adolescents, and to accelerate bone loss in adults and older people. Recommended intakes of vitamin D to meet requirements for growth, development and maintenance of bones and teeth have been established for all life-stage groups by several expert committees. Low vitamin D status has been reported in subgroups of children, adolescents, adults and the elderly in a number of European countries, particularly in winter months, indicative of inadequate vitamin D intake (SCF, 1993; IoM, 1997; AFSSA, 2001; FAO/WHO 2001; EVM, 2002; SCF 2002; Ovesen et al., 2003; Holick, 2004; Davies et al., 2005; Holick, 2005; Greer et al., 2006; Cranney et al., 2007; Norman et al., 2007).

The Panel has already assessed a claim on vitamin D and maintenance of normal bones and teeth with a favourable outcome (EFSA NDA Panel, 2009). The target population was the general population. The conclusion of the Panel was based on the well established role of vitamin D in bone and tooth metabolism as shown by the evidence provided by consensus opinions/reports from authoritative bodies and reviews.

The Panel considers that the role of vitamin D on bone and tooth mineralisation and homeostasis 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 normal development of bones and teeth.

4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: "Vitamin D contributes to normal development of bones and teeth".

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;
- 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/EC¹⁰;
- 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.

¹⁰ 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.

Such amounts can be easily consumed as part of a balanced diet. The target population is infants and children up to three years. A Tolerable Upper Intake Level (UL) has been established for vitamin D in this age group, and has been set at 25 µg/day for infants and 50 µg/day for children aged 1 – 10 years (EFSA NDA Panel, 2012).

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 refers to the importance of vitamin D for normal bone and tooth development. The target population proposed by the applicant is infants and young children from birth to three years of age. Contribution to normal bone and tooth development is a beneficial physiological effect for infants and young children.
- A cause and effect relationship has been established between the dietary intake of vitamin D and contribution to normal development of bones and teeth.
- The following wording reflects the scientific evidence: “vitamin D contributes to normal development of bones and teeth”.
- 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 be easily consumed as part of a balanced diet. The target population is infants and children up to three years. A Tolerable Upper Intake Level has been set at 25 µg/day for infants and 50 µg/day for children aged 1 – 10 years.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on vitamin D and normal development of bones and teeth pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0098_FR). February 2008. Submitted by Specialised Nutrition Europe (formerly IDACE).

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