European Food Safety Authority

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SCIENTIFIC OPINION

Vitamin D and bone growth

Scientific substantiation of a health claim related to vitamin D and bone growth pursuant to Article 14 of Regulation (EC) No 1924/2006[1]

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

(Question No EFSA-Q-2008-323)

Adopted on 2 October 2008

PANEL MEMBERS

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SUMMARY

Following an application from the Association de la Transformation Laitière Française (ATLA) submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to vitamin D and bone growth.

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

The constituent subject of the health claim is vitamin D which is a well recognised nutrient and is measurable in foods by established methods. This evaluation applies to vitamin D naturally present in foods and those forms authorised for addition to foods (Annex II of the Regulation (EC) No 1925/2006).The Panel considers that the food/constituent that is the subject of the health claim (vitamin D) is sufficiently characterised.

The claimed effect is that vitamin D 'is essential for bone growth' of children. The proposed target population for the health claim is children aged 3-18 years. The Panel considers that normal growth and development of bone is beneficial to children's health.

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A total of 19 publications were considered pertinent by the applicant to the health claim - 9 reports from authoritative bodies and reviews and 10 human studies, including 6 intervention studies and 4 observational studies.

Reports from authoritative bodies and reviews show that there is good consensus on the role of vitamin D in growth and development of bone. Adequate status for vitamin D is required for efficient calcium absorption and for the maintenance of normal blood levels of calcium and phosphate that are needed for the normal mineralisation of bone. The serum level of calcidiol (25(OH)D) is a good marker of status for vitamin D. Synthesis of vitamin D in the skin by the action of sunlight is insufficient to meet requirements in European countries, especially during winter months when there is little sunlight exposure. Adequate intake of vitamin D throughout childhood and adolescence is needed to achieve a vitamin D status that is sufficient for normal bone mineralisation, and sub-optimal vitamin D status has been shown to reduce bone mineral accretion in children and adolescents. Recommended intakes of vitamin D for normal growth and development of bone have been established for children and adolescents by several expert committees. Sub-optimal vitamin D status has been reported in sub-groups of children and adolescents in a number of European countries, particularly in winter months, indicative of inadequate vitamin D intake.

The human observational and intervention studies presented support the association between serum 25(OH)D as an indicator of vitamin D status and bone health outcomes (bone mineral density and bone mineral content) in children and adolescents as well as a dose response relationship between vitamin D intake and serum 25(OH)D levels. They also provide evidence for the occurrence of sub-optimal vitamin D status in sub-groups of children in a number of European countries, particularly in winter months.

The Panel concludes that, on the basis of the evidence provided, a cause and effect relationship has been established between the intake of vitamin D and normal growth and development of bone in children and adolescents. Recommended intakes of vitamin D to meet requirements for normal growth and development of bone in children and adolescents have been established. Vitamin D intake may be inadequate in sub-groups of children and adolescents in a number of EU countries.

The following wording reflects the available scientific evidence: “vitamin D is needed for normal growth and development of bone in children”.

The Panel considers that in order to bear the claim a food should be at least a source of vitamin D as per Annex to Regulation 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is children and adolescents (up to 18 years). Tolerable Upper Intake Levels (UL) have been established for vitamin D in children and adolescents (25μg/day up to age 10 years; 50μg/day for age ≥11 years).

Key words: vitamin D, bone, growth, development, children, adolescents

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BACKGROUND

Regulation (EC) No 1924/2006[2] 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 that Regulation and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14 to 17 of that 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 that Regulation, an application for authorisation shall be submitted by the applicant to the national competent authority of a Member State, who will make the application and any supplementary information supplied by the applicant available to European Food Safety Authority (EFSA).

Steps taken by EFSA:

- The application was received on 06/05/2008.
- The scope of the application was proposed to fall under claims referring to children's development and health.
- During the check for completeness[3] of the application, the applicant was requested to provide missing information on 19/05/2008.
- The applicant provided the missing information on 20/06/2008.
- The scientific evaluation procedure started on 15/07/2008.
- During the meeting on 02/10/2008, the NDA Panel, after having evaluated the overall data submitted, adopted an opinion the scientific substantiation of a health claim related to vitamin D and bone growth.

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 bone growth.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of vitamin D, a positive assessment of its safety, nor 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 for use as proposed by the applicant may be subject to changes, pending the

[2] European Parliament and Council (2006). 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. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

[3] In accordance with EFSA "Scientific and Technical guidance for the Preparation and Presentation of the Application for Authorisation of a Health Claim"

scientific evaluation by EFSA and pending the outcome of the authorisation procedure foreseen in Article 17 of Regulation (EC) No 1924/2006.

ACKNOWLEDGEMENTS

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1. Information provided by the applicant

Applicant's name and address: Association de la Transformation Laitière Française (ATLA), 42, rue de Chateaudun, 75314 Paris Cedex 09, France.

1.1. Food/constituent as stated by the applicant

The nutrient for which the health claim is made is vitamin D.

1.2. Health relationship as claimed by the applicant

The health relationship is the role of vitamin D in bone growth of children. Vitamin D is required for calcium absorption and for the maintenance of normal blood levels of calcium and phosphate that are in turn needed for several functions including the normal mineralisation of bone. Moreover, there is fair evidence from the literature of the association between the marker of vitamin D status and bone health outcomes in children and adolescents.

1.3. Wording of the health claim as proposed by the applicant

Vitamin D is essential for the bone growth of children.

1.4 Specific conditions of use as proposed by the applicant

The food products intended to bear the health claim are products containing at least 15% of vitamin D recommended daily allowance (RDA) per 100 g. Target population: children and adolescents from 3 to 18 years of age.

2. Assessment

2.1. Characterisation of the food/constituent

The constituent subject of the health claim is vitamin D which is a well recognised nutrient and is measurable in foods by established methods. Vitamin D occurs naturally in foods as vitamin D_3 (cholecalciferol). Both vitamin D_3 and vitamin D_2 (ergocalciferol) are authorised for addition to foods (Annex II of the Regulation (EC) No 1925/2006). This evaluation applies to vitamin D naturally present in foods and those forms authorised for addition to foods (Annex II of the Regulation (EC) No 1925/2006).

The Panel considers that the food/constituent that is the subject of the health claim (vitamin D) is sufficiently characterised.

2.2. Relevance of the claimed effect to human health

The claimed effect is that vitamin D 'is essential for bone growth' of children. The proposed target population for the health claim is children aged 3-18 years.

The Panel considers that the normal growth and development of bone is beneficial for children's health.

2.3. Scientific substantiation of the claimed effect

The applicant performed a literature search with a private database with the key words "vitamin D", "bone growth", "bone development" and "children or adolescents" from 1992 until December 2007. Included studies were randomised controlled trials (RCT) of vitamin D supplementation (including food sources) compared with placebo in children and adolescents

without co-existent medical conditions affecting bone metabolism. Studies had to be written in English and be published between 1992 and December 2007 in core clinical journals. Studies other than RCT could be included if they were relevant for the assessment of the association between 25(OH)D and bone health outcomes.

Due to the limited selection of studies (only one RCT and one prospective study), the U.S. Department of Health and Health Services report on effectiveness and safety of vitamin D in relation to bone health (Cranney *et al.,* 2007) was taken into account with particular attention to their bibliographical review and selection. Included publications were on studies related to children and adolescents (target population) and dealing with the relationship between vitamin D intake, serum 25(OH)D and bone health outcomes (mainly bone mineral density (BMD) bone mineral content (BMC), and serum parathyroid hormone (PTH)). Finally, the review articles on vitamin D and bone health included in the list of health claims under the scope of Article 13 of Regulation (EC) No. 1924/2006 were selected and taken into consideration for this application.

Of the 47 publications identified through the strategies reported, a total of 19 were considered as pertinent to the health claim by the applicant (9 reports from authoritative bodies and reviews and 10 human studies, see reference list). The human studies presented were as follows:

- Six intervention studies, including 5 randomised controlled studies (Schou *et al.,* 2003; Ala-Houhala *et al.,* 1988; Fuleihan *et al.,* 2006; Guillemant *et al.,* 2001; Viljakainen *et al.,* 2006) and one non-randomised non-controlled study (Rajakumar *et al.,* 2005) on the effects of vitamin D supplementation on vitamin D status and on bone health in children and adolescents aged 6-18 years.

- Four observational studies in humans, including three prospective cohort studies (Guillemant *et al.,* 1999; Guillemant *et al.*, 2001; Lehtonen *et al.,* 2002), and one cross-sectional study (Pirainen *et al.,* 2007) on the relationship between dietary vitamin D intake and vitamin D status (observation periods between 18 months to 3 years) in children and adolescents aged 3-18 years.

The evidence provided by the reports from authoritative bodies and reviews shows that there is good consensus on the role of vitamin D in bone growth and development. It is well established that adequate status for vitamin D is required for efficient calcium absorption and for the maintenance of normal blood levels of calcium and phosphate that are in turn needed for the normal mineralisation of bone. Serum calcidiol (25(OH)D) concentration is a good marker of status for vitamin D. Synthesis of vitamin D in the skin by the action of sunlight is insufficient to meet requirements in European countries, especially during winter months when there is little sunlight exposure. Adequate intake of vitamin D throughout childhood and adolescence is needed to achieve a vitamin D status that is sufficient for normal bone mineralisation and sub-optimal vitamin D status has been shown to reduce bone mineral accretion in children and adolescents. Recommended intakes of vitamin D have been established for children and adolescents by several expert committees. Sub-optimal vitamin D status has been reported in sub-groups of children and adolescents in a number of European countries, particularly in winter months, indicative of inadequate vitamin D intake (Cranney *et al.,,* 2007; Davies *et al.*, 2005; EVM, 2002; FAO/WHO 2001; Greer *et al.,* 2006; Holick, 2004, 2005; AFSSA, 2001; Ovesen *et al.,* 2003; SCF, 1993, SCF 2002).

The human observational and intervention studies support the association between serum 25(OH)D as an indicator of nutritional status and bone health outcomes (BMD and BMC) in children and adolescents as well as a dose response relationship between vitamin D intake and

serum 25(OH)D levels. They also provide evidence for the occurrence of sub-optimal vitamin D status in sub-groups of children and adolescents in European countries, particularly in winter months (Ala-Houhala *et al.,* 1988; Fuleihan *et al.,* 2006; Guillemant *et al.,* 1999; Guillemant *et al.,* 2001; Lehtonen *et al.,* 2002; Pirainen *et al.,* 2007; Rajakumar *et al.,* 2005; Schou *et al.,* 2003; Viljakainen *et al.,* 2006).

The Panel considers that a cause and effect relationship is established between the intake of vitamin D and normal growth and development of bone in children and adolescents; recommended intakes of vitamin D to meet requirements for normal growth and development of bone in children and adolescents have been established. Vitamin D intake may be inadequate in sub-groups of children and adolescents in a number of EU countries.

2.4 Panel's comments on the proposed wording

Taking into account the scientific evidence presented, the Panel considers that the following wording reflects the scientific evidence: "vitamin D is needed for the normal growth and development of bone in children".

2.5 Conditions and restrictions of use

The Panel considers that in order to bear the claim a food should be at least a source of vitamin D as per Annex to Regulation 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is children and adolescents (up to 18 years). Tolerable Upper Intake Levels (UL) have been established for vitamin D in children and adolescents (25μg/day up to age 10 years; 50μg/day for age ≥11 years; SCF, 2002).

CONCLUSIONS AND RECOMMENDATIONS

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

- The constituent that is the subject of the health claim (vitamin D) is sufficiently characterised.
- The claimed effect is that vitamin D 'is essential for normal bone growth'. Normal growth and development of bone is beneficial to children's health.
- A cause and effect relationship is established between the intake of vitamin D and normal growth and development of bone in children and adolescents; recommended intakes of vitamin D to meet requirements for normal growth and development of bone in children and adolescents have been established.
- Vitamin D intake may be inadequate for normal growth and development of bone in sub-groups of children and adolescents in a number of EU countries.
- The following wording reflects the scientific evidence: 'vitamin D is needed for the normal growth and development of bone in children'.
- In order to bear the claim a food should be at least a source of vitamin D as per Annex to Regulation 1924/200. Such amounts can be easily consumed as part of a balanced diet. The target population is children and adolescents (up to 18 years).
- Tolerable Upper Intake Levels (UL) have been established for vitamin D in children and adolescents (25μg/day up to age 10 years; 50μg/day for age ≥11 years).

DOCUMENTATION PROVIDED TO EFSA

Health claim application on vitamin D and bone growth regarding children's development and health pursuant to Article 14 of the Regulation (EC) No 1924/2006 (Claim serial No: 0160-FR). May 2008. Submitted by the Association de la Transformation Laitière Française (ATLA).

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GLOSSARY / ABBREVIATIONS

BMC	Bone mineral content
BMD	Bone mineral density
PTH	Parathyroid hormone
RCT	Randomised controlled trial
RDA	Recommended daily allowance
UL	Tolerable Upper Intake Levels