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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**

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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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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).

REFERENCES

- AFSSA (Agence Française de Sécurité Sanitaire des Aliments), 2001. Vitamine D. In: Apports Nutritionnels Conseillés pour la population française. Editions Tec & Doc, Paris, 229-236.
- Backström MC, Mäki R, Kuusela AL, Sievänen H, Koivisto AM, Koskinen M, Ikonen RS, and Mäki M, 1999a. The long-term effect of early mineral, vitamin D, and breast milk intake on bone mineral status in 9- to 11-year-old children born prematurely. *Journal of Pediatric Gastroenterology and Nutrition*, 29, 575-582.
- Backström MC, Mäki R, Kuusela AL, Sievänen H, Koivisto AM, Ikonen RS, Kouri T, and Mäki M. 1999b. Randomized controlled trial of vitamin D supplementation on bone density and

- biochemical indices in preterm infants. *Archives of Diseases in Childhood Fetal and Neonatal Edition*. 80, F161-F166.
- Brunvand L and Brunvatne R, 2001. [Health problems among immigrant children in Norway]. *Tidsskrift for Den Norske Laegeforen*, 121, 715-718 (article in Norwegian, English abstract).
- CEDAP (Commission interministérielle d'Etude des produits Destinés à une Alimentation Particulière), 1997. Avis de la commission interministérielle d'étude des produits destinés à une alimentation particulière (CEDAP) en date du 18 décembre 1996 sur les recommandations relatives au caractère non trompeur des seuils des allégations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Répression des fraudes) du 7 octobre 1997.
- CFIA (Canadian Food Inspection Agency), 2003. Guide to Food labelling and Advertising <http://www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml>
- Chan GM, Roberts CC, Folland D and Jackson R, 1982. Growth and bone mineralization of normal breast-fed infants and the effects of lactation on maternal bone mineral status. *American Journal of Clinical Nutrition*, 36, 438-443.
- Cioffia M, Molinari A, Gazzero P, Di Finizio B, Fratta M, Deufemia A and Puca GA, 1997. Serum Osteocalcin in 1634 Healthy Children. *Clinical Chemistry*, 43, 543-545.
- Cranney A, Horsley T, O'Donnell S, Weiler HA, Puil L, Ooi DS, Atkinson SA, Ward LM, Moher D, Hanley DA, Fang M, Yazdi F, Garrity C, Sampson M, Barrowman N, Tsertsvadze A and Mamaladze V, 2007. Effectiveness and safety of vitamin D in relation to bone health. *Evidence Report/Technology Assessment (Full Rep)*, 158, 1-235.
- Cranney A, Weiler HA, O'Donnell S and Puil L, 2008. Summary of evidence-based review on vitamin D efficacy and safety in relation to bone health. *American Journal of Clinical Nutrition*, 88, 513S-519S.
- Davies JH, Evans BA, Gregory JW, 2005. Bone mass acquisition in healthy children. *Archives of Disease in Childhood*, 90, 373-378.
- EFSA (European Food Safety Authority), 2008a. Scientific Opinion of the Panel on Dietetic Products Nutrition and Allergies on a request from Association de la Transformation Laitière related to the scientific substantiation of a health claim on vitamin D and bone growth pursuant to Article 14 of Regulation (EC) No 1924/2006. *The EFSA Journal* 2008, 827, 1-10.
- EFSA (European Food Safety Authority), 2008b. Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from Yoplait Dairy Crest Limited on the scientific substantiation of a health claim related to calcium and vitamin D and bone strength pursuant to Article 14 of Regulation (EC) No 1924/2006. *The EFSA Journal* 2008, 828, 1-13.
- EFSA (European Food Safety Authority), 2008c. Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from Danone SA on the scientific substantiation of a health claim related to dairy fresh cheese and bone growth pursuant to Article 14 of Regulation (EC) No 1924/2006. *The EFSA Journal* 2008, 895, 1-10.
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2009. Scientific Opinion on the substantiation of health claims related to vitamin D and maintenance of bone and teeth (ID 150, 151, 158), absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations (ID 152, 157), cell division (ID 153), and thyroid function (ID 156) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from the European Commission. *EFSA Journal* 2009;7(9):1227, 19 pp. doi:10.2903/j.efsa.2009.1227

- 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
- Emmett P, Rogers I, Symes C, and ALSPAC Study Team, 2002. Avon longitudinal study of pregnancy and childhood. Food and nutrient intakes of a population sample of 3-year-old children in the south west of England in 1996. *Public Health Nutrition*, 5, 55-64.
- EVM (Expert Group on Vitamins and Minerals), 2002. Review of Vitamin D – Revised Version. Food Standards Agency, London, UK.
- Fantino M and Gourmet E, 2008. [Nutrient intakes in 2005 by non-breast-fed children of less than 36 months]. *Archives of Pediatrics*, 15, 446-455 (article in French, English abstract).
- FAO/WHO (Food and Agricultural Organization of the United Nations/World Health Organization), 2001. Report of a FAO/WHO expert consultation on human vitamin and mineral requirements. Bangkok, Thailand.
- FNFC/FOSHU (Japanese Ministry of Health, Labour and Welfare). Food with Health Claims, Food for Special Dietary Uses, and Nutrition Labelling <http://www.mhlw.go.jp/english/topics/foodsafety/fhc/01.html>
- FoSIM (Food Safety Information System of Malaysia), 1985. Food Regulation, Part IV. Food Labelling, Art. 18E Nutrient/function claims http://fsis.moh.gov.my/fqc/ReferenceBooks/actDetail.asp?id=33&FAD_ID=536&vn=18E&FAS_Title=Part%20IV%20Labelling&FAC_ID=21
- Greer FR and Marshall S. 1989. Bone mineral content, serum vitamin D metabolite concentrations, and ultraviolet B light exposure in infants fed human milk with and without vitamin D2 supplements. *Journal of Pediatrics*, 114, 204-212.
- Greer FR, 2008. 25-Hydroxyvitamin D: functional outcomes in infants and young children. *American Journal of Clinical Nutrition*, 88, 529S-533S.
- Greer FR, Krebs NF, American Academy of Pediatrics Committee on Nutrition, 2006. Optimizing bone health and calcium intakes of infants, children, and adolescents. *Pediatrics*, 117, 578-585.
- Greer FR, Searcy JE, Levin RS, Steichen JJ, Asch PS, and Tsang RC, 1981. Bone mineral content and serum 25-hydroxyvitamin D concentration in breast-fed infants with and without supplemental vitamin D. *Journal of Pediatrics*, 98, 696-701.
- Greer FR, Searcy JE, Levin RS, Steichen JJ, Steichen-Asche PS, and Tsang RC, 1982. Bone mineral content and serum 25-hydroxyvitamin D concentrations in breast-fed infants with and without supplemental vitamin D: one-year follow-up. *Journal of Pediatrics*, 114, 204-212.
- Holick MF and Chen TC, 2008. Vitamin D deficiency: a worldwide problem with health consequences. *American Journal of Clinical Nutrition*, 87, 1080S-1086S.
- Holick MF, 2004. Sunlight and vitamin D for bone health and prevention of autoimmune diseases, cancers, and cardiovascular disease. *American Journal of Clinical Nutrition*, 80, 1678S-1688S.
- Holick MF, 2005. The vitamin D epidemic and its health consequences. *Journal of Nutrition*, 135, 2739S-2748S.
- Holick MF, 2009. Vitamin D and Health: evolution, biologic functions and recommended dietary intakes for vitamin D. *Clinical Reviews in Bone and Mineral Metabolism*, 7, 2-19.
- Huybrechts I, and De Henauw S, 2007. Energy and nutrient intakes by pre-school children in Flanders- Belgium. *British Journal of Nutrition*, 98, 600-610.

- IoM (Institute of Medicine), 1997. Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride. National Academies Press, Washington DC. Gibney MJ, Vorster HH, Kok FJ, 2002. Introduction to Human Nutrition, Blackwell Science, Oxford 2002, 134-138.
- JHCI (Joint Health Claims Initiative). Final Technical Report – A List of Well Established Nutrient Function Statements JHCI/76/03 http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf
- Koo WW, Krug-Wispe S, Neylan M, Succop P, Oestreich AE and Tsang RC, 1995. Effect of three levels of vitamin D intake in preterm infants receiving high mineral-containing milk. *Journal of Pediatric Gastroenterology and Nutrition*, 21, 182-199.
- Liu M, Zheng H, Peng M, Liu L, Peng Z, Yang D, Shang J, Huang L and Suo L, 2001. A study of bone development and metabolism in childhood. *Hua Xi Yi Ke Da Xue Xue Bao*, 32, 529-331.
- Mølgaard C and Michaelsen KF, 2003. Vitamin D and bone health in early life. *Proceedings of Nutrition Society*, 62, 823-828.
- Namgung R and Tsang RC, 2000. Factors affecting newborn bone mineral content: *in utero* effects on newborn bone mineralization. *Proceedings of Nutrition Society*, 59, 55-63.
- NHPD (Natural Health Products Directorate), 2004. Health Canada permitted health claims. <http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/236932.html#Section-B.01.603>
- Noble S, Emmett P; and ALSPAC Study Team, 2001. Avon longitudinal study of pregnancy and childhood. Food and nutrient intake in a cohort of 8-month-old infants in the south-west of England in 1993. *European Journal of Clinical Nutrition*, 55, 698-707.
- Norman AW, Bouillon R, Whiting SJ, Vieth R, Lips P, 2007. 13th Workshop Consensus for vitamin D nutritional guidelines. *Journal of Steroid Biochemistry and Molecular Biology*, 103, 204-205.
- OFSP (L'Office fédéral de la santé publique), 2006. Vitamines et sels minéraux dans les denrées alimentaires: mentions autorisées. Berne, Switzerland.
- Ovesen L, Andersen R and Jacobsen J, 2003. Geographical differences in vitamin D status, with particular reference to European countries. *Proceedings of Nutrition Society*, 62, 813-821.
- Pal BR and Shaw NJ, 2001. Rickets resurgence in the United Kingdom: improving antenatal management in Asians. *Journal of Pediatrics*, 139, 337-338.
- Rigo J, Pieltain C, Salle B, and Senterre J, 2007. Enteral calcium, phosphate and vitamin D requirements and bone mineralization in preterm infants. *Acta Paediatrica*. 96, 969-974.
- Ruff C, 2003. Growth in bone strength, body size, and muscle size in a juvenile longitudinal sample. *Bone*, 33, 317-329.
- SCF (Scientific Committee for Food), 1993. Nutrient and energy intakes for the European Community. SCF (Scientific Committee on Food), 2002. Opinion on the Tolerable Upper Intake Level of Vitamin D. European Commission, Brussels.
- SCF (Scientific Committee for Food), 2003. Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and follow-on Formulae. European Commission, Brussels, 150-152.
- Sichert-Hellert W, Wenz G, and Kersting M, 2006. Vitamin intakes from supplements and fortified food in German children and adolescents: results from the DONALD study. *Journal of Nutrition*, 136, 1329-1333.
- SNF (Swedish Nutrition Foundation), 2004. Health Claims in the Labelling and Marketing of Food Products. Swedish Food Sector's Code of Practice, revised version, Stockholm, Sweden. <http://www.snf.ideon.se/snf/en/rh/Swedishcode.htm> http://www.hp-info.nu/SweCode_2004_1.pdf

- Southard RN, Morris JD, Mahan JD, Hayes JR, Torch MA, Sommer A and Zipf WB, 1991. Bone mass in healthy children: measurement with quantitative DXA. *Radiology*, 179, 735-738.
- Strain JJ and Cashman KD, 2002. Minerals and trace elements. In: *Introduction to Human Nutrition*. Eds Gibney MJ, Vorster HH, Kok FJ. Blackwell Publishing, Oxford, UK.
- Tommasi M, Bacciottini L, Benucci A, Brocchi A, Passeri A, Saracini D, D'Agata A and Cappelli G, 1996. Serum biochemical markers of bone turnover in healthy infants and children. *International Journal of Biological Markers*, 11, 159-164.