Calcium and contribution to the normal development of bones: evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006

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Calcium and contribution to the normal development of bones: evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006

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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 calcium and contribution to the normal development of bones. The Panel considers that calcium is sufficiently characterised and that contribution to the normal development of bones is a beneficial physiological effect. The target population proposed by the applicant is infants (from birth) and young children up to 3 years of age. The Panel has previously assessed a claim on calcium and normal growth and development of bone with a favourable outcome. The target population was children and adolescents. The Panel considers that the role of calcium in the development of bones applies to all ages including infants and young children up to 3 years of age. The Panel concludes that a cause and effect relationship has been established between the dietary intake of calcium and contribution to the normal development of bones.

Keywords: calcium, infants, children, bones, health claims

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

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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 calcium and contribution to the normal development of bones.

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 health claim applications.

The food constituent that is the subject of the health claim is calcium, which is an essential nutrient and can be measured in foods by established methods. The Panel considers that calcium is sufficiently characterised.

The claimed effect proposed by the applicant is that calcium 'is important for the development of bones'. The target population proposed by the applicant is infants (from birth) and young children up to 3 years of age. The Panel considers that contribution to the normal development of bones is a beneficial physiological effect.

The Panel has previously assessed a claim on calcium and normal growth and development of bone with a favourable outcome. The target population was children and adolescents. The Panel considers that the role of calcium in the development of bones applies to all ages including infants and young children up to 3 years of age.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of calcium and contribution to the normal development of bones.

The following wording reflects the scientific evidence: 'Calcium contributes to the normal development of bones'.

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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 14–17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction in 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: calcium and contribution to the normal development of bones.

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of calcium, a positive assessment of its safety, nor a decision on whether calcium 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

A health claim on calcium and maintenance of normal bones has already been assessed by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) with a favourable outcome (EFSA NDA Panel, 2009, 2010).

Moreover, a health claim on calcium and normal growth and development of bone has already been assessed by the EFSA NDA Panel with a favourable outcome (EFSA NDA Panel, 2008a,b).

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 health claim is calcium.

Health relationship as claimed by the applicant:

- According to the applicant, calcium has 'a critical role in the formation of bone'.
- The applicant stated that calcium 'plays an important role during the growth of infants and children', and that calcium is 'indispensable for proper and sufficient formation of bones'.

Wording of the health claim as proposed by the applicant:

- The applicant has proposed the following wording: 'Calcium is important for the development of bones'.

[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.

- The following alternative wordings, indicated by the applicant to be equivalent, were proposed: 'Calcium contributes to/is involved in/is important for/plays an important role for/is necessary for/participates to/is needed for/supports the (proper) development of/the (normal) function of bones'.

Specific conditions of use as proposed by the applicant:

- The target population proposed by the applicant is infants (from birth) and young children up to 3 years of age.
- According to the applicant, the quantities needed to be able to make the claim are as follows:
  - For follow-on formulae, the content in calcium should be within the range set in Directive 2006/141/EC.
  - For foods for special medical purposes, the content in calcium should be within the range set in Directive 1999/21/EC.
  - For processed cereal-based foods and baby foods, the content in calcium should reach at least 15% of the Nutrient Reference Values set in Directive 2006/125/EC, i.e. 15% of 400 mg/100 g or 100 mL or per serving, as reconstituted.
  - For foods other than follow-on formulae, processed cereal-based foods and baby foods, the content in calcium should reach at least 15% of the Nutrient Reference Value set in Directive 2006/141/EC, i.e. 15% of 550 mg/100 mL product ready for use.

2.1.2. Data provided by the applicant

Health claim application on calcium and contribution to the normal development of bones pursuant to Article 14 of Regulation 1924/2006, 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, 2011).

As outlined in the General guidance for stakeholders on health claim applications, it is the responsibility of the applicant to provide the totality of the available evidence (EFSA NDA Panel, 2016).

2.2. Methodologies

The general approach of the NDA Panel for the evaluation of health claim applications is outlined in the EFSA general guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016).

3. Assessment

3.1. Characterisation of the food/constituent

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

Calcium occurs naturally in foods in various forms, which are generally well utilised by the body. Different forms of calcium 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], Directive 2001/15/EC[6]). This evaluation applies to calcium 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, calcium, which is the subject of the health claim, is sufficiently characterised.

[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.

3.2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is that calcium 'is important for the development of bones'. The target population proposed by the applicant is infants (from birth) and young children up to 3 years of age.

The Panel considers that contribution to the normal development of bones is a beneficial physiological effect.

3.3. Scientific substantiation of the claimed effect

The Panel has previously assessed a claim on calcium and maintenance of normal bones pursuant to Article 13(1) of Regulation 1924/2006, i.e. for the general population (EFSA NDA Panel, 2009, 2010). The Panel considered that calcium is an important structural component of bones and concluded that a cause and effect relationship has been established between the dietary intake of calcium and the maintenance of normal bones (EFSA NDA Panel, 2009, 2010).

The Panel has also assessed a claim on calcium and normal growth and development of bone pursuant to Article 14 of Regulation 1924/2006, i.e. referring to children's development and health (EFSA NDA Panel, 2008a,b). The Panel concluded that a cause and effect relationship has been established between the intake of calcium and normal growth and development of bone (EFSA NDA Panel, 2008a,b). The target population was children and adolescents (up to 18 years).

The Panel considers that the role of calcium in the development of bones applies to all ages, including infants from birth and young children up to 3 years of age.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of calcium and contribution to the normal development of bones.

3.4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: 'Calcium contributes to the normal development of bones'.

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.
- 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 3 years of age. Dietary reference values for calcium have been set for infants and young children (EFSA NDA Panel, 2015). No Tolerable Upper Intake Levels for calcium have been set for this age group (EFSA NDA Panel, 2012).

4. Conclusions

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

- The food constituent, calcium, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is that calcium 'is important for the development of bones'. The target population proposed by the applicant is infants (from birth) and young children up to 3 years of age. Contribution to the normal development of bones is a beneficial physiological effect.

- A cause and effect relationship has been established between the dietary intake of calcium and contribution to the normal development of bones.
- The following wording reflects the scientific evidence: 'Calcium contributes to the normal development of bones'.
- 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 3 years of age. No Tolerable Upper Intake Levels have been set for calcium for this age group.

Steps taken by EFSA

1) Health claim application on calcium and 'is important for the development of bones' pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim Serial No: 0048_FR). Submitted by Specialised Nutrition Europe (SNE, formerly IDACE), 9-31 Avenue des Nerviens, 1040 Brussels, Belgium.
2) This 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 13 April 2016, EFSA received the missing information as submitted by the applicant.
6) The scientific evaluation procedure started on 2 May 2016.
7) During its meeting on 21 September 2016, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to calcium and contribution to the normal development of bones.

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EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2010. Scientific Opinion on the substantiation of health claims related to calcium and maintenance of normal bone and teeth (ID 2731, 3155, 4311, 4312, 4703), maintenance of normal hair and nails (ID 399, 3155), maintenance of normal blood LDL-cholesterol concentrations (ID 349, 1893), maintenance of normal blood HDL-cholesterol concentrations (ID 349, 1893), reduction in the severity of symptoms related to the premenstrual syndrome (ID 348, 1892), "cell membrane permeability" (ID 363), reduction of tiredness and fatigue (ID 232), contribution to normal psychological functions (ID 233), contribution to the maintenance or achievement of a normal body weight (ID 228, 229) and regulation of cell division and differentiation (ID 237) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(10):1725, 30 pp. doi:10.2903/j.efsa.2010.1725

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Abbreviations

NDA EFSA Panel on Dietetic Products, Nutrition and Allergies
SNE Specialised Nutrition Europe