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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to magnesium and contribution to normal development of bone pursuant to Article 14 of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from 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 magnesium and contribution to normal development of bone. The food constituent, magnesium, which is the subject of the health claim, is sufficiently characterised. Contribution to normal development of bone is a beneficial physiological effect for infants and young children. A claim on magnesium and maintenance of normal bone in the general population has already been assessed with a favourable outcome. The Panel notes that the role of magnesium on bone 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 dietary intake of magnesium and contribution to normal development of bone. The following wording reflects the scientific evidence: "Magnesium contributes to normal development of bone". The target population is infants and children up to three years.

KEY WORDS

Magnesium, infants, children, development, bone, health claims

[1] On request from the Competent Authority of France following an application by IDACE, Question No EFSA-Q-2008-150, adopted on 11 July 2013.

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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.

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SUMMARY

Following an application from 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 magnesium and contribution to normal development of bone.

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 magnesium, which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that magnesium is sufficiently characterised.

The claimed effect proposed by the applicant is "supports the development of healthy and strong bone in children". The target population proposed by the applicant is "infants (from birth onwards) and young children (until three years of age)". The Panel considers that contribution to normal development of bone is a beneficial physiological effect for infants and young children.

A claim on magnesium and maintenance of normal bone in the general population has already been assessed with a favourable outcome. Some 50 to 60 % of the total body magnesium content in normal adults resides in bone as a surface constituent of the hydroxyapatite mineral component of bone. The magnesium in bone is readily exchangeable with serum, and therefore it may serve as a reservoir for maintaining a normal extracellular magnesium concentration. Magnesium deficiency in animals results in decreased bone strength and volume, and impaired bone development.

The Panel notes that the role of magnesium on bone 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 dietary intake of magnesium and contribution to normal development of bone.

The following wording reflects the scientific evidence: "Magnesium contributes to normal development of bone".

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. No Tolerable Upper Intake Level has been established for magnesium in this age group.

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BACKGROUND

Regulation (EC) No 1924/2006[4] 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 08/05/2013, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 20/06/2013.
- During its meeting on 11/07/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to magnesium and contribution to normal development of bone.

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: magnesium and contribution to normal development of bone.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of magnesium, a positive assessment of its safety, nor a decision on whether magnesium 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: IDACE (Association of the Food Industries for Particular Nutritional Uses of the European Union), 194, rue de Rivoli, 75001, Paris, France.

Food/constituent as stated by the applicant

According to the applicant, the food constituent for which the claim is made is magnesium.

Health relationship as claimed by the applicant

According to the applicant, magnesium is generally considered as a key element in the development and maintenance of healthy bones: it not only constitutes one of the main mineral components of the bone, but also plays a capital role in homeostasis of bone mineralization. Magnesium supports the development of healthy and strong bone in children.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "magnesium supports the development of strong/healthy bones".

As equivalent alternative wordings, the applicant has also proposed: "magnesium/contributes to/is involved in/is important for/plays an important role for/is necessary for/participates in/is essential for/supports/helps maintain/the development of strong/healthy bones/the normal development of strong/healthy bones".

Specific conditions of use as proposed by the applicant

According to the applicant, the target population is infants (from birth onwards) and young children (until three years of age) as defined in Directive 89/398/EEC on foodstuffs intended for particular nutritional uses. The claim should be used on foods that are exclusively intended for the category of infants and young children, and in line with the composition laid down in the specific directives (Directive 2006/141/EC; Directive 2006/125/EC; Directive 1999/21/EC).

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

- For follow-on formulae, the content in magnesium should be within the range set in Directive 2006/141/EC.
- For dietary foods for special medical purposes, the content in magnesium should be within the range set in Directive 1999/21/EC.
- For processed cereal-based foods and baby foods, the content in magnesium should be within the range set in Directive 2006/125/EC.
- For processed cereal-based foods and baby foods, the content in magnesium should reach at least 15 % of the Nutrient Reference Values set in Directive 2006/141/EC (replacing Directive 91/321/EC), i.e. 15 % of 80 mg 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 magnesium should reach at least 15 % of

the Nutrient Reference Values set in Directive 2006/141/EC (replacing Directive 91/321/EC), i.e. 15 % of 80 mg per 100 ml product ready for use.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is magnesium, which is a well recognised nutrient and is measurable in foods by established methods.

Magnesium occurs naturally in foods and is authorised for addition to foods (Annex I of Regulation (EC) No 1925/2006[5], Annex I of Directive 2002/46/EC[6], Annex III of Directive 2006/141/EC[7], Annex IV of Directive 2006/125/EC[8], Directive 2001/15/EC[9]). This evaluation applies to magnesium 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, magnesium, 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 "supports the development of healthy and strong bone in children". The target population proposed by the applicant is "infants (from birth onwards) and young children (until three years of age)".

The Panel considers that contribution to normal development of bone 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 Medline using "magnesium" as a search term, covering a period from 1950 to 2008, and including studies in healthy children below 15 years of age. The applicant identified one human intervention study and two observational studies as being pertinent to the health claim. The human intervention study evaluated the effect of magnesium supplementation on bone mass at various skeletal sites in girls aged 8-14 years (Carpenter et al., 2006). The observational studies investigated the effect of dietary magnesium intake on bone mineral content in infants and children (Wang et al., 1999; Bounds et al., 2005).

The Panel has already assessed a claim on magnesium and maintenance of normal bone with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009). The target population was the general population.

[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 total magnesium content in the body of an infant weighing 3.5 kg is approximately 760 mg, while the total amount in an adult man is estimated to be around 27 g. In order to accumulate approximately 27 g of magnesium from infancy to adulthood, an average daily accretion of about 3.6 mg would be necessary during this period (IoM, 1997).

Some 50 to 60 % of the total body magnesium content in normal adults resides in bone as a surface constituent of the hydroxyapatite mineral component of bone. The magnesium in bone is readily exchangeable with serum, and therefore it may serve as a reservoir for maintaining a normal extracellular magnesium concentration (FAO/WHO, 2002). Magnesium deficiency in animals results in decreased bone strength and volume, and impaired bone development (Volpe, 2006).

The Panel notes that the role of magnesium on bone 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 dietary intake of magnesium and contribution to normal development of bone.

4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: "Magnesium contributes to normal development of bone".

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/EC[10];
- 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. No Tolerable Upper Intake Level (UL) has been established for magnesium in this age group.

CONCLUSIONS

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

- The food constituent, magnesium, which is the subject of the health claim, is sufficiently characterised.

[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.

- The claimed effect proposed by the applicant is "supports the development of healthy and strong bone in children". The target population proposed by the applicant is "infants (from birth onwards) and young children (until three years of age)". Contribution to normal development of bone is a beneficial physiological effect for infants and young children.

- A cause and effect relationship has been established between dietary intake of magnesium and contribution to normal development of bone.

- The following wording reflects the scientific evidence: "Magnesium contributes to normal development of bone".

- 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. No UL has been set for magnesium in this age group.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on magnesium and normal development of bone pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0080_FR). February 2008. Submitted by IDACE.

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GLOSSARY/ABBREVIATIONS

UL Tolerable Upper Intake Level