

## SCIENTIFIC OPINION

### Scientific Opinion on the substantiation of a health claim related to zinc and normal growth pursuant to Article 14 of Regulation (EC) No 1924/2006<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>

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 zinc and normal growth. The food constituent, zinc, which is the subject of the health claim, is sufficiently characterised. Normal growth is a beneficial physiological effect for infants and young children. The Panel considers that the role of zinc in normal growth is well established. Growth retardation is one of the clinical manifestations of severe zinc deficiency. Zinc supplementation has been reported to stimulate growth and development in zinc-deficient infants and young children. The Panel concludes that a cause and effect relationship has been established between the dietary intake of zinc and normal growth. The following wording reflects the scientific evidence: “zinc contributes to normal growth”. The target population is infants and children up to three years of age.

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#### KEY WORDS

zinc, infants, children, growth, health claims

<sup>1</sup> On request from the Competent Authority of France following an application by Specialised Nutrition Europe (formerly IDACE), Question No EFSA-Q-2008-190, adopted on 30 October 2014.

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## SUMMARY

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted for the 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 this health claim related to zinc and normal growth.

The scope of the application was proposed to cover a health claim relating to children's development and health.

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

The claimed effect proposed by the applicant is "zinc is essential for growth". The target population proposed by the applicant is infants and young children from birth to three years of age. The Panel considers that normal growth is a beneficial physiological effect for infants and young children.

The Panel considers that the role of zinc in normal growth is well established. Growth retardation is one of the clinical manifestations of severe zinc deficiency. Zinc supplementation has been reported to stimulate growth and development in zinc-deficient infants and young children.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of zinc and normal growth.

The following wording reflects the scientific evidence: "zinc contributes to normal growth".

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

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## BACKGROUND

Regulation (EC) No 1924/2006<sup>4</sup> 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 24/06/2014, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 01/08/2013, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 27/08/2014.
- During its meeting on 30/10/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to zinc and normal 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 zinc and normal growth.

## EFSA DISCLAIMER

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

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<sup>4</sup> 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 zinc.

### Health relationship as claimed by the applicant

According to the applicant, zinc is required for DNA synthesis, cell division and growth, for protein synthesis and macronutrient metabolism, and for the development and appropriate function of most body systems. Zinc is essential for growth and development, as well as testicular maturation, neurological function, wound healing and immunocompetence. Human growth retardation from zinc deficiency was first reported over 40 years ago. More recently, maternal zinc deficiency was shown to occur during pregnancy and infancy, and to be prevalent throughout the world. Numerous processes seem to contribute to growth failure, including the role of zinc in the transcription and translation of genetic material and the role of zinc in the primary endocrine system. Zinc is essential for the mechanisms of taste and smell acuity and appetite regulation, and it has been suggested that zinc deficiency may lead to reduced food and thus nutrient intake via these mechanisms, contributing further to growth retardation. The positive effect of zinc supplementation on children's growth helps to demonstrate the critical role of zinc in growth. Many intervention trials have been conducted in many countries to assess the effect of zinc supplementation on children's growth, with positive outcomes. However, inconsistencies in some results may be due to differences in the pre-existing zinc status of the subjects, the content and bioavailability of zinc in the local diet and the incidence of common infections that can affect growth, independently of an individual's zinc status.

### Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "zinc is essential for growth".

Equivalent wordings: "zinc promotes growth", "zinc plays a role in growth", "zinc is needed for growth", "zinc is required for growth", "zinc is important for growth", "zinc is essential for growth".

### 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 of zinc should be within the range set in Directive 2006/141/EC.
- For dietary foods for special medical purposes, the content of zinc should be within the range set in Directive 1999/21/EC.
- For processed cereal-based foods and baby foods, the content of zinc should be within the range set in Directive 2006/125/EC.
- For processed cereal-based foods and baby foods, the content of zinc should reach at least 15 % of the Nutrient Reference Values set in Directive 2006/125/EC, i.e. 15 % of 4 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 of zinc should reach at least 15 % of the Nutrient Reference Values set in Directive 2006/141/EC, i.e. 15 % of 5 mg per 100 mL of product ready for use.

## ASSESSMENT

### 1. Characterisation of the constituent

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

Different forms of zinc occur naturally in foods, and zinc is authorised for addition to foods and for use in food supplements (Annex II of Regulation (EC) No 1925/2006<sup>5</sup>, Annex II of Directive 2002/46/EC<sup>6</sup>, Annex III of Directive 2006/141/EC<sup>7</sup>, Annex IV of Directive 2006/125/EC<sup>8</sup>, Directive 2001/15/EC<sup>9</sup>). This evaluation applies to zinc 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 zinc, 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 “essential for growth”. The target population proposed by the applicant is infants and young children from birth to three years of age.

The Panel considers that normal growth is a beneficial physiological effect for infants and young children.

### 3. Scientific substantiation of the claimed effect

The Panel considers that the role of zinc in normal growth is well established. Growth retardation is one of the clinical manifestations of severe zinc deficiency (Younoszai, 1983; EFSA NDA Panel, 2014). Zinc supplementation has been reported to stimulate growth and development in zinc-deficient infants and young children (Bhutta et al., 2008; Strain and Cashman, 2009).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of zinc and normal growth.

### 4. Panel’s comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: “zinc contributes to normal growth”.

### 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

<sup>5</sup> 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.

<sup>6</sup> 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.

<sup>7</sup> 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.

<sup>8</sup> 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.

<sup>9</sup> 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.

infants should comply with the criteria of composition of these foods as laid down in Directive 1999/21/EC<sup>10</sup>;

- 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 easily be consumed as part of a balanced diet. The target population is infants and children up to three years of age. A Tolerable Upper Intake Level has been established for zinc in this age group, and has been set at 7 mg/day (SCF, 2002).

## CONCLUSIONS

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

- The food constituent zinc, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is “zinc is essential for growth”. The target population proposed by the applicant is infants and young children from birth to three years of age. Normal growth is a beneficial physiological effect for infants and young children.
- A cause and effect relationship has been established between the dietary intake of zinc and normal growth.
- The following wording reflects the scientific evidence: “zinc contributes to normal growth”.
- 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 easily be consumed as part of a balanced diet. The target population is infants and children up to three years of age. A Tolerable Upper Intake Level has been established for zinc in this age group, and has been set at 7 mg/day (SCF, 2002).

## DOCUMENTATION PROVIDED TO EFSA

Health claim application on zinc and normal growth pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0110\_FR). February 2008. Submitted by Specialised Nutrition Europe (formerly IDACE).

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<sup>10</sup> 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.

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