

SCIENTIFIC OPINION

Scientific Opinion on the Substantiation of a health claim related to Iodine and the growth of children pursuant to Article 14 of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

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ABSTRACT

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 iodine and the growth of children. The scope of the application was proposed to fall under claims referring to children's development and health. The food constituent that is the subject of the health claim is iodine which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that the food/constituent, iodine, which is the subject of the health claim is sufficiently characterised. The Panel considers that normal growth is beneficial to children's health. Evidence provided by reports from authoritative bodies and reviews shows that there is good consensus on the role of iodine in growth and development. A wide spectrum of iodine deficiency disorders (IDD) has been observed, depending on the degree of deficiency and the life stage at which the deficiency occurs. Most countries in the world have some degree of IDD including several European countries. The Panel concludes that a cause and effect relationship has been established between the intake of iodine and normal growth of children and adolescents. Recommended intakes of iodine to meet requirements for normal growth in children and adolescents have been established. Iodine intakes may be inadequate in sub-groups of children and adolescents in some EU countries. The following wording reflects the scientific evidence: "iodine contributes to the normal growth of children".

1 On request from Transformation Laitière Française via the Competent Authority of France, Question No EFSA-Q-2008-324, adopted on 15 October 2009.

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KEY WORDS

Iodine, thyroid function, thyroid gland, thyroid hormones, 3,5,3'-triiodothyronine, T₃, 3,5,3',5'-tetraiodothyronine, thyroxin, T₄, TSH, children, adolescents, growth, health claims

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: iodine and the growth of children.

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

The food constituent that is the subject of the health claim is iodine which is a well recognised nutrient and is measurable in foods by established methods. Iodine occurs naturally in foods in many forms which are generally well utilised by the body. This evaluation applies to iodine 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, iodine, which is the subject of the health claim is sufficiently characterised.

The claimed effect is that iodine is "necessary for the growth of children". The proposed target population for the health claim is children aged 3-18 years. The Panel considers that normal growth is beneficial to children's health.

The applicant provided 17 publications on human trials and 31 other publication such as reviews and reports on the role and function of iodine, and on iodine deficiency disorders.

Iodine is an essential dietary element for mammals being required for the synthesis of the thyroid hormones. The biological function of the thyroid hormones encompasses the regulation of energy yielding metabolism and endocrine function by cellular oxidation, energy yielding metabolism, thermoregulation, intermediate metabolism, protein and enzyme synthesis, nitrogen retention, gluconeogenesis and pituitary gonadotropins including an increased of the transcription and secretion of growth hormone.

Evidence provided by reports from authoritative bodies and reviews shows that there is good consensus on the role of iodine in growth and development. A wide spectrum of iodine deficiency disorders (IDD) has been observed, depending on the degree of deficiency and the life stage at which the deficiency occurs. Deficiency disorders range from mild goitre to the very severe forms of endemic cretinism (congenital, severe, irreversible mental and growth retardation). The most severe manifestations arise from iodine deficiency in the foetus or during the first months of life.

Most countries in the world have some degree of IDD including several European countries. The Panel concludes that a cause and effect relationship has been established between the intake of iodine and normal growth of children and adolescents. Iodine intakes may be inadequate in sub-groups of children and adolescents in some EU countries.

The following wording reflects the scientific evidence: "Iodine contributes to the normal growth of children".

The Panel considers that, in order to bear the claim, a food should be at least a source of iodine 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 children as 200 µg/day for 1-3 years of age, 250 µg/day for 4-6 years, 300 µg/day for 7-10 years, 450 µg/day for 11-14 years and 500 µg/day for 15-17 years.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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 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 the 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 a health claim referring to disease risk reduction.
- During the check for completeness⁵ of the application, the applicant was requested to provide missing information on 20/06/2008.
- The scientific evaluation procedure started on 15/05/2009.
- During the meeting on 15/10/2009, the NDA Panel, after having evaluated the overall data submitted, adopted an opinion on the scientific substantiation of a health claim related to iodine and children's growth.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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: iodine and the growth of children.

EFSA DISCLAIMER

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

⁵ In accordance with EFSA "Scientific and Technical guidance for the Preparation and Presentation of the Application for Authorisation of a Health Claim"

Information provided by the applicant

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

Food/constituent as stated by the applicant

Iodine

Health relationship as claimed by the applicant

Children require iodine to ensure their full growth and development potential. Iodine's primary role is as a constituent of thyroid hormones that are essential for the regulation and stimulation of key physiological processes such as temperature control, metabolism, growth and development.

Wording of the health claim as proposed by the applicant

"Iodine is necessary for the growth of children"

Specific conditions of use as proposed by the applicant

The target population is children aged 3 to 18 years old.

The food products bearing this health claim should contain the following minimum quantity per daily intake: 15 % of the RDA for iodine, as specified per Directive 90/496/EEC.

1. Assessment

1.1. Characterisation of the food/constituent

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

Iodine occurs naturally in foods and is authorised for addition to foods (Annex I of the Regulation (EC) No 1925/2006⁶ and Annex I of Directive 2002/46/EC⁷). This evaluation applies to iodine naturally present in foods and those forms authorised for addition to foods (Annex II of the Regulation (EC) No 1925/2006 and Annex II of Directive 2002/46/EC).

The Panel considers that the food constituent, iodine, which is the subject of the health claim, is sufficiently characterised.

1.2. Relevance of the claimed effect to human health

The claimed effect is that iodine is "necessary for the growth of children". The proposed target population for the health claim is children aged 3-18 years.

The Panel considers that normal growth is beneficial for children's health.

⁶ 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.

⁷ 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.

1.3. Scientific substantiation of the claimed effect

The applicant performed a literature search in the database Medline (1950 to date of submission) by using the keywords: iodine, child, children, adolescent, growth and development. The search included clinical trials, meta-analyses, reviews and guidelines. Seventeen publications on human studies were considered pertinent to the claim by the applicant, including 8 randomised controlled trials (RCTs) in humans, 4 non-controlled human trials, 4 observational studies, a Cochrane systematic review on iodine supplementation for preventing iodine deficiency disorders (IDD) in children (Angermayr and Clar, 2007; Bautista et al., 1982; Jiang et al., 1997; Jooste et al., 2000; Lim et al. 2006; Melse-Boonstra et a., 1998; van Stuijvenberg et al., 1999; Vanderpas et al., 1986; Vejberg et al., 2007; Zimmermann et al., 2003; Zimmerman et al., 2004a, b; Zimmermann et al., 2007). In addition to human studies, the applicant provided 31 other publications, such as reviews and reports on the role and function of iodine, and on iodine deficiency disorders.

Iodine is an essential dietary element for mammals being required for the synthesis of the thyroid hormones thyroxine T₄ which contains approximately 65 % by weight of iodine, and of its active form thyronine T₃, which contains about 59 % by weight of iodine (SCF, 2002). The biological function of the thyroid hormones encompasses the regulation of energy yielding metabolism and endocrine function by cellular oxidation, thermoregulation, intermediary metabolism, protein and enzyme synthesis, nitrogen retention, gluconeogenesis and pituitary gonadotropins (including an increase of the transcription and secretion of growth hormone) (Houston, 1998; SCF, 2002).

Evidence provided by reports from authoritative bodies and reviews shows that there is good consensus on the role of iodine in growth and development of children (Sadler et al., 1999; SCF, 1993, 2002; IOM, 2002; Garrow et al., 2000; Strain and Cashman, 2002). A wide spectrum of iodine deficiency disorders (IDD) has been observed, depending on the degree of deficiency and the life stage at which the deficiency occurs. Deficiency disorders range from mild goitre to the very severe forms of endemic cretinism (congenital, severe, irreversible mental and growth retardation) (Delange, 2002; WHO, 2001; WHO, 2004). The most severe manifestations arise from iodine deficiency in the foetus or the first months of life (Boyages, 1994; Bleichrodt and Born, 1994).

Most countries in the world have some degree of IDD including several European countries (Stanbury et al., 1998; WHO, 1999; Delange, 2002, WHO, 2007). The WHO (1998) reported on IDDs in Europe and the recurrence of goitre, and occasionally of endemic cretinism, in some countries in Eastern Europe after the interruption of salt iodisation programmes.

The Panel concludes that a cause and effect relationship has been established between the intake of iodine and normal growth of children and adolescents. Iodine intakes may be inadequate in sub-groups of children and adolescents in some EU countries.

1.4. 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:

“Iodine contributes to the normal growth of children”.

1.5. Conditions and restrictions of use

The Panel considers that in order to bear the claim a food should be at least a source of iodine as per Annex to Regulation 1924/2006. A Tolerable Upper Intake Level (UL) has been established for iodine as 600 µg/day in adults and during pregnancy and lactation. For children and adolescents the UL was established as 200 µg/day for 1-3 years, 250 µg/day for 4-6 years, 300 µg/day for 7-10 years,

450 µg/day for 11-14 years and 500 µg/day for 15-17 years (SCF, 2002). The target population is the general population.

CONCLUSIONS

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

- The food constituent, iodine, that is the subject of the health claim (i.e., iodine) is sufficiently characterised.
- The claimed effect is that iodine is ‘necessary for the growth of children’. Normal growth is beneficial to children’s health.
- A cause and effect relationship has been established between the intake of iodine and normal growth of children.
- Iodine intakes may be inadequate in sub-groups of children in some EU countries.
- The following wording reflects the scientific evidence: “Iodine contributes to normal growth of children”.
- In order to bear the claim a food should be at least a source of iodine 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 children and adolescents. ULs were established as 200 µg/day for 1-3 years, 250 µg/day for 4-6 years, 300 µg/day for 7-10 years, 450 µg/day for 11-14 years and 500 µg/day for 15-17 years (SCF, 2002).

DOCUMENTATION PROVIDED TO EFSA

Health claim application on iodine and “necessary for the growth of children” pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0161_FR). May 2008. Submitted by Association de la Transformation Laitiere Francaise (ATLA).

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