



**EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to iodine and contribution to normal cognitive 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 iodine and contribution to normal cognitive development 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 iodine and contribution to normal cognitive development. The food constituent, iodine, which is the subject of the health claim, is sufficiently characterised. Contribution to normal cognitive development is a beneficial physiological effect for infants and young children. A claim on iodine and contribution to normal cognitive and neurological function in the general population has already been assessed with a favourable outcome. In addition, there is a large body of evidence indicating a crucial role for iodine in growth and development. The Panel notes the well established role of iodine in preventing iodine deficiency disorders such as retarded mental and physical development in children and adolescents, and impaired mental function and reduced cognitive capacity for people of all ages. The Panel concludes that a cause and effect relationship has been established between the dietary intake of iodine and contribution to normal cognitive development.

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#### KEY WORDS

iodine, infants, children, cognitive development, neurological development, 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-2008-145, adopted on 11 December 2013.

<sup>2</sup> Panel members: Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean (J.J.) Strain, Inge Tetens, Daniel Tomé, Dominique Turck and Hans Verhagen. Correspondence: [nda@efsa.europa.eu](mailto:nda@efsa.europa.eu)

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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 iodine and contribution to normal cognitive development.

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 iodine, which is an essential nutrient and is measurable in foods by established methods. The Panel considers that iodine is sufficiently characterised.

The claimed effect proposed by the applicant refers to the importance of iodine for normal cognitive 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 cognitive development is a beneficial physiological effect for infants and young children.

A claim on iodine and contribution to normal cognitive and neurological function in the general population has already been assessed with a favourable outcome. In addition, there is a large body of evidence indicating a crucial role for iodine in growth and development.

The Panel notes the well established role of iodine in preventing iodine deficiency disorders such as retarded mental and physical development in children and adolescents, and impaired mental function and reduced cognitive capacity for people of all ages.

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

The following wording reflects the scientific evidence: "Iodine contributes to normal cognitive development".

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 for iodine has been established for children, and has been set at 200 µg/day for children of 1-3 years of age.

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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 26/03/2008, during the validation process of the application, EFSA sent a request to the applicant asking it to provide missing information.
- On 26/07/2013, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 17/10/2013.
- During its meeting on 11/12/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to iodine and contribution to normal cognitive 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: iodine and contribution to normal cognitive development.

## EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for 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.

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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 iodine.

### Health relationship as claimed by the applicant

According to the applicant, iodine has an essential role in the development of the nervous system of the fetus and the infant. Lack of iodine can lead to disturbances of fetal development, manifesting itself as cretinism or, in milder cases, mental retardation, goitre and growth impairment.

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

The applicant has proposed the following wording for the health claim: "iodine is important for cognitive development".

As equivalent alternative wordings, the applicant has also proposed: "iodine contributes to/is involved in/is important for/plays an important role for/is necessary for/participates to/is needed for/supports the (cognitive) development of/the (normal) function of senses/neural systems".

### 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 iodine should be within the range set in Directive 2006/141/EC.
- For dietary foods for special medical purposes, the content in iodine should be within the range set in Directive 1999/21/EC.
- For processed cereal-based foods and baby foods, the content in iodine should be within the range set in Directive 2006/125/EC.
- For processed cereal-based foods and baby foods, the content in iodine should reach at least 15 % of the Nutrient Reference Values set in Directive 2006/125/EC, i.e. 15 % of 70 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 iodine should reach at least 15 % of the Nutrient Reference Values set in Directive 2006/141/EC, i.e. 15 % of 80 µg 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 iodine, which is an essential nutrient and is measurable in foods by established methods.

Iodine occurs naturally in foods and is authorised for addition to foods (Annex I of Regulation (EC) No 1925/2006<sup>5</sup>, Annex I 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 iodine 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, iodine, 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 refers to the importance of iodine for normal cognitive 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 cognitive development 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, HighWire and Scirus, using the search terms “iodine”, “growth”, “development”, “brain”, “mental”, “cognitive”, “infant”, “children” and “clinical studies”. Further pertinent references were searched for in the retrieved literature. The search focussed on randomised controlled trials and on reviews/pooled analyses/meta-analyses in the target population of the claim. In addition, one (mechanistic) animal study was included.

The applicant identified three human studies (Bleichrodt et al., 1988; Cao et al., 1994; Choudhury and Gorman, 2003) and one animal study (Mitchell et al., 1998) as being pertinent to the health claim. In addition, the applicant indicated eight reviews (Kasper, 1987; Pharoah, 1993; Kretchmer et al., 1996; Suter, 2002; Black, 2003; Dunn, 2003; Verhoef et al., 2003; Thamm et al., 2007), three expert assessments (JHCI, 2003; SCF, 2003; EFSA NDA Panel, 2010) and three “other” references (Van den Briel et al., 2000; Zimmermann et al., 2006; Wijaya-Erhardt et al., 2007) as relevant for the claim.

The Panel has already assessed a claim on iodine and contribution to normal cognitive and neurological function with a favourable outcome (EFSA NDA Panel, 2010). The target population was the general population.

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<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.

In addition, there is a large body of evidence indicating a crucial role for iodine in growth and development (Sadler et al., 1999; Garrow et al., 2000; WHO, 2001; IoM, 2002; Strain and Cashman, 2009). A wide spectrum of iodine deficiency disorders has been observed, depending on the degree of deficiency and the life stage at which the deficiency occurs. These disorders include goitre, hypothyroidism and impaired mental function, including the most severe forms of endemic cretinism (congenital, severe, irreversible mental and growth retardation). Other symptoms of severe iodine deficiency disorders (arising from iodine deficiency in the fetus) include deaf-mutism, squint, disorders of stance and gait, and dry skin and swollen subcutaneous tissue (Delange, 2000; EVM, 2003; WHO, 2007).

The Panel notes the well established role of iodine in preventing iodine deficiency disorders such as retarded mental and physical development in children and adolescents, and impaired mental function and reduced cognitive capacity for people of all ages (WHO, 2001).

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

#### **4. Panel's comments on the proposed wording**

The Panel considers that the following wording reflects the scientific evidence: "Iodine contributes to normal cognitive development".

#### **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<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 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) for iodine has been established for children, and has been set at 200 µg/day for children of 1-3 years of age (SCF, 2002).

## **CONCLUSIONS**

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

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

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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.



- The claimed effect proposed by the applicant refers to the importance of iodine for normal cognitive development. The target population proposed by the applicant is infants and young children from birth to three years of age. Contribution to normal cognitive development is a beneficial physiological effect for infants and young children.
- A cause and effect relationship has been established between the dietary intake of iodine and contribution to normal cognitive development.
- The following wording reflects the scientific evidence: “Iodine contributes to normal cognitive development”.
- 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. The Tolerable Upper Intake Level has been set at 200 µg/day for children of 1-3 years of age.

## DOCUMENTATION PROVIDED TO EFSA

Health claim application on iodine and contribution to normal cognitive development pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0065\_FR). February 2008. Submitted by Specialised Nutrition Europe (formerly IDACE).

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