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Scientific Opinion on the substantiation of a health claim related to iron and
contribution to normal cognitive development pursuant to Article 14 of Regulation (EC
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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to iron and contribution to normal cognitive development pursuant to Article 14 of Regulation (EC) No 1924/2006¹

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 iron and contribution to normal cognitive development. The food constituent, iron, 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 iron and cognitive development in children (up to 18 years) has already been assessed with a favourable outcome. The Panel notes that the role of iron in normal cognitive development also applies to 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 iron and contribution to normal cognitive development. The following wording reflects the scientific evidence: “Iron contributes to normal cognitive development”. The target population is infants and children up to three years.

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KEY WORDS

Iron, infants, children, cognitive development, health claims

¹ On request from the Competent Authority of France following an application by IDACE, Question No EFSA-Q-2008-199, adopted on 11 July 2013.

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

The claimed effect proposed by the applicant is "important for the cognitive development of infants and young children". 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.

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is consensus on the role of iron in cognitive development and function. Insufficient iron intake results in iron deficiency signs and symptoms, including anaemia, impaired psychomotor development and impaired cognitive performance. The cognitive deficiency symptoms observed in subjects with iron-deficiency anaemia include deficits in attention, perceptual motor speed, memory and verbal fluency.

A claim on iron and cognitive development in children (up to 18 years) has already been assessed by the Panel with a favourable outcome. The Panel notes that the role of iron in normal cognitive development also applies to 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 iron and contribution to normal cognitive development.

The following wording reflects the scientific evidence: "Iron 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 2006/125/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 Upper Tolerable Intake Level has been set for iron in this age group.

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BACKGROUND

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 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 iron 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: iron 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 iron, a positive assessment of its safety, nor a decision on whether iron 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 iron.

Health relationship as claimed by the applicant

According to the applicant, iron is important for the cognitive development of infants and young children.

According to the applicant, insufficient iron intake results in a deficiency condition called anaemia, leading to well-documented, potentially irreversible delays in the cognitive development of infants and young children, which can in turn be responsible for low performance in cognitive skills.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "with iron, important for cognitive development".

As equivalent alternative wordings, the applicant has also proposed: "iron/contributes to/is involved in/is important for/plays an important role for/is necessary for/participates to/is needed for/supports/the development of cognitive system or brain/the normal development of cognitive system or brain/the function of cognitive system or brain/the normal function of cognitive system or brain".

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. 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 iron should be within the range set in Directive 2006/141/EC.
- For dietary foods for special medical purposes, the content in iron should be within the range set in Directive 1999/21/EC.
- For processed cereal-based foods and baby foods, the content in iron should be within the range set in Directive 2006/125/EC.
- For processed cereal-based foods and baby foods, the content in iron should reach at least 15 % of the Nutrient Reference Values set in Directive 2006/125/EC, i.e. 15 % of 6 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 iron 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 8 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 iron, which is a well recognised nutrient and is measurable in foods by established methods.

Iron occurs naturally in foods in various forms, principally haem iron derived from haemoglobin and myoglobin in flesh foods, and non-haem iron in plants foods (IoM, 2001). Different forms of iron are authorised for addition to foods (Annex I of Regulation (EC) No 1925/2006⁵, Annex I of Directive 2002/46/EC⁶, Annex III of Directive 2006/141/EC⁷, Annex IV of Directive 2006/125/EC⁸, Directive 2001/15/EC⁹). This evaluation applies to iron 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, iron, 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 “important for the cognitive development of infants and young children”. 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 Medline, Ovid and the Cochrane database, without specifying which period was covered. The search terms were “iron deficiency” OR “iron deficiency anaemia and psychomotor development” OR “cognitive development” OR “brain in infants and iron deficiency anaemia” and/or “psychomotor development in infants”. The applicant identified seven human intervention studies, two observational studies and one meta-analysis as being pertinent to the health claim. The human intervention studies investigated the effect of iron supplementation on mental and/or psychomotor development in iron deficient infants and young children (Aukett et al., 1986; Walter et al., 1989; Williams et al., 1999; Idjradinata and Pollitt, 1993; Moffatt et al., 1994; Lozoff et al., 1996; Morley et al., 1999). The observational studies evaluated the association between iron supplementation and the development of the central nervous system in infants and young children (Roncagliolo et al., 1998; Algarin et al., 2003). The meta-analysis included randomised controlled

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.

trials which investigated the effect of iron on psychomotor development in iron deficient infants and young children (Logan et al., 2001).

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is consensus on the role of iron in cognitive development and function (Grantham and Ani, 2001; Hunt, 2005; SACN, 2009; Schulze and Dreyfuss, 2005; WHO, 2003).

Iron is an essential trace element with important metabolic functions, including oxygen transport, and is involved in several redox reactions. Insufficient iron intake results in iron deficiency signs and symptoms, including anaemia, impaired psychomotor development and impaired cognitive performance (EFSA, 2004). The cognitive deficiency symptoms observed in subjects with iron-deficiency anaemia include deficits in attention, perceptual motor speed, memory and verbal fluency (Malestrom, 2002).

The Panel has already assessed a claim on iron and cognitive development of children with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009). The target population was children and adolescents up to 18 years. The Panel notes that the role of iron in normal cognitive development also applies to 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 iron 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: "Iron 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/EC¹⁰;
- 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 2006/125/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 set for iron (EFSA, 2004).

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.

CONCLUSIONS

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

- The food constituent, iron, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is “important for the cognitive development of infants and young children”. 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 dietary intake of iron and contribution to normal cognitive development.
- The following wording reflects the scientific evidence: “Iron 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 2006/125/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 iron in this age group.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on iron and contribution to normal cognitive development pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0119_FR). February 2008. Submitted by IDACE.

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GLOSSARY/ABBREVIATIONS

UL Tolerable Upper Intake Level