

ADOPTED: 28 June 2016

doi: 10.2903/j.efsa.2016.4548

## Iron and contribution to the normal function of the immune system: evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006

### EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

#### Abstract

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 iron and contribution to the normal function of the immune system. The scope of the application was proposed to fall under a health claim referring to children's development and health. The Panel considers that the food constituent, iron, which is the subject of the health claim, is sufficiently characterised and that contribution to the normal function of the immune system is a beneficial physiological effect. The target population proposed by the applicant is 'infants and young children from birth to 3 years of age'. The Panel has previously assessed a claim on iron and contribution to the normal function of the immune system in the general population with a favourable outcome. The Panel considers that the role of iron in the functioning of the immune system applies to all ages, including infants and young children up to 3 years of age. The Panel concludes that a cause and effect relationship has been established between the dietary intake of iron and contribution to the normal function of the immune system. The following wording reflects the scientific evidence: 'Iron contributes to the normal function of the immune system'. The target population is infants and young children up to 3 years of age.

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**Keywords:** iron, infants, children, immune system, health claims

**Requestor:** Competent Authority of France following an application by Specialised Nutrition Europe (SNE, formerly IDACE)

**Question number:** EFSA-Q-2008-146

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**Acknowledgements:** The Panel wishes to thank the members of the Working Group on Claims: Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Harry McArdle, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Sean (J.J.) Strain, Hendrik Van Loveren and Peter Willatts, for the preparatory work on this scientific opinion.

**Suggested citation:** EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016. Scientific opinion on iron and contribution to the normal function of the immune system: evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2016;14(7):4548, 8 pp. doi:10.2903/j.efsa.2016.4548

**ISSN:** 1831-4732

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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 iron and contribution to the normal function of the immune system.

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

The general approach of the NDA Panel for the evaluation of health claim applications is outlined in the EFSA general guidance for stakeholders on health claim applications.

The food constituent that is the subject of the health claims is iron, which is an essential nutrient and can be measured in foods by established methods. The Panel considers that iron is sufficiently characterised.

The claimed effect and the target population proposed by the applicant are 'needed for the immune system' and 'infants and young children from birth to 3 years of age'. From the information provided, the Panel notes that the claimed effect refers to the normal function of the immune system. Contribution to the normal function of the immune system is a beneficial physiological effect.

The Panel has previously assessed a claim on iron and contribution to the normal function of the immune system in the general population with a favourable outcome. Iron plays a role in the functioning of the immune system. The Panel considers that the role of iron in the functioning of the immune system applies to all ages, including infants and young children up to 3 years of age.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of iron and contribution to the normal function of the immune system.

The following wording reflects the scientific evidence: 'Iron contributes to the normal function of the immune system'.

In order to bear the claim, follow-on formulae should comply with the criteria for the 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 for the 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 for the composition of these foods as laid down in Directive 2006/125/EC; and other foodstuffs intended for infants and young children should provide at least 15% of the reference values for the nutritional labelling of 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 young children up to 3 years of age. No Tolerable Upper Intake Level has been set for iron.

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## 1. Introduction

### 1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1924/2006<sup>1</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 14–17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction in 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).

### 1.2. Interpretation of the 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 the normal function of the immune system.

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.

### 1.3. Additional information

A health claim on iron and contribution to the normal function of the immune system has already been assessed by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) with a favourable outcome (EFSA NDA Panel, 2009).

## 2. Data and methodologies

### 2.1. Data

#### 2.1.1. Information provided by the applicant

##### 2.1.1.1. Food/constituent as stated by the applicant

According to the applicant, the food which is the subject of the health claim is iron.

##### 2.1.1.2. Health relationship as claimed by the applicant

According to the applicant, iron 'is needed for the immune system of infants and young children'.

The applicant stated that iron is an essential nutrient and a key element for the metabolism of almost all living organisms. It plays an important role for the proper functioning of all cells of the immune system.

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

The applicant has proposed the following wording for the health claim: 'Iron is needed for the immune system of infants and young children'.

<sup>1</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.

#### 2.1.1.4. Specific conditions of use as proposed by the applicant

The target population proposed by the applicant is infants and young children from birth to 3 years of age.

According to the applicant, the quantities needed to achieve the claimed effects are as follows:

- For follow-on formulae, the content of iron should be within the range set in Directive 2006/141/EC.
- For Foods for Special Medical Purpose, the content of iron should be within the range set in Directive 1999/21/EC, except if this is contrary to the intended use of the product.
- For processed cereal-based foods and baby foods, the content of iron should reach at least 15% of the Nutrient Reference Values set in Directive 2006/125/EC, i.e. 15% of 6 mg/100 g or 100 mL per serving, as reconstituted.
- For the other foods intended for infants and young children, the content of iron should reach at least 15% of the Nutrient Reference Values set in Directive 2006/141/EC, i.e. 15% of 8 mg (1.2 mg) per 100 mL product ready for use, with a maximum of 3 mg/100 kcal.

#### 2.1.2. Data provided by the applicant

Health claim application on iron and contribution to the normal function of the immune system pursuant to Article 14 of Regulation 1924/2006, presented in a common and structured format as outlined in the Scientific and technical guidance for the preparation and presentation of applications for authorisation of health claims (EFSA NDA Panel, 2011).

As outlined in the General guidance for stakeholders on health claim applications, it is the responsibility of the applicant to provide the totality of the available evidence (EFSA NDA Panel, 2016).

### 2.2. Methodologies

The general approach of the NDA Panel for the evaluation of health claim applications is outlined in the EFSA general guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016).

## 3. Assessment

### 3.1. Characterisation of the food

The food constituent that is the subject of the health claims is iron, which is an essential nutrient and can be measured 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 plant foods (IoM, 2001). Different forms of iron are authorised for addition to foods (Annex I of Regulation (EC) No 1925/2006<sup>2</sup>, Annex I of Directive 2002/46/EC,<sup>3</sup> Annex III of Directive 2006/141/EC,<sup>4</sup> Annex IV of Directive 2006/125/EC,<sup>5</sup> Directive 2001/15/EC<sup>6</sup>). 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.

### 3.2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is 'needed for the immune system'. The target population proposed by the applicant is 'infants and young children from birth to 3 years of age'.

<sup>2</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>3</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>4</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>5</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>6</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.

From the information provided, the Panel notes that the claimed effect refers to the normal function of the immune system.

The Panel considers that contribution to the normal function of the immune system is a beneficial physiological effect.

### 3.3. Scientific substantiation of the claimed effect

The Panel has previously assessed a claim on iron and contribution to the normal function of the immune system with a favourable outcome (EFSA NDA Panel, 2009). The target population was the general population. The Panel considered that iron plays a role in the functioning of the immune system.

The Panel considers that the role of iron in the functioning of the immune system applies to all ages, including infants and young children (from birth to 3 years of age). Dietary Reference Values for iron have been set for infants and young children (EFSA NDA Panel, 2015).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of iron and contribution to the normal function of the immune system.

### 3.4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: 'Iron contributes to the normal function of the immune system'.

### 3.5. Conditions and restrictions of use

The Panel considers that in order to bear the claim:

- Follow-on formulae should comply with the criteria for the 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 for the 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 for the 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 the nutritional labelling of 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 young children up to 3 years of age. No Tolerable Upper Intake Level has been set for iron (EFSA, 2004).

## 4. 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 'needed for the immune system'. The target population proposed by the applicant is 'infants and young children from birth to 3 years of age'. Contribution to the normal function of the immune system is a beneficial physiological effect.
- a cause and effect relationship has been established between the dietary intake of iron and contribution to the normal function of the immune system.
- the following wording reflects the scientific evidence: 'Iron contributes to the normal function of the immune system'.
- in order to bear the claim, follow-on formulae should comply with the criteria for the 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 for the 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 for the composition of these foods as laid down in Directive 2006/125/EC; and other foodstuffs intended for infants and young children should provide at least 15% of the reference values for the nutritional labelling of 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 young children up to 3 years of age. No Tolerable Upper Intake Level has been set for iron.

## Steps taken by EFSA

- 1) Health claim application on iron and 'is needed for the immune system' pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim Serial No. 0066\_FR). Submitted by Specialised Nutrition Europe (SNE, formerly IDACE), 9-31 Avenue des Nerviens, 1040 Brussels, Belgium.
- 2) This application was received by EFSA on 14/2/2008.
- 3) The scope of the application was proposed to fall under a health claim referring to children's development and health.
- 4) On 26/3/2008, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- 5) On 10/3/2016, EFSA received the missing information as submitted by the applicant.
- 6) The scientific evaluation procedure started on 4/4/2016.
- 7) During its meeting on 28/6/2016, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to iron and contribution to the normal function of the immune system.

## References

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- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2009. Scientific Opinion on the substantiation of health claims related to iron and formation of red blood cells and haemoglobin (ID 249, ID 1589), oxygen transport (ID 250, ID 254, ID 256), energy-yielding metabolism (ID 251, ID 1589), function of the immune system (ID 252, ID 259), cognitive function (ID 253) and cell division (ID 368) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from the European Commission. EFSA Journal 2009;7(9):1215, 20 pp. doi:10.2903/j.efsa.2009.1215
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- IoM (Institute of Medicine), 2001. *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium and Zinc*. National Academy Press, Washington, DC.

## Abbreviations

EC	European Commission
NDA Panel	EFSA Panel on Dietetic Products, Nutrition and Allergies