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**Vitamin C 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**

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## **Vitamin C 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 vitamin C and 'helps to support a healthy immune system'. The Panel considers that vitamin C is sufficiently characterised, and that contribution to the normal function of the immune system is a beneficial physiological effect. The Panel has previously assessed a claim on vitamin C and its contribution to the normal function of the immune system with a favourable outcome. The target population was the general population. The Panel considers that the role of vitamin C in the functioning of the immune system applies to all ages, including infants and young children (from birth to three years of age). The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C and contribution to the normal function of the immune system. The following wording reflects the scientific evidence: 'Vitamin C contributes to the normal function of the immune system.' The target population is infants and young children up to three years of age.

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**Keywords:** vitamin C, 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-2008-177

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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 European Food Safety Authority (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 vitamin C and its 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 EFSA's general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims.

The food constituent that is the subject of the health claim is vitamin C, which is an essential nutrient and can be measured in foods by established methods. Vitamin C occurs naturally in foods and is authorised for addition to foods and for use in food supplements. The Panel considers that vitamin C is sufficiently characterised.

The claimed effect proposed by the applicant is that vitamin C 'helps to support a healthy immune system'. The target population proposed by the applicant is infants and young children from birth to three years of age. 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.

The Panel has previously assessed a claim on vitamin C and its contribution to the normal function of the immune system with a favourable outcome. The target population was the general population.

The Panel considers that the role of vitamin C in the functioning of the immune system applies to all ages, including infants and young children (from birth to three years). Dietary Reference Values for vitamin C have been set for infants and young children.

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

The following wording reflects the scientific evidence: 'Vitamin C 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 three years of age.

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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 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).

### 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 vitamin C and its 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 vitamin C, a positive assessment of its safety, or a decision on whether vitamin C 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 vitamin C and its 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

Food/constituent as stated by the applicant:

- According to the applicant, the food which is the subject of the claim is vitamin C.

Health relationship as claimed by the applicant:

- According to the applicant, vitamin C 'helps to support a healthy immune system'.
- The applicant states that vitamin C has been shown to have numerous biochemical functions which impact upon the capacity of the immune system to function optimally. The applicant also argues that vitamin C is directly or indirectly related to both non-specific and specific immune responses.

<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.

Wording of the health claim as proposed by the applicant:

- 'Vitamin C helps support a healthy immune system'.
- The following alternative wordings were proposed by the applicant: 'Vitamin C/Ascorbic acid helps to support/contributes to/is necessary for baby's/babies/a healthy/the functioning of the immune system'.

Specific conditions of use as proposed by the applicant:

- The target population proposed by the applicant is infants and young children from birth to three 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 vitamin C should be within the range set in Directive 2006/141/EC.
  - For dietary foods for special medical purposes, the content of vitamin C should be within the range set in Directive 1999/21/EC.
  - For processed cereal-based foods and baby foods, the content of vitamin C should be within the range set in Directive 2006/125/EC.
  - For processed cereal-based foods and baby foods other than fruit juices, nectars and vegetable juices, the content of vitamin C should reach at least 15% of the Nutrient Reference Values set in Directive 2006/125/EC, i.e. 15% of 25 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 vitamin C should reach at least 15% of the Nutrient Reference Values set in Directive 2006/141/EC, i.e. 15% of 45 mg per 100 mL product ready for use.

### 2.1.2. Data provided by the applicant

The applicant provided a health claim application on vitamin C and contribution to the normal function of the immune system pursuant to Article 14 of Regulation 1924/2006. The application was 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, 2011a).

As outlined in EFSA's general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims (EFSA NDA Panel, 2011b), it is the responsibility of the applicant to provide all the available evidence.

## 2.2. Methodologies

The general approach of the NDA Panel for the evaluation of health claim applications is outlined in EFSA's general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims (EFSA NDA Panel, 2011b).

### 3. Assessment

#### 3.1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is vitamin C, which is an essential nutrient and can be measured in foods by established methods.

Vitamin C occurs naturally in foods and is authorised for addition to foods (Annex II of Regulation (EC) No 1925/2006<sup>2</sup>, Annex II 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> and Annex of Directive 2001/15/EC<sup>6</sup>). This evaluation applies to vitamin C 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 and Annex of Directive 2001/15/EC).

The Panel considers that the food constituent, vitamin C, 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 that vitamin C 'helps to support a healthy immune system'. The target population proposed by the applicant is infants and young children from birth to three years of age.

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 vitamin C and its 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 vitamin C plays a role in the functioning of the immune system.

The Panel considers that the role of vitamin C in the functioning of the immune system applies to all ages, including infants and young children (from birth to three years of age). Dietary Reference Values for vitamin C have been set for infants and young children (EFSA NDA Panel, 2013).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C 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: 'Vitamin C contributes to the normal function of the immune system.'

<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.



### 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 three years of age.

## 4. Conclusions

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

- The food constituent, vitamin C, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is that vitamin C 'helps to support a healthy immune system'. The target population proposed by the applicant is infants and young children from birth to three 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 vitamin C and contribution to the normal function of the immune system.
- The following wording reflects the scientific evidence: 'Vitamin C 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 three years of age.

## Documentation provided to EFSA

1. Health claim application on vitamin C and 'helps to support a healthy immune system' pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0097\_FR). Submitted by Specialised Nutrition Europe (SNE; formerly IDACE), 9-31 Avenue des Nerviens, 1040 Brussels, Belgium.
2. The application was received by EFSA on 14 February 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 March 2008, during the validation of the application, EFSA sent a request to the applicant to provide missing information.
5. On 29 June 2015, EFSA received the missing information as submitted by the applicant.
6. On 24 July 2015, during the validation of the application, EFSA sent a request to the applicant to provide missing information.
7. On 22 September 2015, EFSA received the missing information as submitted by the applicant.
8. The scientific evaluation procedure started on 25 September 2015.
9. During its meeting on 28 October 2015, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to vitamin C and contribution to the normal function of the immune system.

## References

- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2009. Scientific Opinion on the substantiation of health claims related to vitamin C and protection of DNA, proteins and lipids from oxidative damage (ID 129, 138, 143, 148), antioxidant function of lutein (ID 146), maintenance of vision (ID 141, 142), collagen formation (ID 130, 131, 136, 137, 149), function of the nervous system (ID 133), function of the immune system (ID 134), function of the immune system during and after extreme physical exercise (ID 144), non-haem iron absorption (ID 132, 147), energy-yielding metabolism (ID 135), and relief in case of irritation in the upper respiratory tract (ID 1714, 1715) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. *EFSA Journal* 2009;7(9):1226, 28 pp. doi:10.2903/j.efsa.2009.1226
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2011a. Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (revision 1). *EFSA Journal* 2011;9(5):2170, 36 pp. doi:10.2903/j.efsa.2011.2170
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2011b. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. *EFSA Journal* 2011;9(4):2135, 24 pp. doi:10.2903/j.efsa.2011.2135
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on Dietary Reference Values for vitamin C. *EFSA Journal* 2013;11(11):3418, 68 pp. doi:10.2903/j.efsa.2013.3418