

## SCIENTIFIC OPINION

### Scientific Opinion on the substantiation of a health claim related to thiamine and carbohydrate and energy-yielding metabolism 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 IDACE 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 thiamine and carbohydrate and energy-yielding metabolism. Thiamine is a well recognised nutrient and is measurable in foods by established methods. Thiamine is considered to be characterised. Normal carbohydrate and energy-yielding metabolism is considered to be a beneficial physiological effect. Four opinions of authoritative/scientific bodies and two review papers were identified by the applicant as being pertinent to the health claim, of which one review did not address the role of thiamine in carbohydrate and energy-yielding metabolism. It is well recognised, that thiamine pyrophosphate, the active form of thiamine, is a cofactor of several enzymes involved in energy-yielding, branched-chain amino acid and carbohydrate metabolism. The Panel concludes that a cause and effect relationship has been established between the dietary intake of thiamine and normal carbohydrate and energy-yielding metabolism. The following wording reflects the scientific evidence: “Thiamine contributes to normal carbohydrate and energy-yielding metabolism.” The target population is infants and children up to 18 years. © European Food Safety Authority, 2010.

#### KEY WORDS

Thiamine, infants, children, carbohydrates, energy-yielding metabolism, health claim.

---

<sup>1</sup> On request from IDACE, Question No EFSA-Q-2008-183, adopted on 09 July 2010.

<sup>2</sup> Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen.

Correspondence: [nda@efsa.europa.eu](mailto:nda@efsa.europa.eu)

<sup>3</sup> Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

Suggested citation: Scientific Opinion on the substantiation of a health claim related to thiamine and carbohydrate and energy-yielding metabolism pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2010; 8(7):1690. [9 pp.]. doi:10.2903/j.efsa.2010.1690. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

## SUMMARY

Following an application from IDACE 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 thiamine and normal carbohydrate and energy-yielding metabolism.

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

The claimed effect is "vitamin B1 plays an important role in the carbohydrate and energy metabolism of food". The proposed target population for the health claim is children from birth to three years. The Panel considers that normal carbohydrate and energy-yielding metabolism is a beneficial physiological effect.

The applicant provided four opinions of authoritative/scientific bodies and two review papers which were retrieved following a literature search in Pubmed. One of the reviews did not address the role of thiamine in carbohydrate and energy-yielding metabolism. The other review dealt with the role of B-vitamins in mitochondrial energy-yielding metabolism.

It is well recognised, that thiamine pyrophosphate, the active form of thiamine, is a cofactor of several enzymes involved in energy-yielding, branched-chain amino acid and carbohydrate metabolism.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the dietary intake of thiamine and normal carbohydrate and energy-yielding metabolism.

The Panel considers that the following wording reflects the scientific evidence: "Thiamine contributes to normal carbohydrate and energy-yielding metabolism."

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, all other foodstuffs should be at least a source of thiamine as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is infants and children up to 18 years.

## TABLE OF CONTENTS

Abstract .....	1
Summary .....	2
Table of contents .....	3
Background as provided by the European Commission.....	4
Terms of reference as provided by the European Commission.....	4
EFSA Disclaimer.....	4
Information provided by the applicant .....	5
Assessment .....	6
1. Characterisation of the food/constituent.....	6
2. Relevance of the claimed effect to human health .....	7
3. Scientific substantiation of the claimed effect.....	7
4. Panel’s comments on the proposed wording .....	7
5. Conditions and restrictions of use.....	8
Conclusions .....	8
Documentation provided to EFSA .....	9
References .....	9

## BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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 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 14/02/2008.
- The scope of the application was proposed to fall under a health claim referring to children's development and health.
- During the check for completeness<sup>5</sup> of the application, the applicant was requested to provide missing information on 26/03/2008.
- The applicant provided the missing information on 08/04/2010.
- The scientific evaluation procedure started on 15/05/2010.
- During the meeting on 09/07/2010, the NDA Panel, after having evaluated the overall data submitted, adopted an opinion on the scientific substantiation of a health claim related to thiamine and normal carbohydrate and energy-yielding metabolism.

## 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: thiamine and normal carbohydrate and energy-yielding metabolism.

### EFSA DISCLAIMER

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

---

<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. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

<sup>5</sup> 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:** IDACE, rue de l'Association 50, 1000 Brussels, Belgium.

**Food/constituent as stated by the applicant**

Vitamin B1 (thiamine).

**Health relationship as claimed by the applicant**

Vitamin B1 plays an important role in the carbohydrate and energy metabolism of food.

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

Vitamin B1 (thiamine) is necessary to release energy from carbohydrates.

Vitamin B1 (thiamine) is necessary for the normal metabolism of carbohydrates.

Vitamin B1 (thiamine) helps release energy from food.

Vitamin B1 (thiamine) helps in carbohydrate metabolism.

**Specific conditions of use as proposed by the applicant**

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

Quantity

The application concerns food products intended for infants and young children. For most of these products, the vitamin B1 content is regulated, as shown below:

Products	Directive	µg per 100 kJ		µg per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
Follow-on formulae	2006/141/EC	14	72	60	300
Food for special medical purpose, nutritionally complete (or incomplete) for young children proteins	1999/21/EC	10 (-)	75	40 (-)	300
Food for special medical purpose, nutritionally complete (or incomplete) for young children	1999/21/EC	15 (-)	120	60 (-)	500
Processed cereal-based foods	2006/125/EC		120		500
Baby foods	2006/125/EC		60		250

For being able to make the claim,

- For follow-on formulae, the content in vitamin B1 should be within the range set in Dir. 2006/141/EC.
- For Foods for Special Medical Purpose, the content in vitamin B1 should be within the range set in Dir. 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 in vitamin B1 should reach at least 15% of the Nutrient Reference Values set in Dir. 2006/125/EC i.e. 15% of 500 µg (75 µg) per 100 g or 100 ml per serving, as reconstituted.
- For the other foods intended for infants and young children the content in vitamin B1 should reach at least 15% of the Nutrient Reference Values set in Dir. 2006/141/EC i.e. 15% of 500 µg (75 µg) per 100 ml product ready for use.

#### Pattern of consumption

- Follow-on formulae constitute the principal liquid element in a progressively diversified diet for infants over six months until 12 to 18 months of age. The recommended daily intake is between 500 mL and 600 mL. Based on the requirements for follow-on formulae at 67 kcal per 100 mL, the daily intake of vitamin B1 from the source would be between 8 and 40% per 100 mL, and for a 500 mL per day intake, 40 and 200 % of the reference value for nutritional labelling.
- Foods for Special Medical Purpose can be either the only source of nourishment or only part of the diet. They are always used under medical supervision and in quantities recommended by health care professionals.
- For Growing-up Milk/Toddlers milk (GUM), 250 mL are recommended to be taken 2 times a day.
- The different types of cereal-based weaning food and other baby foods are fed as part of a mixed diet according to recommendations from national scientific authorities that are country specific.

## ASSESSMENT

### 1. Characterisation of the food/constituent

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

Thiamine occurs naturally in foods and is authorised for addition to foods (Annex I of the Regulation (EC) No 1925/2006<sup>6</sup>, Annex I of Directive 2002/46/EC<sup>7</sup>, Annex III of Directive 2006/141/EC<sup>8</sup>, Annex IV of Directive 2006/125/EC<sup>9</sup>, Directive 2001/15/EC<sup>10</sup>). This evaluation applies to thiamine 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, Annex III of Directive 2006/141/EC, Annex IV of Directive 2006/125/EC, Directive 2001/15/EC).

---

<sup>6</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>7</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>8</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>9</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>10</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.

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

## **2. Relevance of the claimed effect to human health**

The claimed effect is “vitamin B1 plays an important role in the carbohydrate and energy metabolism of food”. The proposed target population for the health claim is children from birth to three years.

The Panel considers that normal carbohydrate and energy-yielding metabolism is a beneficial physiological effect.

## **3. Scientific substantiation of the claimed effect**

The applicant performed a literature search in Pubmed. Search terms were B-vitamin, thiamine, riboflavin, niacin, niacinamide, pantothenic acid, folic acid, pyridoxine, mitochondrial metabolism, energy production in various combinations limited to “humans”, “clinical trial”, “randomised clinical trial”, “meta-analysis”, “review”, and to “all infant: birth-23 months” and “preschool child: 2-5 years”. These searches did not retrieve any publication.

Therefore, the applicant performed another search using the search terms “B vitamin [ti]” AND “mitochondrial” AND “metabolism”, limited to “humans” and “review” which resulted in the identification of one review on the role of B-vitamins in mitochondrial energy-yielding metabolism. A search for further publications of the same authors related to the same subject produced another review article on the role of B-vitamins on the one-carbon transfer pathways. Both reviews were considered by the applicant pertinent to the claimed effect. The Panel notes that one of the reviews did not address the role of thiamine in carbohydrate and energy-yielding metabolism.

In addition, the applicant provided four opinions of authoritative/scientific bodies.

It is well recognised, that thiamine pyrophosphate, the active form of thiamine, is a cofactor of several enzymes involved in the metabolism of carbohydrates and branched-chain amino acids (WHO/FAO, 2002). Thiamine pyrophosphate is essential to the activity of cytosolic transketolase as well as three mitochondrial dehydrogenases (pyruvate,  $\alpha$ -ketoglutarate and branched-chain ketoacid dehydrogenases) (Depeint et al., 2006). Pyruvate,  $\alpha$ -ketoglutarate and branched-chain amino acid dehydrogenase multienzyme complex systems catalyse oxidative decarboxylation reactions leading to the production of acetyl-coenzyme A (CoA), succinyl CoA and the appropriate derivatives of branched chain amino acids, respectively. The products of these reactions are important in energy-yielding, branched-chain amino acid and carbohydrate metabolism (EVM, 2002).

The Panel has already addressed the role of thiamine in normal carbohydrate and energy-yielding metabolism for the general population with a favourable outcome in a previous opinion under Article 13(1) of Regulation (EC) No 1924/2006 (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009) and it notes that the role of thiamine in normal carbohydrate and energy-yielding metabolism is not specific to any population group.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of thiamine and normal carbohydrate and energy-yielding metabolism.

## **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: “Thiamine contributes to normal carbohydrate and energy-yielding metabolism.”

## 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>11</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 2006/125/EC;
- all other foodstuffs should be at least a source of thiamine as per Annex to Regulation (EC) No 1924/2006.

Such amounts can be easily consumed as part of a balanced diet. The target population is infants and children up to 18 years. Tolerable Upper Intake Levels (UL) have not been established for thiamine in children, adolescents and adults.

## CONCLUSIONS

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

- The food constituent, thiamine, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is “vitamin B1 plays an important role in the carbohydrate and energy metabolism of food”. Normal carbohydrate and energy-yielding metabolism is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of thiamine and normal carbohydrate and energy-yielding metabolism.
- The following wording reflects the scientific evidence: “Thiamine contributes to normal carbohydrate and energy-yielding metabolism.”
- 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, all other foodstuffs should be at least a source of thiamine as per Annex to Regulation (EC) No

---

<sup>11</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.

1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is infants and children up to 18 years.

#### **DOCUMENTATION PROVIDED TO EFSA**

Health claim application on thiamine and “plays an important role in the carbohydrate and energy metabolism of food” pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0103\_FR). 08 April 2010. Submitted by IDACE.

#### **REFERENCES**

Depeint F, Bruce WR, Shangari N, Mehta R and O'Brien PJ, 2006. Mitochondrial function and toxicity: role of the B vitamin family on mitochondrial energy metabolism. *Chemico-Biological Interactions*, 163, 94-112.

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009. Scientific Opinion on substantiation of health claims related to thiamine and energy-yielding metabolism (ID 21, 24, 28), cardiac function (ID 20), function of the nervous system (ID 22, 27), maintenance of bone (ID 25), maintenance of teeth (ID 25), maintenance of hair (ID 25), maintenance of nails (ID 25), maintenance of skin (ID 25) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. *EFSA Journal*, 7(9):1222, 18 pp.

EVM (Expert Group on Vitamins and Minerals), 2002. Revised Review of Thiamine.

WHO/FAO (World Health Organization/Food and Agriculture Organization of the United Nations), 2002. Human vitamin and mineral requirements. Report of a joint FAO/WHO expert consultation. Bangkok, Thailand.