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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to thiamin and maintenance of normal neurological development and function pursuant to Article 14 of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from HiPP GmbH submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to thiamin and maintenance of normal neurological development and function. Thiamin is a well recognised nutrient and is measurable in foods by established methods. Thiamin is considered to be sufficiently characterised. Maintenance of normal neurological development and function is considered to be a beneficial physiological effect. It is well recognised that the clinical signs of thiamin deficiency include mental changes, such as apathy, decrease in short-term memory, confusion and irritability as well as polyneuritis and paralysis of the peripheral nerves. All essential nutrients, including vitamins and minerals, are required for normal development of infants and children. The Panel concludes that a cause and effect relationship has been established between the dietary intake of thiamin and maintenance of normal neurological development and function. The following wording reflects the scientific evidence: "Thiamin contributes to the maintenance of normal neurological development and function." The target population is infants and children up to 3 years.

KEY WORDS

Thiamin, infants, children, neurological function, development, health claims.

[1] On request from the from the Competent Authority of Germany following an application by HiPP GmbH, Question No EFSA-Q-2009-00455, adopted on 28 January 2011.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific 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.

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SUMMARY

Following an application from HiPP GmbH submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to thiamin and maintenance of normal neurological development and function.

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

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

The claimed effect is "thiamin in the diet is necessary for the normal development and function of the neurological system". The proposed target population for the health claim is children from birth to three years. The Panel considers that maintenance of normal neurological development and function is a beneficial physiological effect.

The applicant identified two human intervention studies, seven observational studies, three reviews and one medical position paper on the composition of infant formulae, four opinions of authoritative/scientific bodies and five textbook chapters as pertinent to the claim.

It is well recognised that the clinical signs of thiamin deficiency include mental changes, such as apathy, decrease in short-term memory, confusion and irritability as well as polyneuritis and paralysis of the peripheral nerves. Manifestations are seen in the autonomic, the sensory and the motor systems.

The Panel notes that all essential nutrients, including vitamins and minerals, are required for normal development of infants and children.

The Panel also notes that the role of thiamin in normal neurological function is not specific to any population group.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of thiamin and maintenance of normal neurological development and function.

The Panel considers that the following wording reflects the scientific evidence: "Thiamin contributes to the maintenance of normal neurological development and function."

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 3 years.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1924/2006[4] 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 04/03/2009.
- 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[5] of the application, the applicant was requested to provide missing information on 08/04/2009.
- The applicant provided the missing information on 16/09/2010.
- The scientific evaluation procedure started on 30/09/2010.
- During the meeting on 28/01/2011, the NDA Panel, after having evaluated the overall data submitted, adopted an opinion on the scientific substantiation of a health claim related to thiamin and maintenance of normal neurological development and function.

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: thiamin and maintenance of normal neurological development and function.

EFSA DISCLAIMER

The present opinion does not constitute and cannot be construed as an authorisation to the marketing of thiamin, a positive assessment of its safety, nor a decision on whether thiamin 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. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

[5] 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: HiPP GmbH & Co. Vertrieb KG, Georg-Hipp-Straße 7, 85276 Pfaffenhofen, Germany.

Food/constituent as stated by the applicant

According to the applicant the food constituent for which the claim is made is thiamin (vitamin B1).

Health relationship as claimed by the applicant

According to the applicant, a minimum level of thiamin in the diet is necessary for the normal development and function of the neurological system. For children in particular, the neurological system dramatically develops and evolves in the first years of life and an adequate level of thiamin is required for normal growth and development of infants and young children.

Wording of the health claim as proposed by the applicant

The applicant proposed the following wording for the health claim: "Vitamin B1 for development of the nervous system"

As equivalent wording the following wording is proposed by the applicant: "Vitamin B1/thiamin contributes to/participates to/plays an important role for/is important for/is involved in/is necessary for/ is needed for the function/normal function/normal development of the nervous system."

Specific conditions of use as proposed by the applicant

According to the applicant, the target population is infants and young children from birth to 3 years of age as defined in Directive 89/398/EEC on foodstuffs intended for particular nutritional uses. 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 claimed effect is:

- For follow-on formulae, the content in thiamin should be within the range set in the Directive 2006/141/EC.
- For dietary foods for special medical purposes (FSMP), the content in thiamin should be within the range set in the Directive 1999/21/EC.
- For processed cereal-based foods, the content in thiamin should be within the range set in the Directive 2006/125/EC.
- For baby foods, the content in thiamin should be at least reach 15 % of the Nutrient Reference Value (NRV) set in the Directive 2006/125/EC.
- For other dietary foods intended for infants and young children, the content in thiamin should at least reach 15% of the NRV set in the Directive 2006/141/EC.

ASSESSMENT

1. Characterisation of the food/constituent

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

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

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

2. Relevance of the claimed effect to human health

The claimed effect is "thiamin in the diet is necessary for the normal development and function of neurological system". The proposed target population for the health claim is children from birth to three years.

The Panel considers that maintenance of normal neurological development and function is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant identified two human intervention studies, seven observational studies, three reviews and one medical position paper on the composition of infant formulae, four opinions of authoritative/scientific bodies and five textbook chapters as pertinent to the claim. The literature search strategy has been described.

It is well recognised that the clinical signs of thiamin deficiency include mental changes, such as apathy, decrease in short-term memory, confusion and irritability (IoM, 1998) as well as polyneuritis and paralysis of the peripheral nerves. Manifestations are seen in the autonomic, the sensory and the motor systems (WHO, 1999).

The Panel notes that all essential nutrients, including vitamins and minerals, are required for normal development of infants and children.

The Panel has already addressed the role of thiamin in the normal function of the nervous system 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 thiamin in normal neurological function is not specific to any population group.

[6] 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.
[7] 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.
[8] 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.
[9] 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.
[10] 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 concludes that a cause and effect relationship has been established between the dietary intake of thiamin and maintenance of normal neurological development and function.

4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: "Thiamin contributes to the maintenance of normal neurological development and function."

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[11];
- 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 3 years. Tolerable Upper Intake Levels (UL) have not been established for thiamin in children, adolescents and adults (SCF, 2001).

CONCLUSIONS

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

- The food constituent, thiamin, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is "thiamin in the diet is necessary for the normal development and function of the neurological system". The proposed target population for the health claim is children from birth to three years. Maintenance of normal neurological development and function is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of thiamin and maintenance of normal neurological development and function.
- The following wording reflects the scientific evidence: "Thiamin contributes to the maintenance of normal neurological development and function."
- 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-

[11] 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.

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 3 years.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on thiamin and maintenance of normal neurological development and function pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0243_DE). September 2010. Submitted by HiPP GmbH.

REFERENCES

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.

IoM (Institute of Medicine), 1998. Dietary Reference Intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin and choline. National Academy Press, Washington D.C.

SCF (Scientific Committee on Food), 2001. Scientific Opinion on the Tolerable Upper Intake Level of Vitamin B1.

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