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Scientific Opinion on the substantiation of a health claim related to choline and
“development of brain” pursuant to Article 14 of Regulation (EC) No 1924/2006**

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to choline and “development of brain” 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 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 choline and “development of brain”. The food constituent, choline, which is the subject of the health claim, is sufficiently characterised. The claimed effect proposed by the applicant is “development of brain” and the target population is infants and young children from birth to three years of age. Taking into account that no evidence was provided for an effect of dietary choline deficiency in the normal development of the brain in infants and young children, the Panel considers that the claimed effect, “development of brain” for infants and young children from birth to three years in relation to dietary choline, is not sufficiently defined for a scientific evaluation. The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

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KEY WORDS

choline, brain, health claims

¹ On request from the Competent Authority of France following an application by Specialised Nutrition Europe (formerly IDACE), Question No EFSA-Q-2008-134, adopted on 10 April 2014.

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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 choline and “development of brain”.

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 choline, which is measurable in foods by established methods. The Panel considers that choline is sufficiently characterised.

The claimed effect proposed by the applicant is “development of brain”. The target population proposed by the applicant is infants and young children from birth to three years of age.

Claims on the maintenance of (unspecified) functions of the nervous system have been evaluated by the Panel with a positive outcome for some essential nutrients on the basis of a well-established biochemical role of such nutrients in neural transmission, or deficiency symptoms involving the nervous system.

As choline can be synthesised endogenously and it has not been established that dietary choline deficiency in humans is associated with impaired brain development or function, claims on the improvement, maintenance or reduced loss of (unspecified) neural, brain or psychological functions in general are not sufficiently defined for a scientific evaluation. No specific function of the nervous system was identified by the applicant as the subject of the claim.

Taking into account that no evidence was provided for an effect of dietary choline deficiency in the normal development of the brain in infants and young children, the Panel considers that the claimed effect, “development of brain” for infants and young children from birth to three years in relation to dietary choline, is not sufficiently defined for a scientific evaluation.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

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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 asking it to provide missing information.
- On 06/08/2013, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 04/10/2013.
- On 21/11/2013, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application and the clock was stopped on 29/11/2013.
- On 21/01/2014, EFSA received the requested information and the clock was restarted, in compliance with Article 16(1) of Regulation (EC) No 1924/2006.
- During its meeting on 10/04/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to choline and “development of brain”.

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: choline and “development of brain”.

EFSA DISCLAIMER

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

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.

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.

INFORMATION PROVIDED BY THE APPLICANT

Applicant’s name and address: Specialised Nutrition Europe (formerly IDACE), 9-31 Avenue des Nerviens, 1040, Brussels, Belgium.

Food/constituent as stated by the applicant

According to the applicant, the food constituent for which the claim is made is choline.

Health relationship as claimed by the applicant

According to the applicant, choline is needed for the development of brain of infants and young children from birth to three years.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “choline is needed for the development of brain of infants and young children from birth to three years”.

As equivalent alternative wordings, the applicant has also proposed: “choline/is needed for/is involved in/is important for/plays an important role for/is necessary for/participates to/contributed to/the development of/the normal development of/the function of /the normal function/brain”.

Specific conditions of use as proposed by the applicant

According to the applicant, the target population is infants (from birth onwards) and young children (until three years of age) as defined in Directives 89/398/EEC, 2006/141/EC, and Directive 2006/125/EC.

Those foods are exclusively intended for the category of infants and young children, and in line with the composition laid down in the specific directives.

The Institute of Medicine Recommendations for Adequate Intake published in 1998, are the following (FNB 1998):

- Infants 0-5 months: 125 mg/ day
- Infants 6-11 months: 150 mg/ day
- Young children 1-3 years: 200 mg/day

According to the applicant, the quantity needed to achieve the claimed effect is:

- For infant formulae, the content in choline should be within the range set in Directive 2006/141/EC.
- For follow-on formulae, foods for special medical purposes, processed cereal-based foods and baby foods and foods intended for infants and young children, the content in choline should reach at least 15 % of the Adequate Intake defined above in 100 g or 100 mL of the product.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is choline.

Choline (2-hydroxyethyl-N,N,N-trimethylammonium) is a quaternary ammonium cation generally present in foods with a chloride counter-ion (chloride salt). It can also be bound to an acetyl group (acetylcholine), to a cytidine diphosphate group (citicoline) or, mainly, to a phosphatidyl group (lecithin). Choline is synthesised in the body.

Choline is measurable in foods by established methods.

Choline occurs naturally in foods and is authorised for addition to foods (Annex III of Directive 2006/141/EC⁵, Annex IV of Directive 2006/125/EC⁶, Directive 2001/15/EC⁷). This evaluation applies to choline naturally present in foods and those forms authorised for addition to foods (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, choline, 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 “development of brain”. The target population proposed by the applicant is infants and young children from birth to three years of age.

Claims on the maintenance of (unspecified) functions of the nervous system have been evaluated by the Panel with a positive outcome for some essential nutrients. The scientific substantiation of these claims was based on the well-established biochemical role of such nutrients in neural transmission, or on deficiency symptoms involving the nervous system (e.g. EFSA NDA Panel, 2009a, b, c, d), rather than on weighing the evidence. The use of unspecified functions to substantiate such claims is because symptoms of deficiency of a nutrient can result from effects on multiple physiological functions, and it is sometimes not possible or appropriate to single out a precise function that is affected by deficiency of that nutrient in a particular organ or system.

Taking into account that choline can be synthesised endogenously and that it has not been established that dietary choline deficiency in humans is associated with impaired brain development or function, claims on the improvement, maintenance or reduced loss of (unspecified) neural, brain or psychological functions in general are not sufficiently defined for a scientific evaluation. The specific function of the nervous system which is the subject of the claim, together with appropriate outcome measures which may be used for the scientific evaluation of the claimed effect *in vivo* in humans, must be identified (EFSA NDA Panel, 2012).

Therefore, EFSA requested the applicant to indicate the specific physiological function of the nervous system that is the subject of the health claim, together with the outcome measure(s) which could be used for the scientific evaluation of that function.

⁵ 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.

⁶ 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.

⁷ 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.

In reply, the applicant did not indicate a specific physiological function of the nervous system to be the subject of the health claim.

The Panel notes that the references provided by the applicant as being pertinent to the health claim investigated several outcome measures (e.g. brain concentration of choline or choline-containing compounds, choline status, DNA damage and apoptosis in peripheral lymphocytes, verbal memory, visual function, occurrence of headache, dizziness, motor dysfunction, and memory problems). The Panel considers that from the references provided it is not possible to establish the physiological function of the nervous system that is the subject of the health claim.

Taking into account that no evidence was provided for an effect of dietary choline deficiency in the normal development of the brain in infants and young children, the Panel considers that the claimed effect, “development of brain” for infants and young children from birth to three years in relation to dietary choline, is not sufficiently defined for a scientific evaluation.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

CONCLUSIONS

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

- The food constituent, choline, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is “development of brain”. The target population proposed by the applicant is infants and young children from birth to three years of age. The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on choline and “development of brain” pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0054_FR). February 2008. Submitted by Specialised Nutrition Europe (formerly IDACE).

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EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2009b. Scientific Opinion on the substantiation of health claims related to copper and protection of DNA, proteins and lipids from oxidative damage (ID 263, 1726), function of the immune system (ID 264), maintenance of connective tissues (ID 265, 271, 1722), energy yielding metabolism (ID 266), function of the nervous system (ID 267), maintenance of skin and hair pigment (ID 268, 1724),

iron transport (ID 269, 270, 1727), cholesterol metabolism (ID 369), and glucose metabolism (ID 369) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2009;7(9):1211, 9 pp. doi:10.2903/j.efsa.2009.1211

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2009c. Scientific Opinion on the substantiation of health claims related to niacin and energy-yielding metabolism (ID 43, 49, 54), function of the nervous system (ID 44, 53), maintenance of the skin and mucous membranes (ID 45, 48, 50, 52), maintenance of normal LDL-cholesterol, HDL-cholesterol and triglyceride concentrations (ID 46), maintenance of bone (ID 50), maintenance of teeth (ID 50), maintenance of hair (ID 50, 2875) and maintenance of nails (ID 50, 2875) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2009;7(9):1224, 9 pp. doi:10.2903/j.efsa.2009.1224

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2009d. Scientific Opinion on the substantiation of health claims related to vitamin B6 and protein and glycogen metabolism (ID 65, 70, 71), function of the nervous system (ID 66), red blood cell formation (ID 67, 72, 186), function of the immune system (ID 68), regulation of hormonal activity (ID 69) and mental performance (ID 185) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2009;7(9):1225, 9 pp. doi:10.2903/j.efsa.2009.1225

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