

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to alpha-linolenic acid and contribution to brain and nerve tissue development 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 HiPP GmbH & Co Vertrieb KG 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 alpha-linolenic acid and contribution to brain and nerve tissue development. Alpha-linolenic acid is considered to be sufficiently characterised. Contribution to brain and nerve tissue development is considered to be a beneficial physiological effect. Alpha-linolenic acid is the parent fatty acid of the longer chain n-3 polyunsaturated fatty acids, including docosahexaenoic acid, which is the major structural lipid in brain tissue and the central nervous system. Deficiency of alpha-linolenic acid results in adverse clinical symptoms including neurological abnormalities and poor growth. The Panel notes that for normal brain and nerve tissue development, alpha-linolenic acid, like other essential nutrients, is needed in adequate amounts. The Panel concludes that a cause and effect relationship has been established between the dietary intake of alpha-linolenic acid and contribution to brain and nerve tissue development. The following wording reflects the scientific evidence: “Alpha-linolenic acid, an essential fatty acid, contributes to brain and nerve tissue development.” The target population is infants and children up to three years. © European Food Safety Authority, 2011

KEY WORDS

Alpha-linolenic acid, ALA, infants, children, development, brain, nerve tissue, health claim.

¹ On request from the Competent Authority of Germany, following an application by HiPP GmbH & Co Vertrieb KG, Question No EFSA-Q-2009-00197, adopted on 25 March 2011.

² 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

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SUMMARY

Following an application from HiPP GmbH & Co Vertrieb KG 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 alpha-linolenic acid and contribution to brain and nerve tissue development.

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 alpha-linolenic acid (ALA). ALA is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that ALA is sufficiently characterised.

The claimed effect is "alpha-linolenic acid is important for brain and nervous tissue development". The target population as proposed by the applicant is infants and children from birth to three years. The Panel considers that contribution to brain and nerve tissue development is a beneficial physiological effect.

Alpha-linolenic acid is the parent fatty acid of the longer chain n-3 polyunsaturated fatty acids, including docosahexaenoic acid (DHA). DHA is the major structural lipid in brain tissue and the central nervous system. Also the retina contains high concentrations of DHA. Deficiency of ALA results in adverse clinical symptoms including neurological abnormalities and poor growth.

The Panel has already issued a favourable opinion on ALA and linoleic acid (LA) and normal growth and development of children, as well as on ALA and contribution to brain development.

The Panel notes that for normal brain and nerve tissue development, ALA, like other essential nutrients, is needed in adequate amounts.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of ALA and contribution to brain and nerve tissue development.

The Panel considers that the following wording reflects the scientific evidence: "Alpha-linolenic acid, an essential fatty acid, contributes to brain and nerve tissue development."

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; other foodstuffs intended for infants and young children should contain a minimum of 15 % of the adequate intake of 0.5 E %. Such amounts can be easily consumed as part of a balanced diet. The target population is infants and children up to three years.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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 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 09/01/2009.
- The scope of the application was proposed to fall under a health claim referring to children's development and health.
- During the check for completeness⁵ of the application, the applicant was requested to provide missing information on 10/02/2009.
- The applicant provided the missing information on 15/09/2010.
- The applicant was requested to provide additional information on 12/10/2010.
- The applicant provided the additional information on 19/11/2010.
- The scientific evaluation procedure started on 30/11/2010.
- During the meeting on 25/03/2011, the NDA Panel, after having evaluated the overall data submitted, adopted an opinion on the scientific substantiation of a health claim related to alpha-linolenic acid and contribution to brain and nerve tissue development.

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: alpha-linolenic acid and contribution to brain and nerve tissue development.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of alpha-linolenic acid, a positive assessment of its safety, nor a decision on whether alpha-linolenic acid 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 health claim is made is alpha-linolenic acid.

Health relationship as claimed by the applicant

According to the applicant, alpha-linolenic acid is the precursor for the synthesis of longer chain polyunsaturated fatty acids (such as DHA), that play an important role as structural membrane lipids, particularly in nerve tissue including the brain. The nervous system and especially the brain of the infant still grow and mature during the first 18 to 24 month of life. Its proper structural development is a precondition for mental development and cognitive function. Besides other nutrients an adequate supply with alpha-linolenic acid, which is not synthesised by humans, is required for this development.

Wording of the health claim as proposed by the applicant

The applicant proposed the following wording for the health claim: "Alpha-linolenic acid is important for brain and nervous tissue development".

As alternative wordings, the following examples were proposed by the applicant: "Alpha-linolenic acid supports/contributes to/is involved in the normal function of the nervous system" or "omega-3 is important for the development of brain and nervous tissue".

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 the claimed effect is:

- For infant and follow-on formulae, the content of alpha-linolenic acid should be within the range set in the Directive 2006/141/EC.
- Products should contain a minimum content of alpha-linolenic acid of 15 % RDA per serving and the amount in follow-on formula should additionally be above the legally defined minimum amount.
- An intake of 0.5 % of the energy supply for infants aged 4-12 month as well as for toddlers aged 1-4 years (D-A-CH, 2000). Calculated with the age specific recommended energy intake (700 kcal/day for infants aged 4-12 months and 1100 kcal/day for toddlers aged 1-4 years) the intake of alpha-linolenic acid should be 0.39 g and 0.61 g per day, respectively.
- Accordingly, the minimum amount for products to bear the claim, corresponding to 15 % RDA, would be 0.06 g per serving for infants aged 4-12 months and 0.09 g per serving for infants aged 1-4 years.
- The pattern of consumption should follow the recommendations of the Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae SCF/CS/NUT/IF/65 Final dated 18 May 2003.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is alpha-linolenic acid (ALA).

Alpha-linolenic acid is an essential n-3 polyunsaturated fatty acid with 18 carbon atoms and three double bonds. It is a well recognised nutrient, is well absorbed when consumed in the form of triglycerides and is measurable in foods with established methods. This evaluation applies to all appropriate sources of ALA in the specified amounts.

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

2. Relevance of the claimed effect to human health

The claimed effect is “alpha-linolenic acid is important for brain and nervous tissue development”. The target population as proposed by the applicant is infants and children from birth to three years.

The Panel considers that contribution to brain and nerve tissue development is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant identified five randomised controlled trials (RCTs), three observational studies, two reviews (reporting on 17 RCTs) and 13 animal studies as pertinent to the claim. In addition, several textbook chapters and opinions of authoritative/scientific bodies were submitted. The literature search strategy has been described.

Alpha-linolenic acid is the parent fatty acid of the longer chain n-3 polyunsaturated fatty acids, including docosahexaenoic acid (DHA). DHA is the major structural lipid in brain tissue and the central nervous system. Also the retina contains high concentrations of DHA. Deficiency of ALA results in adverse clinical symptoms including neurological abnormalities and poor growth (IoM, 2005). Evidence for the essentiality of n-3 fatty acids in humans can be drawn from case reports of patients receiving parenteral nutrition with intravenous lipids. Biochemical changes of n-3 fatty acid deficiency include a decrease in plasma and tissue DHA concentrations. There is no accepted cut-off concentration of plasma or tissue DHA concentrations below which functions ascribed to n-3 fatty acids such as visual or neurological functions are impaired (IoM, 2005).

An adequate intake for ALA of 0.5 E % has been proposed by the Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2010).

The Panel has already addressed the role of alpha-linolenic acid in two previous opinions under Article 14 of Regulation (EC) No 1924/2006 referring to children’s development and health. In 2008 the Panel concluded that a cause and effect relationship has been established between the intake of ALA and linoleic acid (LA) and normal growth and development of children (EFSA, 2008). In 2009 the Panel concluded that a cause and effect relationship has been established between the intake of ALA and contribution to brain development (EFSA, 2009).

The Panel notes that for normal brain and nerve tissue development, ALA, like other essential nutrients, is needed in adequate amounts.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of ALA and contribution to brain and nerve tissue development.

4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: "Alpha-linolenic acid, an essential fatty acid, contributes to brain and nerve tissue development."

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;
- other foodstuffs intended for infants and young children should contain a minimum of 15 % of the adequate intake of 0.5 E %.

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

CONCLUSIONS

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

- The food constituent, ALA, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is "alpha-linolenic acid is important for brain and nervous tissue development". The target population as proposed by the applicant is infants and children from birth to three years. Contribution to brain and nerve tissue development is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of ALA and contribution to brain and nerve tissue development.
- The following wording reflects the scientific evidence: "Alpha-linolenic acid, an essential fatty acid, contributes to brain and nerve tissue development."
- 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; other foodstuffs intended for infants and young children should contain a minimum of 15 % of the adequate intake of 0.5 E %. The target population is infants and children up to three years.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on alpha-linolenic acid and "is important for brain and nervous tissue development" pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0231_DE). September 2010. Submitted by HiPP GmbH & Co Vertrieb KG.

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IoM (Institute of Medicine), 2005. Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. National Academies Press, Washington DC.

GLOSSARY / ABBREVIATIONS

ALA	alpha-linolenic acid
DHA	docosahexaenoic acid
LA	linoleic acid
RCT	randomised controlled trial