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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to eicosapentaenoic acid (EPA) and “reduces the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with ADHD-like symptoms” 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 Minami Nutrition Health BVBA, submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, 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 eicosapentaenoic acid (EPA) and “reduces the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with attention deficit hyperactivity disorder (ADHD)-like symptoms”. The food constituent, EPA, which is the subject of the health claim, is sufficiently characterised. The claimed effect proposed by the applicant is “reduces the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with ADHD-like symptoms. These children are also characterised by less hyperactivity and/or coexisting oppositional behaviour”. Upon a request by EFSA for clarification, the applicant indicated that the disease was ADHD, which is classified as such in accordance with the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), that the risk factor for the disease was an elevated AA/EPA ratio in blood, and that the target population for the claim was children with diagnosis of ADHD. The Panel considers that the evidence provided does not establish that reducing the AA/EPA ratio reduces the risk of ADHD in children, and considers that the target population is a diseased population (i.e. children with ADHD). The Panel concludes that the claimed effect relates to the treatment of a disease, and that therefore the health claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

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¹ On request from the Competent Authority of Belgium following an application by Minami Nutrition Health BVBA, Question No EFSA-Q-2012-00573, adopted on 21 March 2013.

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KEY WORDS

Eicosapentaenoic acid, EPA, arachidonic acid, AA/EPA ratio, attention deficit hyperactivity disorder, ADHD, health claims

SUMMARY

Following an application from Minami Nutrition Health BVBA, submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, 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 eicosapentaenoic acid (EPA) and “reduces the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with ADHD-like symptoms”. The scope of the application was proposed to fall under a health claim referring to disease risk reduction.

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

The claimed effect proposed by the applicant is “reduces the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with attention deficit hyperactivity disorder (ADHD)-like symptoms. These children are also characterised by less hyperactivity and/or coexisting oppositional behaviour”. The target population proposed by the applicant is “children 5-13 years of age with ADHD-like symptoms and low blood levels of omega-3 fatty acids”.

Upon a request by EFSA for clarification in relation to the proposed claimed effect, the validity of the risk factor proposed for the disease, and the target population, the applicant indicated that the disease was ADHD, which is classified as such in accordance with the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), that the risk factor for the disease was an elevated AA/EPA ratio in blood, and that the target population for the claim was children with diagnosis of ADHD.

No evidence was provided by the applicant to substantiate that the AA/EPA ratio plays a role in the development of ADHD, that the AA/EPA ratio can predict the incidence of ADHD, or that lowering the AA/EPA ratio can lower the risk of ADHD.

The Panel considers that the evidence provided does not establish that reducing the AA/EPA ratio reduces the risk of ADHD in children.

The Panel notes that the target population for the claim is a diseased population (i.e. children with ADHD).

The Panel concludes that the claimed effect relates to the treatment of a disease, and that therefore the health claim does not comply with the criteria laid down in 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 07/05/2012.
- The scope of the application was proposed to fall under a health claim referring to disease risk reduction.
- On 14/06/2012, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 12/10/2012, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 26/10/2012.
- On 30/11/2012, 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 30/11/2012, in compliance with Article 16(1) of Regulation (EC) No 1924/2006.
- On 07/02/2013, EFSA received the requested information and the clock was restarted on 07/02/2013, in compliance with Article 16(1) of Regulation (EC) No 1924/2006.
- During its meeting on 21/03/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to EPA and “reduces the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with ADHD-like symptoms”.

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: EPA and “reduces the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with ADHD-like symptoms”.

EFSA DISCLAIMER

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

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.

eicosapentanoic 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.

INFORMATION PROVIDED BY THE APPLICANT

Applicant’s name and address: Minami Nutrition Health BVBA, Leugstraat 51, 2630 Aartselaar, Belgium.

Food/constituent as stated by the applicant

According to the applicant, the food constituent that is the subject of the health claim is eicosapentaenoic acid (EPA).

Health relationship as claimed by the applicant

According to the applicant, EPA reduces the AA/EPA fatty acid ratio in blood. Such ratio is claimed by the applicant to correlate to attention performance in children with attention deficit hyperactivity disorder (ADHD)-like symptoms.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “EPA has been shown to reduce the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with ADHD-like symptoms. These children are also characterised by less hyperactivity and/or coexisting oppositional behaviour”.

Specific conditions of use as proposed by the applicant

The applicant has proposed an intake of 500 mg EPA per day with meals. The target population proposed by the applicant is children 5-13 years of age with ADHD-like symptoms and low blood levels of omega-3 fatty acids.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is eicosapentaenoic acid (EPA).

EPA is a 20-carbon fatty acid with five double bonds of the omega-3 series (omega-3 long-chain polyunsaturated fatty acid) which is a well recognised nutrient naturally present in foods from animal sources, especially oily fish. EPA is proposed to be used in the form of triglycerides, ethyl esters or phospholipids for addition to food supplements. EPA is measurable in foods by established methods.

The Panel considers that the food constituent, EPA, 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 “reduces the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with ADHD-like symptoms. These children are also characterised by less hyperactivity and/or coexisting oppositional behaviour”. The target population proposed by the applicant is “children 5-13 years of age with ADHD-like symptoms and low blood levels of omega-3 fatty acids”.

During the evaluation process, EFSA requested clarification from the applicant in relation to the disease that is the subject of the health claim, in relation to the validity of the risk factor proposed for the disease, and in relation to the proposed target population, noting that “attention difficulties” is not a well-defined disease and that “children with ADHD-like symptoms” had not been characterised in relation to the presence or absence of disease. The applicant clarified that the disease was ADHD,

which is classified as such in accordance with the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), that the risk factor for the disease was an elevated AA/EPA ratio in blood, and that the target population for the claim was children with diagnosis of ADHD.

The applicant claims that an elevated AA/EPA ratio in blood is a risk factor in the development of ADHD. The evidence provided to support this statement consisted of four case-control studies in which the AA/EPA ratio in children with ADHD was significantly higher than in healthy controls (Stevens et al., 1995, Chen et al., 2004; Antalis et al., 2006, Colter et al., 2008). The Panel notes that no evidence was provided by the applicant that the AA/EPA ratio plays a role in the development of ADHD; that the AA/EPA ratio can predict the incidence of ADHD; or that lowering the AA/EPA ratio can lower the risk of ADHD; and that reverse causality cannot be excluded from these studies.

The Panel considers that the evidence provided does not establish that reducing the AA/EPA ratio reduces the risk of ADHD in children.

The Panel notes that the target population for the claim is a diseased population (i.e. children with ADHD).

The Panel concludes that the claimed effect relates to the treatment of a disease, and that therefore the health claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

CONCLUSIONS

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

- The food constituent, EPA, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is “reduces the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with ADHD-like symptoms. These children are also characterised by less hyperactivity and/or coexisting oppositional behaviour”. The target population proposed by the applicant is “children 5-13 years of age with ADHD-like symptoms and low blood levels of omega-3 fatty acids”.
- The claimed effect relates to the treatment of a disease, and that therefore the health claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on EPA and “reduces the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with ADHD-like symptoms” pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim Serial No: 0350_BE). May 2012. Submitted by Minami Nutrition Health BVBA.

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GLOSSARY / ABBREVIATIONS

AA	arachidonic acid
ADHD	attention deficit hyperactivity disorder
EPA	eicosapentaenoic acid