

## SCIENTIFIC OPINION

# Scientific Opinion on the substantiation of a health claim related to DHA and contribution to normal brain development 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>

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### ABSTRACT

Following an application from DSM Nutritional Products, submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of the United Kingdom, 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 docosahexaenoic acid (DHA) and contribution to normal brain development. The Panel considers that DHA is sufficiently characterised, and that contribution to normal brain development is a beneficial physiological effect for infants and children. The Panel has already assessed a claim on DHA and maintenance of normal brain function with a favourable outcome. The Panel noted the well-established role of DHA in brain function. The Panel considers that the role of DHA in normal brain function applies to all ages, including brain development in infants and children. The Panel also notes that the developing brain accumulates large amounts of DHA, particularly during the first two years of life, but also later and throughout childhood. The Panel concludes that a cause and effect relationship has been established between the consumption of DHA and contribution to normal brain development. The following wording reflects the scientific evidence: “DHA contributes to normal brain development”. In order to bear the claim, foods for older infants and young children below the age of 24 months should provide a daily intake of 100 mg DHA in one or more servings, while foods for children from 2 to 18 years should provide a daily intake of 250 mg DHA in one or more servings.

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### KEY WORDS

DHA, docosahexaenoic acid, brain development, children, health claims

<sup>1</sup> On request from the Competent Authority of the United Kingdom following an application by DSM Nutritional Products, Question No EFSA-Q-2014-00059, adopted on 18 September 2014.

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## SUMMARY

Following an application from DSM Nutritional Products, submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006, via the Competent Authority of the United Kingdom, 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 docosahexaenoic acid (DHA) and contribution to normal brain development.

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

The food that is the subject of the health claim is DHA (22:6 n-3), which is a well-characterised n-3 long-chain fatty acid that can be quantified in foods by established methods. This evaluation applies to all sources of DHA in the specified amounts. The Panel considers that DHA is sufficiently characterised.

The claimed effect proposed by the applicant is "contributes to brain development". The target population proposed by the applicant is infants and children up to 18 years of age. The Panel considers that contribution to normal brain development is a beneficial physiological effect for infants and children.

The Panel has already assessed a claim on DHA and maintenance of normal brain function with a favourable outcome. The target population was the general population. The Panel considered that DHA is the major structural lipid in brain tissue and the central nervous system, and that the membrane lipids of brain grey matter and the retina contain high concentrations of DHA. The Panel noted the well-established role of DHA in brain function.

The Panel considers that the role of DHA in normal brain function applies to all ages, including brain development in infants and children. The Panel also notes that the developing brain accumulates large amounts of DHA, particularly during the first two years of life, but also later and throughout childhood. Dietary Reference Values for pre-formed DHA have been set for infants and children.

The Panel concludes that a cause and effect relationship has been established between the consumption of DHA and contribution to normal brain development.

The Panel considers that the following wording reflects the scientific evidence: "DHA contributes to normal brain development".

In order to bear the claim, foods for older infants (> 6 months of age) and young children below the age of 24 months should provide a daily intake of 100 mg DHA in one or more servings. Foods for children from 2 to 18 years should provide a daily intake of 250 mg DHA in one or more servings.

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## BACKGROUND

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 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 24/01/2014.
- The scope of the application was proposed to fall under a health claim referring to children's development and health.
- On 04/04/2014, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 15/04/2014, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 24/04/2014.
- During its meeting on 18/09/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to DHA and contribution to normal brain development.

## 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: pre-formed DHA and contributes to brain development.

## EFSA DISCLAIMER

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

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<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, p. 9–25.

## INFORMATION PROVIDED BY THE APPLICANT

**Applicant's name and address:** DSM Nutritional Products, 6450 Dobbin Road, Columbia, MD 21405, USA.

### Food/constituent as stated by the applicant

According to the applicant, the food that is the subject of the health claim is pre-formed DHA (docosahexaenoic acid; 22:6 n-3) from all sources.

### Health relationship as claimed by the applicant

According to the applicant, the ingestion of DHA supports brain development. The applicant argues that the DHA content in the brain increases progressively throughout the developmental period from birth to 18 years of age and that it responds to diet. The applicant also claims that pre-formed DHA favourably influences neurodevelopmental outcomes.

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

The applicant has proposed the following wording for the health claim: "Pre-formed DHA contributes to brain development".

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

The applicant proposed an intake of 250 mg pre-formed DHA/day. The proposed target population is infants and children up to 18 years of age. The applicant proposed that all sources of pre-formed DHA should be acceptable.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food that is the subject of the health claim is docosahexaenoic acid (DHA; 22:6 n-3).

DHA is a well-characterised n-3 long-chain fatty acid that can be quantified in foods by established methods. The absorption of DHA is well documented. This evaluation applies to all sources of DHA in the specified amounts.

The Panel considers that the food constituent, DHA, 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 "contributes to brain development". The target population proposed by the applicant is infants and children up to 18 years of age.

The Panel considers that contribution to normal brain development is a beneficial physiological effect for infants and children.

### 3. Scientific substantiation of the claimed effect

The applicant performed a literature search in Medline, Embase and the Cochrane database. Details of the search strategy, including the search terms, were provided. Studies were included if they were randomised, controlled trials in infants and children (up to 18 years of age) free of neurologic or behavioural disease or disorder and who had been supplemented, post-natally, with at least 0.3 % pre-formed DHA from any source and reported measures of basic neurologic function (excludes measures of cognition/intelligence/visual performance) related to brain development/cerebral maturation. Autopsy reports of human brain tissue content of DHA during various stages of infant/child development and studies in primates and piglets on DHA status of brain tissue were also included.

The applicant identified 14 human studies and 14 animal studies as being pertinent to the health claim.

The Panel has already assessed a claim on DHA and maintenance of normal brain function with a favourable outcome (EFSA NDA Panel, 2010a). The target population was the general population. The Panel considered that DHA is the major structural lipid in brain tissue and the central nervous system, and that the membrane lipids of brain grey matter and the retina contain high concentrations of DHA. The Panel noted the well-established role of DHA in brain function (EFSA NDA Panel, 2010a).

The Panel considers that the role of DHA in normal brain function applies to all ages, including brain development in infants and children. The Panel also notes that the developing brain accumulates large amounts of DHA, particularly during the first two years of life (EFSA NDA Panel, 2014), but also later and throughout childhood (Carver et al., 2001). Dietary Reference Values for pre-formed DHA have been set for infants and children (EFSA NDA Panel, 2010b).

The Panel concludes that a cause and effect relationship has been established between the consumption of DHA and contribution to normal brain development.

### 4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: "DHA contributes to normal brain development".

### 5. Conditions and restrictions of use

The Panel considers that, in order to bear the claim:

- for older infants (> 6 months of age) and young children below the age of 24 months, foods should provide a daily intake of 100 mg DHA in one or more servings (EFSA NDA Panel, 2010b);
- for children from 2 to 18 years, foods should provide a daily intake of 250 mg DHA in one or more servings.

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

## CONCLUSIONS

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

- The food constituent, DHA, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is “contributes to brain development”. The target population proposed by the applicant is infants and children up to 18 years of age. Contribution to normal brain development is a beneficial physiological effect for infants and children.
- A cause and effect relationship has been established between the consumption of DHA and contribution to normal brain development.
- The following wording reflects the scientific evidence: “DHA contributes to normal brain development”.
- In order to bear the claim, foods for older infants (> 6 months of age) and young children below the age of 24 months should provide a daily intake of 100 mg DHA in one or more servings. Foods for children from 2 to 18 years should provide a daily intake of 250 mg DHA in one or more servings.

## DOCUMENTATION PROVIDED TO EFSA

Health claim application on pre-formed DHA and contribution to normal brain development pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0409\_UK). January 2014. Submitted by DSM Nutritional Products.

## REFERENCES

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## ABBREVIATIONS

DHA docosahexaenoic acid