

## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to docosahexaenoic acid (DHA) and maintenance of normal (fasting) blood concentrations of triglycerides (ID 533, 691, 3150), protection of blood lipids from oxidative damage (ID 630), contribution to the maintenance or achievement of a normal body weight (ID 629), brain, eye and nerve development (ID 627, 689, 704, 742, 3148, 3151), maintenance of normal brain function (ID 565, 626, 631, 689, 690, 704, 742, 3148, 3151), maintenance of normal vision (ID 627, 632, 743, 3149) and maintenance of normal spermatozoa motility (ID 628) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>**

**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2, 3</sup>**

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to docosahexaenoic acid (DHA) and maintenance of normal (fasting) blood concentrations

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-1320, EFSA-Q-2008-1416, EFSA-Q-2008-1417, EFSA-Q-2008-1478, EFSA-Q-2008-3882, adopted on 30 April 2010. Question No EFSA-Q-2008-1352, EFSA-Q-2008-1413, EFSA-Q-2008-1414, EFSA-Q-2008-1415, EFSA-Q-2008-1418, EFSA-Q-2008-1419, EFSA-Q-2008-1476, EFSA-Q-2008-1477, EFSA-Q-2008-1491, EFSA-Q-2008-1529, EFSA-Q-2008-1530, EFSA-Q-2008-3880, EFSA-Q-2008-3881, EFSA-Q-2008-3883, adopted on 09 July 2010.

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of triglycerides, protection of blood lipids from oxidative damage, contribution to the maintenance or achievement of a normal body weight, brain, eye and nerve development, maintenance of normal brain function, maintenance of normal vision and maintenance of normal spermatozoa motility. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claim is docosahexaenoic acid (DHA). The Panel considers that DHA is sufficiently characterised.

### **Maintenance of normal (fasting) blood concentrations of triglycerides**

The claimed effect is “heart health”. The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal blood concentrations of triglycerides. The Panel considers that maintenance of normal (fasting) blood concentrations of triglycerides may be a beneficial physiological effect.

Among the references provided, two systematic reviews specifically addressed the effects of DHA alone on blood concentrations of triglycerides. Both reviews reported on randomised clinical trials (RCTs) in humans showing statistically significant reductions in triglyceride concentrations after DHA supplementation at daily doses of 3-4 g, whereas no significant changes were observed at daily doses <2 g per day.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of DHA and the maintenance of normal (fasting) blood concentrations of triglycerides.

In order to obtain the claimed effect, 2 g per day of DHA should be consumed in one or more servings. The target population is adult men and women.

### **Protection of blood lipids from oxidative damage**

The claimed effect is “supportive measure to reduce the level of oxidised cholesterol”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the protection of blood lipids (LDL-cholesterol particles) from oxidative damage. The Panel considers that protection of blood lipids from oxidative damage may be a beneficial physiological effect.

None of the studies provided directly addressed the effects of DHA supplementation on LDL oxidation.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of DHA and the protection of blood lipids from oxidative damage.

### **Contribution to the maintenance or achievement of a normal body weight**

The claimed effect is “weight management”. The target population is assumed to be the general population. The Panel considers that contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.

No references were provided from which scientific conclusions for the scientific substantiation of the claimed effect could be drawn.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of DHA and the contribution to the maintenance or achievement of a normal body weight.

### **Brain, eye and nerve development**

The claimed effects are “brain, eye and nerve development”, “optimisation of brain maturation”, “human neurodevelopment”, “brain health and function”, “brain development and function”, and “maternal health”.

Brain, eye and nerve development is interpreted by the Panel as children’s development. The Panel notes that claims related to children’s development and health are outside the scope of Article 13 of Regulation (EC) No 1924/2006.

### **Maintenance of normal brain function**

The claimed effects are “mental state and performance”, “DHA plays an important role in cognitive functions at any stage of life”, “brain health and function”, “optimisation of brain maturation”, “brain development and function”, “human neurodevelopment”, “maternal health” and “cognitive function in the elderly”. The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal brain function. The Panel considers that maintenance of normal brain function is a beneficial physiological effect.

The Panel notes that there is a well established role of DHA in brain function.

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

The Panel considers that in order to bear the claim, foods should contain 250 mg of DHA in one or more servings. Such amounts can be consumed as part of a balanced diet. The target population is the general population.

### **Maintenance of normal vision**

The claimed effects are “brain, eye and nerve development”, “visual health and function”, and “eye health”. The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal vision. The Panel considers that maintenance of normal vision is a beneficial physiological effect.

The Panel notes that there is a well established role of DHA in retinal function.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of DHA and the maintenance of normal vision.

The Panel considers that in order to bear the claim, foods should contain 250 mg of DHA in one or more servings. Such amounts can be consumed as part of a balanced diet. The target population is the general population.

### **Maintenance of normal spermatozoa motility**

The claimed effect is “supportive measure for male fertility through providing the motility agent for spermatozoa tails”. The target population is assumed to be the general male population. The Panel considers that maintenance of normal spermatozoa motility is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of DHA and the maintenance of normal spermatozoa motility.

**KEY WORDS**

Docosahexaenoic acid, DHA, blood lipids, oxidative damage, weight management, brain function, vision, spermatozoa motility, health claims.

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**BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION**

See Appendix A

**TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION**

See Appendix A

**EFSA DISCLAIMER**

See Appendix B

## INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006<sup>4</sup> submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out<sup>5</sup>. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is docosahexaenoic acid (DHA), which 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 claims is sufficiently characterised.

### 2. Relevance of the claimed effect to human health

#### 2.1. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 533, 691, 3150)

The claimed effect is “heart health”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal blood concentrations of triglycerides.

Triglycerides in plasma are either derived from dietary fats or synthesised in the body from other energy sources like carbohydrates. In fasting conditions, serum triglycerides are mainly transported in very-low-density lipoproteins (VLDL) which are synthesised in the liver. Excess energy intake with a meal is converted to triglycerides and transported to the adipose tissue for storage. Hormones regulate the release of triglycerides from adipose tissue in order to meet energy needs between meals.

The Panel considers that maintenance of normal (fasting) blood concentrations of triglycerides may be a beneficial physiological effect.

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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.

<sup>5</sup> Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims: <http://www.efsa.europa.eu/en/ndameetings/docs/nda100601-ax01.pdf>

## **2.2. Protection of blood lipids from oxidative damage (ID 630)**

The claimed effect is “supportive measure to reduce the level of oxidised cholesterol”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the protection of blood lipids (LDL-cholesterol particles) from oxidative damage.

Reactive oxygen species (ROS) including several kinds of radicals are generated in biochemical processes (e.g. respiratory chain) and as a consequence of exposure to exogenous noxes (e.g. radiation, pollutants). These reactive intermediates damage biologically relevant molecules such as DNA, proteins and lipids if they are not intercepted by the antioxidant network, which includes free radical scavengers such as antioxidant nutrients.

The Panel considers that protection of blood lipids from oxidative damage may be a beneficial physiological effect.

## **2.3. Contribution to the maintenance or achievement of a normal body weight (ID 629)**

The claimed effect is “weight management”. The Panel assumes that the target population is the general population.

Weight management can be interpreted as the contribution to the maintenance of a normal body weight. In this context, weight loss in overweight subjects without achieving a normal body weight is considered to be a beneficial physiological effect.

The Panel considers that contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.

## **2.4. Brain, eye and nerve development (ID 627, 689, 704, 742, 3148, 3151)**

The claimed effects are “brain, eye and nerve development”, “optimisation of brain maturation”, “brain development and function”, “human neurodevelopment”, “brain health and function”, and “maternal health”.

Brain, eye and nerve development is interpreted by the Panel as children’s development. The Panel notes that claims related to children’s development and health are outside the scope of Article 13 of Regulation (EC) No 1924/2006.

## **2.5. Maintenance of normal brain function (ID 565, 626, 631, 689, 690, 704, 742, 3148, 3151)**

The claimed effects are “mental state and performance”, “DHA plays an important role in cognitive functions at any stage of life”, “brain health and function”, “optimisation of brain maturation”, “brain development and function”, “human neurodevelopment”, “maternal health” and “cognitive function in the elderly”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal brain function.

The Panel considers that maintenance of normal brain function is a beneficial physiological effect.



## **2.6. Maintenance of normal vision (ID 627, 632, 743, 3149)**

The claimed effects are “brain, eye and nerve development”, “visual health and function” and “eye health”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal vision.

The Panel considers that maintenance of normal vision is a beneficial physiological effect.

## **2.7. Maintenance of normal spermatozoa motility (ID 628)**

The claimed effect is “supportive measure for male fertility through providing the motility agent for spermatozoa tails”. The Panel assumes that the target population is the general male population.

The Panel considers that maintenance of normal spermatozoa motility is a beneficial physiological effect.

## **3. Scientific substantiation of the claimed effect**

### **3.1. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 533, 691, 3150)**

The references provided for the substantiation of the claimed effect included general reviews, consensus opinions, nutrient recommendations and human intervention studies either on the health effects of combined long-chain n-3 polyunsaturated fatty acids (e.g. EPA plus DHA) from different sources (e.g. fish oil), or on the effects of DHA alone on clinical outcomes other than blood concentrations of triglycerides (e.g. haemostatic function, blood pressure, endothelial function). The Panel considers that no scientific conclusions can be drawn from these references in relation to the role of DHA alone in maintaining normal blood concentrations of triglycerides.

Among the references provided, only two systematic reviews specifically address the effect of DHA alone on blood concentrations of triglycerides (Mori and Woodman, 2006; Von Schacky, 2006). Both reviews reported on randomised clinical trials (RCTs) in humans showing statistically significant reductions in triglyceride concentrations after DHA supplementation at daily doses of 3-4 g, whereas no significant changes were observed at daily doses <2 g per day.

The Panel concludes that a cause and effect relationship has been established between the consumption of DHA and the maintenance of normal (fasting) blood concentrations of triglycerides.

### **3.2. Protection of blood lipids from oxidative damage (ID 630)**

The references provided for the substantiation of the claimed effect included animal and intervention studies on the combined effects of EPA plus DHA on different outcomes, including LDL oxidation. The Panel considers that no scientific conclusions can be drawn from these references in relation to the role of DHA alone in protecting blood lipids from oxidative damage.

Three of the references presented reported on RCTs (Mori et al., 2000; Woodman et al., 2003; Kelley et al., 2007) which investigated the effects of DHA supplementation on LDL particle size and/or the serum concentrations of small and dense LDL particles in humans. None of the studies directly addressed the effects of DHA supplementation on LDL oxidation.

The Panel concludes that a cause and effect relationship has not been established between the consumption of DHA and the protection of blood lipids from oxidative damage.

### 3.3. Contribution to the maintenance or achievement of a normal body weight (ID 629)

The references provided for the substantiation of the claimed effect included human observational and intervention studies on the effects of combined long-chain n-3 polyunsaturated fatty acids (e.g. EPA plus DHA) from different sources (e.g. fish oil) on fat oxidation, thermogenesis, quality of adipose tissue, glucose homeostasis, body composition or weight loss; animal and *in vitro* studies on the effects of DHA, either alone or in combination with EPA, on thermogenesis, lipid profile, fat oxidation, and adipocyte proliferation/differentiation; and general reviews on the molecular effects (e.g. gene expression) of long-chain n-3 polyunsaturated fatty acids. None of the references provided investigated the effects of DHA alone on measures of body weight. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of DHA and contribution to the maintenance or achievement of a normal body weight.

### 3.4. Maintenance of normal brain function (ID 565, 626, 631, 689, 690, 704, 742, 3148, 3151)

Deficiency of alpha linolenic acid, the parent fatty acid of the longer chain n-3 polyunsaturated fatty acids, including DHA, 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 devoid of such fatty acids. Biochemical changes of n-3 fatty acids 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). DHA is the major structural lipid in brain tissue and the central nervous system, and the membrane lipids of brain grey matter and the retina contain very high concentrations of DHA.

The Panel notes that there is a well established role of DHA in brain function.

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

### 3.5. Maintenance of normal vision (ID 627, 632, 743, 3149)

Deficiency of alpha linolenic acid, the parent fatty acid of the longer chain n-3 polyunsaturated fatty acids, including DHA, 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 devoid of such fatty acids. Biochemical changes of n-3 fatty acids 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). DHA is the major structural lipid in brain tissue and the central nervous system and the membrane lipids of brain grey matter and the retina contain very high concentrations of DHA. Biophysical and biochemical properties of DHA affect photoreceptor membrane function by altering permeability, fluidity, thickness, and lipid phase properties (Carlson et al., 1997).

The Panel notes that there is a well established role of DHA in retinal function.

The Panel concludes that a cause and effect relationship has been established between the consumption of DHA and the maintenance of normal vision.

### **3.6. Maintenance of normal spermatozoa motility (ID 628)**

Among the references provided for the substantiation of the claimed effect, one study did not address DHA, which is the food constituent that is the subject of the claim. One study evaluated the metabolism of fatty acids in isolated human testicular cells, another study measured the superoxide dismutase and fatty acid content of spermatozoa from normal vs. subfertile subjects and one study investigated the generation of reactive oxygen species by human spermatozoa in response to DHA exposure. The Panel considers that these endpoints are not appropriate endpoints for the claimed effect.

No intervention studies which evaluated the effect of dietary DHA on spermatozoa motility were provided. Five observational studies in humans evaluated associations between the DHA content of spermatozoa related to motility parameters in healthy, sub-fertile men or patients with retinis pigmentosa. The Panel notes that DHA intakes were not reported in these studies and no conclusions can be drawn for the scientific substantiation of the claimed effect.

Two animal studies did not address relevant endpoints and three animal studies evaluated the effect of an intervention with diets containing mixtures of fatty acids on animal semen composition and functional characteristics (including motility) of the semen. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of DHA and the maintenance of normal spermatozoa motility.

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

### **4.1. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 533, 691, 3150)**

The Panel considers that the following wording reflects the scientific evidence: "DHA contributes to the maintenance of normal blood triglyceride levels".

### **4.2. Maintenance of normal brain function (ID 565, 626, 631, 689, 690, 704, 742, 3148, 3151)**

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

### **4.3. Maintenance of normal vision (ID 627, 632, 743, 3149)**

The Panel considers that the following wording reflects the scientific evidence: "DHA contributes to the maintenance of normal vision."

## **5. Conditions and possible restrictions of use**

### **5.1. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 533, 691, 3150)**

The Panel considers that, in order to obtain the claimed effect, 2 g per day of DHA should be consumed in one or more servings. The target population is adult men and women.

### **5.2. Maintenance of normal brain function (ID 565, 626, 631, 689, 690, 704, 742, 3148, 3151)**

The Panel considers that, in order to bear the claim, foods should contain 250 mg of DHA in one or more servings. Such amounts can be consumed as part of a balanced diet. The target population is the general population.

### **5.3. Maintenance of normal vision (ID 627, 632, 743, 3149)**

The Panel considers that, in order to bear the claim, foods should contain 250 mg of DHA in one or more servings. Such amounts can be consumed as part of a balanced diet. The target population is the general population.

## **CONCLUSIONS**

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

- The food constituent, docosahexaenoic acid (DHA), which is the subject of the health claims, is sufficiently characterised.

### **Maintenance of normal (fasting) blood concentrations of triglycerides (ID 533, 691, 3150)**

- The claimed effect is “supportive measure to reduce the level of oxidised cholesterol”. The target population is assumed to be the general population. Maintenance of normal (fasting) blood concentrations of triglycerides may be a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of DHA and the maintenance of normal (fasting) blood concentrations of triglycerides.
- The following wording reflects the scientific evidence: “DHA contributes to the maintenance of normal blood triglyceride levels”.
- In order to obtain the claimed effect, 2 g per day of DHA should be consumed in one or more servings. The target population is adult men and women.

### **Protection of blood lipids from oxidative damage (ID 630)**

- The claimed effect is “supportive measure to reduce the level of oxidised cholesterol”. The target population is assumed to be the general population. Protection of blood lipids from oxidative damage may be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of DHA and the protection of blood lipids from oxidative damage.

### **Contribution to the maintenance or achievement of a normal body weight (ID 629)**

- The claimed effect is “weight management”. The target population is assumed to be the general population. Contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of DHA and contribution to the maintenance or achievement of a normal body weight.

### **Brain, eye and nerve development (ID 627, 689, 704, 742, 3148, 3151)**

- The claimed effects are “brain, eye and nerve development”, “optimisation of brain maturation”, “human neurodevelopment”, “brain development and function”, “brain health and function”, and “maternal health”.

- Brain, eye and nerve development is interpreted as children's development. Claims related to children's development and health are outside the scope of Article 13 of Regulation (EC) No 1924/2006.

#### **Maintenance of normal brain function (ID 565, 626, 631, 689, 690, 704, 742, 3148, 3151)**

- The claimed effects are "mental state and performance", "DHA plays an important role in cognitive functions at any stage of life", "brain health and function", "optimisation of brain maturation", "brain development and function", "human neurodevelopment", "maternal health" and "cognitive function in the elderly". The target population is assumed to be the general population. Maintenance of normal brain function is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of DHA and the maintenance of normal brain function.
- The following wording reflects the scientific evidence: "DHA contributes to the maintenance of normal brain function."
- In order to bear the claim, foods should contain 250 mg of DHA in one or more servings. The target population is the general population.

#### **Maintenance of normal vision (ID 627, 632, 743, 3149)**

- The claimed effects are "brain, eye and nerve development", "visual health and function", and "eye health". The target population is assumed to be the general population. Maintenance of normal vision is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of DHA and the maintenance of normal vision.
- The following wording reflects the scientific evidence: "DHA contributes to the maintenance of normal vision."
- In order to bear the claim, foods should contain 250 mg of DHA in one or more servings. The target population is the general population.

#### **Maintenance of normal spermatozoa motility (ID 628)**

- The claimed effect is "supportive measure for male fertility through providing the motility agent for spermatozoa tails". The target population is assumed to be the general male population. Maintenance of normal spermatozoa motility is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of DHA and the maintenance of normal spermatozoa motility.

#### **DOCUMENTATION PROVIDED TO EFSA**

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 No EFSA-Q-2008-1320, EFSA-Q-2008-1352, EFSA-Q-2008-1413, EFSA-Q-2008-1414, EFSA-Q-2008-1415, EFSA-Q-2008-1416, EFSA-Q-2008-1417, EFSA-Q-2008-1418, EFSA-Q-2008-1419, EFSA-Q-2008-1476, EFSA-Q-2008-1477, EFSA-Q-2008-1478, EFSA-Q-2008-1491, EFSA-Q-2008-1529, EFSA-Q-2008-1530, EFSA-Q-2008-3880, EFSA-Q-2008-3881, EFSA-Q-2008-3882, EFSA-Q-2008-3883. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

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## APPENDICES

### APPENDIX A

#### BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods<sup>6</sup> (hereinafter "the Regulation") entered into force on 19<sup>th</sup> January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

#### ISSUES THAT NEED TO BE CONSIDERED

##### IMPORTANCE AND PERTINENCE OF THE FOOD<sup>7</sup>

Foods are commonly involved in many different functions<sup>8</sup> of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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<sup>6</sup> OJ L12, 18/01/2007

<sup>7</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>8</sup> The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).



It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

#### **SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE**

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

#### **WORDING OF HEALTH CLAIMS**

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to



describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

## **TERMS OF REFERENCE**

### **HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH**

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

## **APPENDIX B**

### **EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. 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 wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to DHA, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
533	Docosahexaenoic acid (DHA)	Heart Health	<p>“DHA, an omega-3 fatty acid, supports heart health”.</p> <p>“DHA supports a healthy heart”.</p> <p>“DHA supports/helps maintain normal triglyceride levels”.</p>
			<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- At least 120 mg DHA/d. Recommended for the general population.</li> <li>- Amount of consumption: 2 Gramm (g); Upper level: 4 Gramm (g)</li> <li>- Amount of consumption: 200 mg/Tag; min 10% fat (product basis), min 70% UFA (fat basis), max 2% TFA (fat basis); min 30 mg very long chain omega 3 100 g/ml and 100 kcal (product basis), based on 15% of 200 mg GDA for Omega3 (VLC)</li> </ul>
ID	Food or Food constituent	Health Relationship	Proposed wording
565	DHA fatty acid	Mental state and performance	<p>Supports brain and memory activity.</p> <p>Fish oil capsules contain a lot of DHA fatty acids that are essential for the memory and brain activity.</p>
			<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Food supplement with 910 mg of DHA fatty acids derived from fish oil in the daily dose.</li> </ul>
			<p><b>No clarification provided by Member States</b></p>
ID	Food or Food constituent	Health Relationship	Proposed wording
626	DHA (docosahexaenoic acid)	<p>DHA plays an important role in cognitive functions at any stage of life</p> <p><u>Clarification provided</u></p> <p>Increases memory function, mental alertness and concentration ability in the elderly, as compared to their contemporaries who do not consume docosahexaenoic acid</p> <p>DHA is essential in normal brain function. DHA is essential for the vitality of mind.</p>	<p>DHA is essential in normal brain function.</p> <p>DHA contributes to the vitality of mind.</p>
			<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Minimum 25% of the AFSSA RDA per portion (=30mg of DHA/portion)</li> </ul>

	- Algal oil (with 10-40% DPAw6) providing at least 180 mg DHA/day (up to 1.7 g DHA/day).		
ID	Food or Food constituent	Health Relationship	Proposed wording
627	DHA omega-3 fatty acid *Note 'DHA' may be sourced from either fish or algal source.	Brain, eye and nerve development	<p>"DHA is important for normal eye function."</p> <p>"DHA supports visual function."</p> <p>"DHA is important for maintaining optimal cognitive functioning throughout life."</p> <p>"DHA supports optimal cognitive function."</p> <p>"DHA, an omega-3 fatty acid that is most concentrated in the brain and retina, supports normal cognitive and visual function."</p>
			<p><b>Conditions of use</b></p> <p>- 160 - 300 mg per day for pregnant and lactating women</p> <p>- Daily consumption from single or multiple sources of at least 200 mg of DHA</p>
ID	Food or Food constituent	Health Relationship	Proposed wording
628	Docosahexaenoic acid (DHA)	Supportive measure for male fertility through providing the motility agent for spermatozoa tails.	<p>Helps maintain sperm motility</p> <p>helps maintain a healthy male reproductive system</p>
			<p><b>Conditions of use</b></p> <p>- At least 220 mg DHA/day, based on a 2000 kcal diet</p>
ID	Food or Food constituent	Health Relationship	Proposed wording
629	Docosahexaenoic acid (DHA)	Weight management	<p>Helps to control body weight when combined with a healthy diet and exercise.</p> <p>Fits in a weight maintenance programme.</p> <p>Contributes to the reduction of body fat.</p> <p>Helps to control fat metabolism.</p>
			<p><b>Conditions of use</b></p> <p>At least 220 mg DHA/day, based on a 2000 kcal diet.</p>
ID	Food or Food constituent	Health Relationship	Proposed wording
630	Docosahexaenoic acid (DHA)	Supportive measure to reduce the level of oxidised cholesterol ('in vivo' research)	<p>Contributes to good quality of cholesterol particles.</p> <p>Contributes to good quality cholesterol.</p>
			<p><b>Conditions of use</b></p>

At least 220 mg DHA/day, based on a 2000 kcal diet.			
ID	Food or Food constituent	Health Relationship	Proposed wording
631	Docosahexaenoic acid (DHA)	Brain Health and Function <u>Clarification provided</u> Diets that improve DHA status help maintain cognitive ability with normal ageing" "DHA is a building block of the brain and facilitates transmission of messages between neurons" "DHA is the most abundant omega-3 in the brain"	"DHA is important for/supports brain function" "DHA is important for/supports brain function throughout life" "DHA is an important brain nutrient" "DHA is the most abundant omega-3 fatty acid in the brain"
			<b>Conditions of use</b> - General population
ID	Food or Food constituent	Health Relationship	Proposed wording
632	Docosahexaenoic acid (DHA)	Visual Health and Function	"DHA is important for/supports visual function" "DHA supports visual health" "DHA is an important eye nutrient" "DHA is the most abundant omega-3 fatty acid in the eye" "DHA is important for/supports visual development"
			<b>Conditions of use</b> - 85 mg per day - General Population
ID	Food or Food constituent	Health Relationship	Proposed wording
689	Docosahexaenoic acid (DHA)	Optimization of brain maturation <u>Clarification provided</u> Essential for membrane functions such as activity of membrane-bound enzymes and receptors, and signal transduction. Diets that improve DHA status help maintain cognitive ability with normal ageing. DHA is a building block of the brain and facilitates transmission of messages between	Helps optimize brain maturation/supports normal brain development/supports cognitive function and mental balance in early life

		neurons	
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 55 - 160 mg per day</li> <li>- Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance Number of nutrients/other substances that are essential to claimed effect: 1. Names of nutrient/other substances and Quantity in Average daily serving: 200 miligrams Docosahexaenoic acid (DHA omega-3). Daily amount to be consumed to produce claimed effect: 100 gram(s). Are there factors that could interfere with bioavailability: No. Length of time after consumption for claimed effect to become apparent: Uncertain. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No</li> </ul>			
ID	Food or Food constituent	Health Relationship	Proposed wording
690	Docosahexaenoic acid (DHA)	Cognitive function in the elderly	DHA may help maintain working memory and brain performance in aging adults/DHA is a building block of the brain and helps with the transmission of messages between nerves
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 720 - 1720 mg of DHA per day.</li> </ul>			
ID	Food or Food constituent	Health Relationship	Proposed wording
691	Docosahexaenoic acid (DHA)	Heart health	<p>“DHA, an omega-3 fatty acid, supports heart health”.</p> <p>“DHA supports a healthy heart”.</p> <p>“DHA supports/helps maintain normal triglyceride levels”.</p>
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- At least 120 mg/d DHA recommended for the general population</li> </ul>			
ID	Food or Food constituent	Health Relationship	Proposed wording
704	<p>Long-chain omega 3 (n-3) polyunsaturated fatty acids (LC omega 3 PUFA, LCn-3 PUFA) or EPA and DHA or docosahexaenoic acid (DHA; C22:6n-3) or omega 3 fish oils</p> <p><u>Clarification provided</u></p> <p>Docosahexaenoic acid (DHA; C22:6n-3), a member of the family of long-chain omega-3 (or n-3) polyunsaturated fatty acids (LC omega-3 PUFA, LC n-3 PUFA) consisting of EPA and DHA and present in plant oils like rapeseed oil</p>	Brain development and function	<p>DHA is an important building block of brain structure and therefore plays a role in maintaining normal brain and mental development and in healthy brain function.</p> <p>May help maintain concentration levels and healthy brain development.</p>

	or fish		
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 55 mg/day minimum. Applicable to adults and children</li> <li>- Jugendliche, Erwachsene. 1 Gramm (g)</li> <li>- Jugendliche, Erwachsene. Amount of consumption: 125 – 500 Milligramm (mg). Upper limit: 500 Milligramm (mg). Other condition: DHA/EPA</li> <li>- Amount of consumption: 30 Gramm (g) angenommene durchschnittliche Verzehrsmenge an Rapsspeiseöl pro Tag/entspricht ca. drei Esslöffeln. Other condition: entspricht einer täglichen Aufnahme von 2,88 g Omega-3-Fettsäuren durch 30 g Rapsspeiseöl pro Tag</li> <li>- Beikost + Juniomilch</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
742	Docosahexaenoic acid (DHA)	<p>Human Neurodevelopment</p> <p><u>Clarification provided</u></p> <p>DHA is an important component of brain and nerve structures. It specifically plays an important role in the development and maintenance of brain and nerves and contributes to normal brain, nerve and visual development.</p>	<p>Supports human neurodevelopment/plays an important role in the development of brain and nerves/</p>
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 160 - 300 mg per day for pregnant and lactating women</li> </ul>		
	<p><b>Comments from Member States</b></p> <p>Please amend CoU to include "for pregnant and lactating women".</p> <p>EW: A sufficient supply / regular consumption of DHA by pregnant and lactating mothers is important".</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
743	Docosahexaenoic acid (DHA)	Eye health	DHA is an important part of the structure of the retina and, therefore, plays a role in visual development and normal eye function
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 85 mg per day</li> <li>- Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance Number of nutrients/other substances that are essential to claimed effect: 1. Names of nutrient/other substances and Quantity in Average daily serving: 58mg DHA. Weight of average daily food serving: 58 miligram(s). Daily amount to be consumed to produce claimed effect: 150 miligram(s). Number of food portions this equates to in everyday food portions: 1. Are there factors that could interfere with bioavailability: Yes. Please give reason: esterification can alter bioavailability in comparison to natural triglycerides. Length of time after consumption for</li> </ul>		



	<p>claimed effect to become apparent: It is apparent after a period of regular use. Number of days: 84. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No</p> <p>- Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance Number of nutrients/other substances that are essential to claimed effect: 1. Names of nutrient/other substances and Quantity in Average daily serving: 30 miligrams Docosahexaenoic acid (DHA Omega-3). Daily amount to be consumed to produce claimed effect: 100 gram(s). Are there factors that could interfere with bioavailability: No.Length of time after consumption for claimed effect to become apparent: uncertain. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording	
3148	Docosahexaenoic acid (DHA)	<p>Brain Health and Function</p> <p><u>Clarification provided</u></p> <p>DHA is an important component of brain and nerve structures. It specifically plays an important role in the development and maintenance of brain and nerves</p>	<p>“DHA is important for/supports brain function”</p> <p>“DHA is important for/supports brain function throughout life”</p> <p>“DHA is an important brain nutrient”</p> <p>“DHA is the most abundant omega-3 fatty acid in the brain”</p> <p>“DHA, an omega-3 fatty acid, supports the normal development of the brain, eye, and nerves”</p> <p>“DHA, an omega-3 fatty acid, supports brain development”</p>	
			<p><b>Conditions of use</b></p> <p>- At least 100 mg DHA/d recommended for the general population</p>	
			<p><b>Comments from Member States</b></p> <p>The firm who sent this health claims originally did not added any new clarification but an another firm sent to this claim clarification from EHPM a ERNA and CIAA.</p>	
ID	Food or Food constituent	Health Relationship	Proposed wording	
3149	Docosahexaenoic acid (DHA)	<p>Visual Health and Function</p> <p><u>Clarification provided</u></p> <p>DHA is an important part of the structure of the retina and, therefore, plays a role in visual development and normal eye function</p>	<p>“DHA is important for/supports visual function”</p> <p>“DHA supports visual health”</p> <p>“DHA is an important eye nutrient”</p> <p>“DHA is the most abundant omega-3 fatty acid in the eye”</p> <p>“DHA is important for/supports visual development”</p>	
			<p><b>Conditions of use</b></p> <p>- At least 100 mg DHA/d recommended for the general population</p>	
			<p><b>Comments from Member States</b></p> <p>The firm who sent this health claims originally did not added any new clarification but an</p>	

	another firm sent to this claim clarification from EHPM a ERNA and CIAA		
ID	Food or Food constituent	Health Relationship	Proposed wording
3150	Docosahexaenoic acid (DHA)	Heart Health <u>Clarification provided</u> contributes to protect the arteries from narrowing and hardening and helps to reduce blood lipid levels and artery wall thickness.	“DHA, an omega-3 fatty acids, supports heart health”. “DHA supports a healthy heart” “DHA supports/helps maintain normal triglyceride levels”
		<b>Conditions of use</b> - At least 120 mg DHA/d. Recommended for the general population.	
		<b>Comments from Member States</b> The firm who sent this health claims originally did not added any new clarification but an another firm sent to this claim clarification from EHPM a ERNA and CIAA.	
ID	Food or Food constituent	Health Relationship	Proposed wording
3151	Docosahexaenoic acid (DHA)	Maternal Health <u>Clarification provided</u> DHA is an important component of brain and nerve structures. It specifically plays an important role in the development and maintenance of brain and nerves and contributes to normal brain, nerve and visual development of foetus and infants.	“DHA, an omega-3 fatty acid, supports maternal health” “DHA supports a healthy pregnancy” “Maternal intake of DHA supports breast milk DHA levels during nursing”
		<b>Conditions of use</b> - At least 200 mg DHA/d. Recommended for the general female population to include women of childbearing age, pregnant or nursing women	

## GLOSSARY AND ABBREVIATIONS

DHA	Docosahexaenoic acid
DNA	Deoxyribonucleic acid
EPA	Eicosapentaenoic acid
LDL	Low-density lipoproteins
RCT	Randomised clinical trial
ROS	Reactive oxygen species
VLDL	Very-low-density lipoproteins