

## SCIENTIFIC OPINION

**Scientific Opinion on the substantiation of health claims related to docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and brain, eye and nerve development (ID 501, 513, 540), maintenance of normal brain function (ID 497, 501, 510, 513, 519, 521, 534, 540, 688, 1323, 1360, 4294), maintenance of normal vision (ID 508, 510, 513, 519, 529, 540, 688, 2905, 4294), maintenance of normal cardiac function (ID 510, 688, 1360), “maternal health; pregnancy and nursing” (ID 514), “to fulfil increased omega-3 fatty acids need during pregnancy” (ID 539), “skin and digestive tract epithelial cells maintenance” (ID 525), enhancement of mood (ID 536), “membranes cell structure” (ID 4295), “anti-inflammatory action” (ID 4688) and maintenance of normal blood LDL-cholesterol concentrations (ID 4719) 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

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-1284, EFSA-Q-2008-1288, EFSA-Q-2008-1295, EFSA-Q-2008-1297, EFSA-Q-2008-1300, EFSA-Q-2008-1301, EFSA-Q-2008-1306, EFSA-Q-2008-1308, EFSA-Q-2008-1312, EFSA-Q-2008-1316, EFSA-Q-2008-1321, EFSA-Q-2008-1323, EFSA-Q-2008-1326, EFSA-Q-2008-1327, EFSA-Q-2008-1475, EFSA-Q-2008-2060, EFSA-Q-2008-2097, EFSA-Q-2008-3638, EFSA-Q-2010-00247, EFSA-Q-2010-00248, EFSA-Q-2010-00641, EFSA-Q-2010-00672, adopted by written procedure on 17 February 2011.

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<sup>3</sup> Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain, and Peter Willatts.

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in relation to docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and brain, eye and nerve development, maintenance of normal brain function, maintenance of normal vision, maintenance of normal cardiac function, “maternal health; pregnancy and nursing”, “skin and digestive tract epithelial cells maintenance”, enhancement of mood, “to fulfil increased omega-3 fatty acids need during pregnancy”, “membranes cell structure”, “anti-inflammatory action” and maintenance of normal blood LDL-cholesterol concentrations. 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 claims is long-chain n-3 polyunsaturated fatty acids (n-3 LCPUFAs), namely docosahexaenoic acid (DHA) in combination with eicosapentaenoic acid (EPA). The Panel considers that DHA and EPA are sufficiently characterised.

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

The claimed effects are “brain development, cognitive development and cognitive function”, “brain, eye and nerve development and function”, and “support of human neurodevelopment”.

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 “brain/cognitive function”, “brain development, cognitive development and cognitive function”, “eye, brain and heart health”, “brain, eye and nerve development and function”, “brain and eye function”, “brain function”, “n-3 are essential fatty acids and have critical roles in the membrane structure and as precursors of eicosanoids”, “support of human neurodevelopment”, “eye, brain and heart health”, “système nerveux, réduction des risques liés au développement de la maladie d’Alzheimer”, “health benefits of food: Dairygold Omega-3 spread contain omega-3 fatty acids (EPA & DHA) which may have a beneficial role to play in the functioning of the brain and can help maintain a healthy heart”, and “membranes cell structure”. The target population is assumed to be the general population. In the context of the proposed wordings and the clarifications provided, the Panel assumes that the claimed effect refers to maintenance of normal brain function.

A claim on DHA and maintenance of normal brain function has already been assessed with a favourable outcome.

### **Maintenance of normal vision**

The claimed effects are “eye health”, “eye, brain and heart health”, “brain, eye and nerve development and function”, “brain and eye function”, “support of human neurodevelopment”, “building block for lipids in the retina’s photoreceptors; eye health”, and “membranes cell structure”. The target population is assumed to be the general population. In the context of the proposed wordings and the clarifications provided, the Panel assumes that the claimed effect refers to maintenance of normal vision.

A claim on DHA and maintenance of normal vision has already been assessed with a favourable outcome.

### **Maintenance of normal cardiac function**

The claimed effects are “eye, brain and heart health”, and “health benefits of food: Dairygold Omega-3 spread contain omega-3 fatty acids (EPA & DHA) which may have a beneficial role to play in the functioning of the brain and can help maintain a healthy heart”. The target population is assumed to be the general population.

A claim on DHA/EPA and maintenance of normal cardiac function has already been assessed with a favourable outcome.

#### **“Maternal health; pregnancy and nursing”**

The claimed effect is “maternal health; pregnancy and nursing”. The Panel assumes that the target population is pregnant and lactating women.

The claimed effect is not sufficiently defined, and no further details were provided in the proposed wordings or the clarifications provided by Member States.

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

#### **“To fulfil increased omega-3 fatty acids need during pregnancy”**

The claimed effect is “to fulfil increased omega-3 fatty acids need during pregnancy”. The Panel assumes that the target population is pregnant and lactating women.

The Panel assumes that the claimed effect refers to the supply of omega-3 fatty acids to the body during pregnancy and lactation. The Panel considers that the claimed effect refers to the supply of a food constituent to the human body, rather than to a relationship between a food/food constituent and health as required by Regulation (EC) No 1924/2006.

#### **“Skin and digestive tract epithelial cells maintenance”**

The claimed effect is “skin and digestive tract epithelial cells maintenance”. The target population is assumed to be the general population.

The claimed effect is not sufficiently defined. The proposed wordings do not provide further clarification or do not refer to a physiological function; the clarifications provided by Member States include several physiological functions; and the references provided did not allow the identification of the specific function which is the target for the claim.

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

#### **Enhancement of mood**

The claimed effect is “mood”. The target population is assumed to be the general population. In the context of the clarifications provided, the Panel assumes that the claimed effect refers to enhancement of mood. The Panel considers that enhancement of mood might be a beneficial physiological effect.

No intervention studies were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect, and one observational study showed no association between the consumption of DHA/EPA and mood.

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/EPA and enhancement of mood.

#### **“Membranes cell structure”**

The claimed effect is “membranes cell structure”. The target population is assumed to be the general population.

The claimed effect is not sufficiently defined. The proposed wordings do not provide further clarification, and from the references provided it was not possible to establish which effect is the target for the claim.

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

#### **“Anti-inflammatory action”**

From the proposed wordings, the Panel assumes that the claimed effect refers to anti-inflammatory action in the context of “inflammatory, rheumatic disease”, in which a reduction of inflammation would be a therapeutic target for the treatment of the disease.

The Panel considers that the reduction of inflammation in the context of inflammatory diseases is a therapeutic target for the treatment of a disease, and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

#### **Maintenance of normal blood LDL-cholesterol concentrations**

The claimed effect is “blood health”. 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 maintenance of normal blood LDL-cholesterol concentrations.

A claim on DHA and EPA and maintenance of normal blood LDL-cholesterol concentrations has already been assessed with an unfavourable outcome. The references cited for this claim did not provide any additional scientific data which could be used to substantiate the claim.

#### **KEY WORDS**

Docosahexaenoic acid, DHA, eicosapentaenoic acid, EPA, cardiac function, brain, vision, mood, LDL-cholesterol, 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 long-chain n-3 polyunsaturated fatty acids (n-3 LCPUFAs), namely docosahexaenoic acid (DHA) in combination with eicosapentaenoic acid (EPA).

The n-3 LCPUFAs, EPA and DHA, are well recognised nutrients and are measurable in foods by established methods. They are well absorbed when consumed in the form of triglycerides. This evaluation applies to EPA and DHA from all sources with appropriate bioavailability in the specified amounts.

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

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

#### 2.1. Brain, eye and nerve development (ID 501, 513, 540)

The claimed effects are “brain development, cognitive development and cognitive function”, “brain, eye and nerve development and function”, and “support of human neurodevelopment”.

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.

#### 2.2. Maintenance of normal brain function (ID 497, 501, 510, 513, 519, 521, 534, 540, 688, 1323, 1360, 4294)

The claimed effects are “brain/cognitive function”, “brain development, cognitive development and cognitive function”, “eye, brain and heart health”, “brain, eye and nerve development and function”, “brain and eye function”, “brain function”, “n-3 are essential fatty acids and have critical roles in the membrane structure and as precursors of eicosanoids”, “support of human neurodevelopment”, “eye,

<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>

brain and heart health”, “système nerveux, réduction des risques liés au développement de la maladie d'Alzheimer”, “health benefits of food: Dairygold Omega-3 spread contain omega- 3 fatty acids (EPA & DHA) which may have a beneficial role to play in the functioning of the brain and can help maintain a healthy heart”, and “membranes cell structure”. The Panel assumes that the target population is the general population. In the context of the proposed wordings and the clarifications provided, the Panel assumes that the claimed effects refer to the maintenance of normal brain function.

A claim on DHA and maintenance of normal brain function has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010b).

### **2.3. Maintenance of normal vision (ID 508, 510, 513, 519, 529, 540, 688, 2905, 4294)**

The claimed effects are “eye health”, “eye, brain and heart health”, “brain, eye and nerve development and function”, “brain and eye function”, “support of human neurodevelopment”, “building block for lipids in the retina’s photoreceptors; eye health”, and “membranes cell structure”. The Panel assumes that the target population is the general population. In the context of the proposed wordings and the clarifications provided, the Panel assumes that the claimed effects refer to the maintenance of normal vision.

A claim on DHA and maintenance of normal vision has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010b).

### **2.4. Maintenance of normal cardiac function (ID 510, 688, 1360)**

The claimed effects are “eye, brain and heart health”, and “health benefits of food: Dairygold Omega-3 spread contain omega- 3 fatty acids (EPA & DHA) which may have a beneficial role to play in the functioning of the brain and can help maintain a healthy heart”. The Panel assumes that the target population is the general population. The Panel notes that the claimed effects refer to the maintenance of normal cardiac function.

A claim on DHA and EPA and maintenance of normal cardiac function has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010a).

### **2.5. “Maternal health; pregnancy and nursing” (ID 514)**

The claimed effect is “maternal health; pregnancy and nursing”. The Panel assumes that the target population is pregnant and lactating women.

The claimed effect is not sufficiently defined, and no further details were given in the proposed wording or the clarifications provided by Member States.

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

### **2.6. “To fulfil increased omega-3 fatty acids need during pregnancy” (ID 539)**

The claimed effect is “to fulfil increased omega-3 fatty acids need during pregnancy”. The Panel assumes that the target population is pregnant and lactating women.

The Panel assumes that the claimed effect refers to the supply of omega-3 fatty acids to the body during pregnancy and lactation.

The Panel considers that the claimed effect refers to the supply of a food constituent to the human body, rather than to a relationship between a food/food constituent and health as required by Regulation (EC) No 1924/2006.

### **2.7. “Skin and digestive tract epithelial cells maintenance” (ID 525)**

The claimed effect is “skin and digestive tract epithelial cells maintenance”. The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined. The proposed wordings do not provide further clarification (“a healthy digestive system, gentle on the stomach”) or do not refer to a physiological function (“appearance of skin, healthy looking skin, a part of your daily skin care routine, helps maintain a good complexion”) as required by Regulation (EC) No 1924/2006. The clarifications provided by Member States include several physiological functions, and the references provided do not allow the identification of the specific function which is the target for the claim.

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

### **2.8. Enhancement of mood (ID 536)**

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

In the context of the clarifications provided, the Panel assumes that the claimed effect refers to enhancement of mood. Mood is a well-defined psychological construct and can be measured by validated tests.

The Panel considers that enhancement of mood might be a beneficial physiological effect.

### **2.9. “Membranes cell structure” (ID 4295)**

The claimed effect is “membranes cell structure”. The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined. The proposed wordings did not provide further clarification (“contributes to thin the blood”), and from the references provided it was not possible to establish the effect which was the target for the claim.

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

### **2.10. “Anti-inflammatory action” (ID 4688)**

The claimed effect is “anti-inflammatory action due to EPA and DHA”. The Panel assumes that the target population is the general population.

From the proposed wordings, the Panel assumes that the claimed effect refers to anti-inflammatory action in the context of “inflammatory, rheumatic disease”, in which a reduction of inflammation would be a therapeutic target for the treatment of the disease.

The Panel considers that the reduction of inflammation in the context of inflammatory diseases is a therapeutic target for the treatment of a disease, and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

## 2.11. Maintenance of normal blood LDL-cholesterol concentrations (ID 4719)

The claimed effect is “blood health”. 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 maintenance of normal blood LDL-cholesterol concentrations.

A claim on DHA and EPA and maintenance of normal blood LDL-cholesterol concentrations has already been assessed with an unfavourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009). The references cited for this claim did not provide any additional scientific data which could be used to substantiate the claim.

## 3. Scientific substantiation of the claimed effect

### 3.1. Enhancement of mood (ID 536)

Among the references provided were narrative reviews which mostly reported on the use of omega-3 fatty acids either alone or in conjunction with pharmacological intervention in depression. These studies did not describe the food constituent under investigation or did not address a relevant endpoint. In addition, a number of references reported on studies which were carried out in pregnant women or in patient groups with post-partum depression, major depressive disorder which required inpatient treatment, violence disorders, bipolar disorder and schizophrenia. The Panel considers that the evidence provided does not establish that results obtained in studies in subjects with post-partum depression, major depressive disorder, violence disorders, bipolar disorder and schizophrenia can be extrapolated to the general population with respect to mood. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

One systematic review carried out by Schachter et al. (2005) for the Agency for Healthcare Research and Quality (AHRQ) addressed, *inter alia*, the question of the protective value of n-3 fatty acids with respect to mental health. Three intervention studies, six observational studies and three cross-national ecological studies met the authors' inclusion criteria, and were included in the review. One of the randomised controlled trials assessed the risk of post-partum depression using a supplement containing DHA only, rather than DHA and EPA which is the subject of the claim. The other two intervention studies were based on a dietary change to increase fish consumption, but DHA and EPA intakes were not measured. There were four observational studies on the relationship between fish consumption and depressed mood or prevalence of depression, and three cross-national studies investigating the association of seafood consumption with the prevalence of post-partum depression or depression. The Panel notes that the only epidemiological study in the systematic review, which calculated DHA and EPA intakes on the basis of self-reported fish consumption, showed no association between intake of these fatty acids and prevalence of depression.

Two of the human studies provided were intervention studies (Fontani et al., 2005a; 2005b). One of these studies (Fontani et al., 2005a) investigated the effects of diet and fish oil (containing EPA and DHA) supplementation on an index of mood state in addition to blood lipids, insulin and various biomarkers of inflammatory processes. This study was performed in 33 subjects who were divided into two groups following an open-label, parallel group design. Both groups followed a controlled diet which differed in amount of carbohydrates and proteins (55/15 E% (N diet group, n=17) vs. 40/30 E% (Z diet group, n=16) respectively, 30 E% fat in both). In each diet group a double-blind cross-over design was applied: one sub-group received placebo (olive oil) for 35 days and then fish oil supplementation for another 35 days, while the other sub-group started with fish oil supplementation followed by placebo. Mood state was measured using the Profile of Mood States (POMS) which consists of five negative scales (anger, anxiety, fatigue, confusion, depression) and one positive scale

(vigour). The Panel notes that the statistical analysis employed was not appropriate for the treatment of a cross-over design, and that no corrections for multiple comparisons were made. The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claimed effect.

The other study by Fontani et al. (2005b) used a parallel design in which 33 subjects received EPA and DHA as fish oil for 35 days, and a second group of 16 subjects received a placebo consisting of olive oil capsules for the same period. Mood state was measured on the first and last day of the intervention using the POMS. The Panel notes that the statistical analysis only evaluated within group data, and did not perform comparisons between groups. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claimed effect.

Of the three observational human studies provided, two (Edwards et al., 1998; Tanskanen et al., 2001) were included in the systematic review by Schachter et al. (2005). The observational study by Mamalakis et al. (2002) investigated the association between adipose tissue fatty acid content and depression in 139 participants with a mean age of 39 years. Subjects underwent physical examination and adipose tissue extraction (by aspiration of subcutaneous tissue samples), and completed the Zung Self-rated Depression Scale (translated). The Panel notes that dietary intakes of EPA and DHA were not estimated, that adipose tissue EPA and DHA concentrations are usually only moderately associated with the consumption of EPA and DHA, and that an observational cross-sectional study does not provide evidence on a causal relationship between the intake of DHA and EPA and mood. The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claimed effect.

The Panel notes that no intervention studies were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect, and that the one observational study which evaluated dietary intakes of EPA and DHA showed no association between the consumption of DHA and EPA and prevalence of depression.

The Panel concludes that a cause and effect relationship has not been established between the consumption of DHA and EPA and enhancement of mood.

## CONCLUSIONS

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

- The food constituent, DHA and EPA, which is the subject of the health claims, is sufficiently characterised.

### **Brain, eye and nerve development (ID 501, 513, 540)**

- The claimed effects are “brain development, cognitive development and cognitive function”, “brain, eye and nerve development and function”, and “support of human neurodevelopment”. 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 497, 501, 510, 513, 519, 521, 534, 540, 688, 1323, 1360, 4294)**

- The claimed effects are “brain/cognitive function”, “brain development, cognitive development and cognitive function”, “eye, brain and heart health”, “brain, eye and nerve

development and function”, “brain and eye function”, “brain function”, “n-3 are essential fatty acids and have critical roles in the membrane structure and as precursors of eicosanoids”, “support of human neurodevelopment”, “eye, brain and heart health”, “système nerveux, réduction des risques liés au développement de la maladie d'Alzheimer”, “health benefits of food: Dairygold Omega-3 spread contain omega-3 fatty acids (EPA & DHA) which may have a beneficial role to play in the functioning of the brain and can help maintain a healthy heart”, and “membranes cell structure”. The target population is assumed to be the general population.

- A claim on DHA and maintenance of normal brain function has already been assessed with a favourable outcome.

#### **Maintenance of normal vision (ID 508, 510, 513, 519, 529, 540, 688, 2905, 4294)**

- The claimed effects are “eye health”, “eye, brain and heart health”, “brain, eye and nerve development and function”, “brain and eye function”, “support of human neurodevelopment”, “building block for lipids in the retina’s photoreceptors; eye health”, and “membranes cell structure”. The target population is assumed to be the general population.
- A claim on DHA and maintenance of normal vision has already been assessed with a favourable outcome.

#### **Maintenance of normal cardiac function (ID 510, 688, 1360)**

- The claimed effects are “eye, brain and heart health”, and “health benefits of food: Dairygold Omega-3 spread contain omega-3 fatty acids (EPA & DHA) which may have a beneficial role to play in the functioning of the brain and can help maintain a healthy heart”. The target population is assumed to be the general population.
- A claim on DHA and EPA and maintenance of normal cardiac function has already been assessed with a favourable outcome.

#### **“Maternal health; pregnancy and nursing” (ID 514)**

- The claimed effect is “maternal health; pregnancy and nursing”. The target population is assumed to be pregnant and lactating women.
- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

#### **“To fulfil increased omega-3 fatty acids need during pregnancy” (ID 539)**

- The claimed effect is “to fulfil increased omega-3 fatty acids need during pregnancy”. The Panel assumes that the target population is pregnant and lactating women. It is assumed that the claimed effect refers to the supply of omega-3 fatty acids to the body during pregnancy and lactation.
- The claimed effect refers to the supply of a food constituent to the human body rather than to a relationship between a food/food constituent and health as required by Regulation (EC) No 1924/2006.

### **“Skin and digestive tract epithelial cells maintenance” (ID 525)**

- The claimed effect is “skin and digestive tract epithelial cells maintenance”. The target population is assumed to be the general population.
- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

### **Enhancement of mood (ID 536)**

- The claimed effect is “mood”. The target population is assumed to be the general population. Enhancement of mood might be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of DHA and EPA and enhancement of mood.

### **“Membranes cell structure” (ID 4295)**

- The claimed effect is “membranes cell structure”. The target population is assumed to be the general population.
- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

### **“Anti-inflammatory action” (ID 4688)**

- The claimed effect is “anti-inflammatory action due to EPA and DHA”. The target population is assumed to be the general population. From the proposed wordings, the Panel assumes that the claimed effect refers to anti-inflammatory action in the context of “inflammatory, rheumatic disease”, in which a reduction of inflammation would be a therapeutic target for the treatment of the disease.
- Reduction of inflammation in the context of inflammatory diseases is a therapeutic target for the treatment of a disease, and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

### **Maintenance of normal blood LDL-cholesterol concentrations (ID 4719)**

- The claimed effect is “blood health”. The target population is assumed to be the general population.
- A claim on DHA and EPA and maintenance of normal blood LDL-cholesterol concentrations has already been assessed with an unfavourable outcome. The references cited for this claim did not provide any additional scientific data which could be used to substantiate the claim.

### **DOCUMENTATION PROVIDED TO EFSA**

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1284, EFSA-Q-2008-1288, EFSA-Q-2008-1295, EFSA-Q-2008-1297, EFSA-Q-2008-1300, EFSA-Q-2008-1301, EFSA-Q-2008-1306, EFSA-Q-2008-1308, EFSA-Q-2008-1312, EFSA-Q-2008-1316, EFSA-Q-2008-1321, EFSA-Q-2008-1323, EFSA-Q-2008-1326, EFSA-Q-2008-1327, EFSA-Q-2008-1475, EFSA-Q-2008-2060, EFSA-Q-2008-2097, EFSA-Q-2008-3638, EFSA-Q-2010-00247, EFSA-Q-2010-00248, EFSA-Q-2010-00641, EFSA-Q-2010-00672). 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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- EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010a. Scientific Opinion on the substantiation of health claims related to eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), docosapentaenoic acid (DPA) and maintenance of normal cardiac function (ID 504, 506, 516, 527, 538, 703, 1128, 1317, 1324, 1325), maintenance of normal blood glucose concentrations (ID 566), maintenance of normal blood pressure (ID 506, 516, 703, 1317, 1324), maintenance of normal blood HDL-cholesterol concentrations (ID 506), maintenance of normal (fasting) blood concentrations of triglycerides (ID 506, 527, 538, 1317, 1324, 1325), maintenance of normal blood LDL-cholesterol concentrations (ID 527, 538, 1317, 1325, 4689), protection of the skin from photo-oxidative (UV-induced) damage (ID 530), improved absorption of EPA and DHA (ID 522, 523), contribution to the normal function of the immune system by decreasing the levels of eicosanoids, arachidonic acid-derived mediators and pro-inflammatory cytokines (ID 520, 2914), and “immunomodulating agent” (4690) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. *EFSA Journal*, 8(10):1796, 32 pp.
- EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010b. 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(3) of Regulation (EC) No 1924/2006. *EFSA Journal*, 8(10):1734, 27 pp.
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## APPENDICES

### APPENDIX A

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

The Regulation (EC) No 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 and EPA, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
497	Fish oil	Brain / cognitive function	Omega-3 fatty acids can help maintain:
			- optimal brain function
			- optimal cognitive function
<b>Conditions of use</b>			
- 1.5g daily of EPA/DHA is recommended. Do not use if taking anti-coagulant medication (e.g. warfarin or aspirin)			
<b>No clarification provided by Member States</b>			
ID	Food or Food constituent	Health Relationship	Proposed wording
501	Long chain Omega 3 fatty acids	Brain development, cognitive development and cognitive function	Long chain omega 3 fatty acids contribute to mental and cognitive function
		<u>Clarification provided</u> - Long chain omega-3 fatty acids are essential in normal brain and mental development. - Long chain omega-3 fatty acids are essential in normal brain function - DHA is the major fatty acid constituent in mammalian brain tissue - Long chain Omega 3 fatty acids are structural components of nervose cells and therefore necessary in proper brain development. Long chain fatty acids are important for functional maintenance of the CNS - Improve cognitive functions - Maintain membrane fluidity in brain cells.	
<b>Conditions of use</b>			
- Amount of consumption: mind. 300 mg langkettige n-3-Fettsäuren (EPA + DHA) / d			
- Amount of consumption: 160 mg/Tag. Upper limit: 300. Other condition: Verzehrsmenge für Schwangere und Stillende			

	<ul style="list-style-type: none"> <li>- min 10% fat (product basis), max 33% SAFA (fat basis), max 2% TFA (fat basis); min 30mg VLC Omega 3 per 100g/ml and 100kcal (product basis), based on 15% of 200mg GDA for VLC Omega3</li> <li>- Minimum 500mg of LC-PUFA (AFSSA RDA value) per day</li> <li>- Fruit drink that contain 18-30 mg/100 g, 45-75 mg/serving of omega-3 fatty acids.</li> <li>- Omega 3 (EPA and DHA) At least 250 mg of total omega 3 (EPA+DHA).</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
508	Omega 3 fatty acids	Eye health	<p>Show anti-inflammatory properties</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><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Richtiges Verhältnis von omega-3 und omega-6 Fettsäuren zugunsten der omega-3 Fettsäuren</li> <li>- In Verbindung mit Vitamin C, E, B6, B12 und Zink</li> <li>- Erwachsene. Amount of consumption: 160 Milligramm (mg). Period of consumption: Dauersupplementierung. Upper limit: 3 Gramm (g). Other condition: betrifft nur DHA und EPS (aus Fischöl)</li> <li>- 125 - 500 mg</li> <li>- 10mg lutein between 500 and 1000mg of Omega 3</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
510	DHA+EPA - long chain omega 3 fatty acids	Eye, brain and heart health	Omega 3 fatty acids support a healthy heart.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Minimum 0.3 g per 100g (15% of the 2 g RDI suggested by SCF)</li> </ul>		
	<p><b>No clarification provided by Member States</b></p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
513	Long-chain omega-3 fatty acids EPA and DHA	Brain, eye and nerve development and function	<p>“Long-chain Omega-3 fatty acids EPA and DHA are important for brain development and function”</p> <p>“Long-chain Omega-3 fatty acids EPA and DHA support normal development of the brain, eyes and nerves”</p> <p>“Long-chain Omega-3 fatty acids EPA and DHA support optiDHA, an omega-3 fatty acid that is most concentrated in the brain and retina, supports normal cognitive and</p>

			<p>visual function.”</p> <p>“DHA is important for brain development and function.”</p> <p>“DHA supports normal cognitive development.”</p> <p>“DHA is important for normal eye development and function.”</p> <p>“DHA supports visual development and function.”</p>
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Erwachsene. Amount of consumption: 200 Milligramm (mg). Upper limit: 500 Milligramm (mg). Other condition: DHA/EPA</li> <li>- Daily consumption from single or multiple sources of at least 200 mg of DHA</li> <li>- General population. Minimum 15% RDI per 100g or 100kcal. (RDI for EPA+DHA assumed as 200mg/day)</li> <li>- Food supplement with 580mg of EPA fatty acids and 83 mg of DHA fatty acids in the daily dose.</li> <li>- Food supplement with 500-3000 mg of fish oil omega-3-fatty acids (EPA and DHA) in the daily dose.</li> <li>- 55 mg/day minimum</li> <li>- General population. Minimum 15% RDI per 100g or 100kcal (RDI for EPA+DHA assumed as 200mg/day)</li> </ul>			
ID	Food or Food constituent	Health Relationship	Proposed wording
514	Long-chain Omega-3 fatty acids EPA and DHA	<p>Maternal Health; Pregnancy and nursing</p> <p><u>Clarification provided</u></p> <p>The omega-3 fatty acids EPA and DHA help sustain pregnancy duration. Consumption of long chain omega-3 fatty acids increases breast milk DHA levels during nursing. Consumption of long chain omega-3 fatty acids during pregnancy and nursing increases the mother's DHA stores. Maternal consumption of EPA and DHA during pregnancy may support neural and visual development in the unborn baby.</p>	<p>“Long-chain Omega-3 fatty acids EPA and DHA during pregnancy support mum's DHA levels”“Long-chain Omega-3 fatty acids EPA and DHA during breast-feeding supports DHA levels in breast milk”“Long-chain Omega-3 fatty acids EPA and DHA support a healthy pregnancy”</p>
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- General population. Minimum 15% RDI per 100g or 100kcal (RDI for EPA+DHA assumed</li> </ul>			

	<p>as 200mg/day)</p> <ul style="list-style-type: none"> <li>- Minimum 15% RNI per 100g or 100kcal or Or amount to provide minimum 200 mg DHA/d 300-400mg DHA, 36-60mg EPA per day</li> </ul> <p>General Population.</p> <p>Minimum 15% RDI per 100g or 100kcal. (RDI for EPA+DHA assumed as 200mg/day)</p>		
	<p><b>Comments from Member States</b></p> <p>No comment received from applicant in the Netherlands UK proposal: The omega-3 fatty acids EPA and DHA help sustain pregnancy duration. Consumption of long chain omega-3 fatty acids increases breast milk DHA levels during nursing. Consumption of long chain omega-3 fatty acids during pregnancy and nursing increases the mother's DHA stores. Maternal consumption of EPA and DHA during pregnancy may support neural and visual development in the unborn baby.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
519	Long Chain Fatty Acids (EPA/DHA)	Brain and Eye Function	May help maintain brain and eye function
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 5-10ml per day</li> <li>- Food supplement with 450-900 mg of EPA fatty acids and 200-400 mg of DHA fatty acids in the daily dose.</li> <li>- Food supplement with 580mg of EPA fatty acids and 83 mg of DHA fatty acids in the daily dose.</li> <li>- Food supplement with 500-3000mg of EPA fatty acids and DHA fatty acids in the daily dose.</li> <li>- Amount of consumption: 200mg/Tag. Other condition: min 10% fat (product basis), max 33% SAFA (fat basis), max 2% TFA (fat basis); min 30mg VLC Omega 3 per 100g/ml and 100kcal (product basis), based on 15% of 200mg GDA for VLC Omega3</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
521	Long Chain Fatty Acids (EPA/DHA)	Brain Function	Supplementation of omega 3 oils may help maintain mental function during pregnancy and lactation.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Senioren. Amount of consumption: 720 mg/Tag. Upper limit: 1720 Milligramm (mg)</li> <li>- 110-220 mg DHA entspricht 290-580 mg DHA reiches Algenöl</li> <li>- Amount of consumption: 55 mg/Tag. Upper limit: 160</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
525	Omega-3 fish body oil - PUFAs	Skin and digestive tract epithelial cells maintenance	May help maintain a healthy digestive system Gentle on the stomach Appearance of skin,

		<p><u>Clarification provided</u></p> <p>Helps to maintain fluidity of cell membranes thus helping to increase the moisture content of epithelial tissue (which includes skin and gut mucosa). Increases moisture content of skin cells thus improving the appearance of dry skin. Increases elasticity of epithelial tissue. Used by the body to produce certain prostaglandins (series 1 &amp; 3) that play a role in reducing inflammation Improves the structure of villi hence play a role in improving absorption of nutrients. Maintains structure of the epithelial layer of gastrointestinal mucosa therefore can help to improve ability to absorb nutrients. Increase surface area and thickness of cells lining the intestines resulting in enhanced absorption of nutrients. Plays a role in mitigating the damaging effects associated with excessive saturated fat intake by readdressing the balance/Plays a role in mitigating against potential damage caused by excessive levels of saturated fat. Increase the time food spends in the stomach resulting in increased time for breakdown thus improved digestion.</p>	<p>healthy looking skin, a part of your daily skin care routine, helps maintain a good complexion.</p>
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Food supplement with 500-3000mg of EPA fatty acids and DHA fatty acids in the daily dose</li> <li>- Usual consumption as traditional foodstuff in a normal diet.. 340mg total Omega 3 fatty acids daily.</li> </ul>			
ID	Food or Food constituent	Health Relationship	Proposed wording
529	Omega 3 fatty acids (DHA/EPA)	Eye health	DHA is an important component of the retina and helps to maintain visual faculty

	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 150-350mg DHA, 36-100mg EPA per day. 125 - 500mg omega-3 fatty acids per day.</li> <li>- Jugendliche, Erwachsene. Amount of consumption: 50 – 150</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
534	Fish oil 1 N-3 (EPA, DHA)	<p>n-3 are essential fatty acids and have critical roles in the membrane structure and as precursors of eicosanoids</p> <p><u>Clarification provided</u></p> <p>Fish oil is important for brain function and improves memory and attention.</p>	<p>Fish oil helps maintain brain function</p> <p>Fish oil helps maintain vigour</p> <p>Fish oil helps maintain mental strength and energy</p> <p>Fish oil is an important component of the brain</p> <p>Fish oil helps/contribute to maintain a healthy memory</p>
			<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Minimum 1g fish oil equal to on average 320 EPA and 220 DHA</li> <li>- Säuglingsanfangsnahrung–DHA mindestens 0,2% von Gesamtfettsäuren, Verhältnis ARA/DHA mindestens 1 —Frühgeborennahrung–DHA mindestens 0,2% von Gesamtfettsäuren, Verhältnis ARA/DHA mindestens 1</li> </ul>
ID	Food or Food constituent	Health Relationship	Proposed wording
536	EPA and DHA Omega-3 fatty acids	<p>Mood</p> <p><u>Clarification provided</u></p> <p>Regular Omega-3 intake can help reduce how often you feel sad and low</p>	<p>Omega-3 EPA and DHA support normal emotional wellbeing</p>
			<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- General Population. Minimum 15% RDI per 100g or 100kcal. (RDI for EPA+DHA assumed as 200mg/day)</li> <li>- Food supplement with 450-900 mg of EPA and 200-400 mg of DHA fatty acids derived from fish oil in the daily dose.</li> <li>- Equivalent of 200mg to 1,2g/d of Long Chain Poly Unsaturated Fatty Acids (LC-PUFA) omega 3 (EPA and/or DHA)</li> <li>- DHA: 0,8 g to 1,8 g per day or/and EPA: 0,9 g to 1,6 g per day or ALA: 9 g per day.</li> <li>- Omega 3 (EPA and DHA) At least 300 mg per day of total essential fatty acids (EPA + DHA)</li> </ul>
ID	Food or Food constituent	Health Relationship	Proposed wording
539	Omega-3 fatty acids (incl. DHA)	<p>To fulfil increased omega-3 fatty acids need during pregnancy</p> <p><u>Clarification provided</u></p> <p>To fulfil increased omega-3 fatty acids need during pregnancy, necessary to</p>	<p>To fulfil increased omega-3 fatty acids need during pregnancy</p>

		cover the increased metabolism and tissue growth	
<b>Conditions of use</b> - 125 - 500 mg - 125 - 500 mg			
ID	Food or Food constituent	Health Relationship	Proposed wording
540	Omega-3 fatty acids (incl. DHA)	<p>Support of human neurodevelopment</p> <p><u>Clarification provided</u></p> <p>It supports normal brain and nerves structure and function, being integral part of the nervous system cells.</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>It supports an optimal brain development</p> <p>It supports human neurodevelopment,</p> <p>Plays an important role in the development of brain and nerves,</p> <p>Contributes to normal brain, nerve and visual development.</p>
<b>Conditions of use</b> - 125 - 500 mg			
ID	Food or Food constituent	Health Relationship	Proposed wording
688	DHA+EPA - long chain omega 3 fatty acids	<p>Eye, brain and heart health</p> <p><u>Clarification provided</u></p> <p>Eye health: Omega-3 / Omega-6-fatty are molecule precursor affecting the production and quality of tear film composition (by affecting lipid profiles of meibomian gland secretions)</p>	Omega 3 fatty acids support a healthy heart.
<b>Conditions of use</b> - Jugendliche, Erwachsene. Amount of consumption: 200 – 600 . - In Verbindung mit Vitamin C, E, B6, B12 und Zink - Richtiges Verhältnis von omega-3 und omega-6 Fettsäuren zugunsten der omega-3 Fettsäuren			
ID	Food or Food constituent	Health Relationship	Proposed wording
1323	Poisson sauvage	<p>Système nerveux</p> <p>Réduction des risques liés au</p>	Contribue à un bon équilibre nerveux

		développement de la maladie d'Alzheimer	Favorise un bon équilibre mental chez les personnes âgées Pour garder une bonne mémoire Pour conserver une bonne mémoire
<b>Conditions of use</b>			
- Huile 6 x 500mg/jour			
ID	Food or Food constituent	Health Relationship	Proposed wording
1360	Name of Food product: Dairygold Omega-3 Spread  Description of food in terms of food legislation categories: food not covered by specific food legislation  Was food on Irish market before 1st July 2007: Yes	Health benefits of food: Dairygold Omega-3 spread contain omega-3 fatty acids (EPA & DHA) which may have a beneficial role to play in the functioning of the brain and can help maintain a healthy heart  Do benefits relate to a disease risk factor: No  Target group: All of the general population including children and adults	Exact wording of claim as it appears on product: Front of Pack: Dairygold Omega 3. Low fat (38%) spread with omega 3 for healthy hearts* and minds. (Heart Health Claim submitted separately).  Back of pack: Omega 3 fatty acids (EPA & DHA) are important nutrients for brain function and therefore may enhance learning and concentration.  Examples of any alternative wording that may be used in relation to claim: Packaging contains the omega symbol but this is not directly implicit of the health claim.  Is claim a picture: No
<b>Conditions of use</b>			
- Number of nutrients/other substances that are essential to claimed effect: 1. Names of nutrient/other substances and Quantity in Average daily serving: 148 milligrams Omega-3 fatty acids. Weight of average daily food serving: 148 milligram(s). Daily amount to be consumed to produce claimed effect: 450 milligram(s). Number of food portions this equates to in everyday food portions: 3. Are there factors that could interfere with bioavailability: Yes. Please give reason: Omega-3 fatty acids are derived from fish oil and are susceptible to oxidation. Due to the lipid content of this food matrix, the EPA and DHA content are relatively stable and are unlikely to oxidize. However, over exposure of the spread to atmospheric oxygen for long periods should be avoided. Length of time after consumption for claimed effect to become apparent: Cognitive improvements have been reported in children following 3 months supplementation with Omega-3 fatty acids. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No. Where applicable outline nutritional composition (g per 100g) of food: Total Fat: 38.00, Saturated Fat: 11.00, Trans Fat: .00, Sugar: .10, Salt: 1.50, Sodium: .60. Other conditions for use: Long chain PUFA's (Omega 3 & 6 fatty acids) from fish oil are well documented to have an important role to play in the functioning of the brain. Omega fatty acids comprise one third of the total fatty acids in brain tissue and are thought to have a myriad of functions including maintaining membrane fluidity which in turn affects			

	<p>neural signaling. n-3 PUFA's also affect neurotransmission in the frontal lobes of the brain. It is well recognised that western diets are deficient in Omega-3. Diarygold Omega 3 spread contributes a rich, readily available, source of omega-3 fatty acids to the diet. 3 x 10g portions will provide one third of the recommended daily intake of Omega 3 fatty acids (RDI 450mg). The remainder should be achieved through a healthy balanced diet including at least 2-3 portions of fish per week, one of which should be oily.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
2905	Long-chain omega-3 (n-3) polyunsaturated fatty acids (LC omega-3 PUFA, LC n-3 PUFA) or docosahexaenoic acid or eicosapentaenoic acid or omega-3 fish oils	Building block for lipids in the retina's photoreceptors; 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 and healthy vision
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Applicable to adults and children</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
4294	fish oil (EPA, DHA)	Membranes cell structure	Contributes to the normal membrane cell structure (brain and retina cell)
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Dose: 24mg/day of fish oil Target group: old people, people having slight fall of concentration and memorization</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
4295	fish oil (EPA, DHA)	Membranes cell structure	Contributes to thin the blood
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Dose: 24mg/day of fish oil Target group: old people, people having slight fall of concentration and memorization</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
4688	Omega 3-Fatty acids containing eicosapentaenoic acid-EPA and docosahexaenoic acid (DHA).	Anti-inflammatory action due to EPA and DHA.	Function in the synthesis of prostaglandins. Helps in inflammatory, rheumatismal disease.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Adults and children: 500 - 1000 mg Omega 3 per day.</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
4719	Pure salmon oil 500 mg. D alpha tocopherol10 mg.-cps	Blood Health	Supports the normal level of blood cholesterol.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 2 capsules/ day - 1000 mg. /day, min. 90 days</li> </ul>		

## **GLOSSARY AND ABBREVIATIONS**

AHRQ	Agency for healthcare research and quality
DHA	Docosahexaenoic acid
EPA	Eicosapentaenoic acid
LCPUFA	Long-chain polyunsaturated fatty acids
POMS	Profile of mood states
RCT	Randomised controlled trial