

## SCIENTIFIC OPINION

**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<sup>1</sup>**

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

European Food Safety Authority (EFSA), Parma, Italy

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## 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 eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), docosapentaenoic acid (DPA) and maintenance of normal cardiac function, maintenance of normal blood glucose concentrations, maintenance of normal blood pressure, maintenance of normal blood HDL-cholesterol concentrations, maintenance of normal (fasting) blood concentrations of triglycerides, maintenance of normal blood LDL-cholesterol concentrations, protection of the skin from photo-oxidative (UV-induced) damage, improved absorption of EPA and DHA, contribution to the normal function of the immune system by decreasing the levels of eicosanoids, arachidonic acid-derived mediators and pro-inflammatory cytokines, and “immunomodulating agent”. 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 mixed long-chain n-3 polyunsaturated fatty acids (n-3 LCPUFA), namely docosahexaenoic acid (DHA) in combination with eicosapentaenoic acid (EPA) and, for ID 703, with docosapentaenoic acid (DPA). The Panel considers that the food constituent, EPA, DHA and DPA, which is the subject of the health claims, is sufficiently characterised.

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

The claimed effects are “cardiovascular system: maintenance and promotion of heart health and healthy circulation”, “normal cardiovascular function”, “eye, brain and heart health”, “cardiovascular health” and “heart health”. The target population is assumed to be the general population. The Panel considers that maintenance of normal cardiac function is a beneficial physiological effect.

Recommendations for dietary intake of EPA and DHA of national and international bodies have been based on the inverse relationship observed between the consumption of these long-chain n-3 PUFAs (primarily from fish and fish oils) and a lower risk of coronary artery disease.

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

The Panel considers that intakes of EPA and DHA of about 250 mg per day are required to obtain the claimed effect. Such an amount can be consumed as part of a balanced diet. The target population is the general population.

### **Maintenance of normal blood glucose concentrations**

The claimed effect is “carbohydrate metabolism and insulin sensitivity”. The target population is assumed to be the general population. The Panel considers that long-term maintenance of normal blood glucose concentrations 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 EPA and DHA and long-term maintenance of normal blood glucose concentrations.

### **Maintenance of normal blood pressure**

The claimed effects are “cardiovascular health”, “heart health”, “normal cardiovascular function” and “heart health”. The target population is assumed to be the general population.

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

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

The claimed effect is “normal cardiovascular function”. The target population is assumed to be the general population.

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

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

The claimed effects are “normal cardiovascular function”, “cardiovascular health”, “heart health”, “for cardiovascular system metabolism (cholesterol, triglycerides)” and “decrease triglycerides”. The target population is assumed to be the general population. The Panel considers that maintenance of normal (fasting) blood concentrations of triglycerides may be a beneficial physiological effect.

A claim on EPA and DHA and the maintenance of normal (fasting) blood concentrations of triglycerides has been already assessed with a favourable outcome.

With reference to its previous opinion, the Panel considers that intakes of EPA and DHA of 2 g per day are required to obtain the claimed effect. Such an amount can be consumed as part of a balanced diet. The target population is adult men and women.

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

The claimed effects are “cardiovascular health”, “heart health”, “cholesterol-lowering” and “for cardiovascular system metabolism (cholesterol, triglycerides)”. The target population is assumed to be the general population.

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

#### **Protection of the skin from photo-oxidative (UV-induced) damage**

The claimed effect is “skin health”. The target population is assumed to be the general population. The Panel considers that protection of the skin from photo-oxidative (UV-induced) damage is a beneficial physiological effect.

No human studies have been 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 EPA and DHA and the protection of the skin from photo-oxidative (UV-induced) damage.

#### **Improved absorption of EPA and DHA**

The claimed effects are “intake of emulsified fish oil improves the digestion and absorption of omega-3 fatty acids” and “intake of emulsified cod liver oil improves the digestion and absorption of omega-3 fatty acids”. The target population is assumed to be the general population.

The Panel notes that the claimed effects relate to the bioavailability of the food constituents (EPA and DHA) rather than to the relationship between a food constituent and health as required by Regulation (EC) No 1924/2006.

### **Contribution to the normal function of the immune system by decreasing the levels of eicosanoids, arachidonic acid-derived mediators and pro-inflammatory cytokines**

The claimed effects are “immune function” and “normal immune system function”. The target population is assumed to be the general population. From the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to supporting a normal/healthy immune function in the context of decreasing the level or production of eicosanoids, arachidonic acid-derived mediators and pro-inflammatory cytokines.

Whether or not reduction of inflammatory markers is considered beneficial would depend on the context in which the claim is made. The Panel considers that the evidence provided does not define the context whereby decreasing the level or production of eicosanoids, arachidonic acid-derived mediators and pro-inflammatory cytokines might be a beneficial physiological effect in the general healthy population.

The Panel concludes that a cause and effect relationship has not been established between the consumption of DHA and EPA and a beneficial physiological effect related to the contribution to the normal function of the immune system by decreasing the levels of eicosanoids, arachidonic acid-derived mediators and pro-inflammatory cytokines.

#### **“Immunomodulating agent”**

The claimed effect is “immunomodulating agent due to EPA and DHA”. The target population is assumed to be the general population. “Immunomodulating agent” is not sufficiently defined and no further details are given in the proposed wording. The references that were cited for the scientific substantiation of the claimed effect addressed several endpoints and it is not possible to establish which specific effect is the target for the claim. In the absence of such information, the Panel considers that the claimed effect is not sufficiently defined for a scientific evaluation.

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.

#### **KEY WORDS**

DHA, EPA, DHA, DPA, blood pressure, cardiovascular, blood lipids, triglycerides, HDL-cholesterol, 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 which is the subject of the health claims is mixed long-chain n-3 polyunsaturated fatty acids (n-3 LCPUFA), namely docosahexaenoic acid (DHA) in combination with eicosapentaenoic acid (EPA) and, for ID 703, with docosapentaenoic acid (DPA).

The n-3 LCPUFA EPA, DHA and DPA are 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, DHA and, for ID 703, DPA from all sources with suitable bioavailability in the specified amounts.

The Panel considers that the food constituent, EPA, DHA and DPA, 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 cardiac function (ID 504, 506, 516, 527, 538, 703, 1128, 1317, 1324, 1325)

The claimed effects are “cardiovascular system: maintenance and promotion of heart health and healthy circulation”, “normal cardiovascular function”, “eye, brain and heart health”, “cardiovascular health” and “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 notes that the claimed effects relate to the maintenance of normal cardiac function.

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

#### 2.2. Maintenance of normal blood glucose concentrations (ID 566)

The claimed effect is “carbohydrate metabolism and insulin sensitivity”. The Panel assumes that the target population is the general population.

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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>

In the context of the proposed wording, the Panel assumes that the claimed effect refers to the long-term maintenance or achievement of normal blood glucose concentrations.

The Panel considers that long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.

### **2.3. Maintenance of normal blood pressure (ID 506, 516, 703, 1317, 1324)**

The claimed effects are “cardiovascular health”, “heart health”, “normal cardiovascular function” and “heart health”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings or clarifications provided by Member States, the Panel assumes that the claimed effect relates to the maintenance of normal blood pressure.

A claim on EPA and DHA and the maintenance of normal blood pressure has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009).

### **2.4. Maintenance of normal blood HDL-cholesterol concentrations (ID 506)**

The claimed effect is “normal cardiovascular function”. The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal blood HDL-cholesterol concentrations.

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

### **2.5. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 506, 527, 538, 1317, 1324, 1325)**

The claimed effects are “normal cardiovascular function”, “cardiovascular health”, “heart health”, “for cardiovascular system metabolism (cholesterol, triglycerides)” and “decrease triglycerides”. 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 relates to the maintenance of normal (fasting) 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) synthesised in the liver. Excess calorie 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.



## **2.6. Maintenance of normal blood LDL-cholesterol concentrations (ID 527, 538, 1317, 1325, 4689)**

The claimed effects are “cardiovascular health”, “heart health”, “cholesterol-lowering” and “for cardiovascular system metabolism (cholesterol, triglycerides)”. 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 LDL-cholesterol concentrations.

A claim on EPA and DHA and the 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) and the references cited for this claim did not provide any additional scientific data that could be used to substantiate the claim.

## **2.7. Protection of the skin from photo-oxidative (UV-induced) damage (ID 530)**

The claimed effect is “skin 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 claim refers to the protection of the skin from photo-oxidative (UV-induced) damage.

The Panel considers that the protection of the skin from photo-oxidative (UV-induced) damage is a beneficial physiological effect.

## **2.8. Improved absorption of EPA and DHA (ID 522, 523)**

The claimed effects are “intake of emulsified fish oil improves the digestion and absorption of omega-3 fatty acids” and “intake of emulsified cod liver oil improves the digestion and absorption of omega-3 fatty acids”. 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 effects relate to an improved absorption of EPA and DHA from emulsified fish oils as compared to other (non emulsified) sources of EPA and DHA.

Regulation (EC) No 1924/2006 defines health claims made on foods 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” (Article 2.5), whereas that “the nutrient or other substance for which the claim is made is in a form that is available to be used by the body” (Article 5.1(c)) is a general condition for all claims.

The Panel notes that the claimed effects relate to the improved absorption of the food constituents (EPA and DHA) rather than to the relationship between a food constituent and health as required by Regulation (EC) No 1924/2006.

## **2.9. 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)**

The claimed effects are “immune function” and “normal immune system function”. The target population is assumed to be the general population.

From the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to supporting a normal/healthy immune function in the context of decreasing the level or production of eicosanoids, arachidonic acid-derived mediators and pro-inflammatory cytokines.

Inflammation is a non-specific physiological response to tissue damage that is mediated by the immune system. Adequate inflammatory responses are of primary importance for the defence against injury of any origin. Changes in markers of inflammation such as decreasing the levels of eicosanoids, arachidonic acid-derived mediators and pro-inflammatory cytokines do not indicate a beneficial physiological effect *per se*.

Chronic inflammation is associated with a number of diseases, and under certain circumstances reducing levels of markers of inflammation might indicate a beneficial physiological effect.

Whether or not reduction of inflammatory markers is considered beneficial would depend on the context in which the claim is made. The Panel considers that the evidence provided does not define the context whereby decreasing the level or production of eicosanoids, arachidonic acid-derived mediators and pro-inflammatory cytokines might be a beneficial physiological effect in the general healthy population.

The Panel concludes that a cause and effect relationship has not been established between the consumption of DHA and EPA and a beneficial physiological effect related to the contribution to the normal function of the immune system by decreasing the levels of eicosanoids, arachidonic acid-derived mediators and pro-inflammatory cytokines.

## **2.10 “Immunomodulating agent” (ID 4690)**

The claimed effect is “immunomodulating agent due to EPA and DHA”. The Panel assumes that the target population is the general population.

“Immunomodulating agent” is not sufficiently defined and no further details are given in the proposed wording. In the references, that were cited for the scientific substantiation of the claimed effect several effects were mentioned (related for example to coronary heart disease, rheumatoid arthritis, asthma or eczema) and it is not possible to establish which specific effect is the target for the claim.

In the absence of such information, the Panel considers that the claimed effect is not sufficiently defined for a scientific evaluation.

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.

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

### **3.1. Maintenance of normal cardiac function (ID 504, 506, 516, 527, 538, 703, 1128, 1317, 1324, 1325)**

National and international bodies have based their recommendations for dietary intake of EPA and DHA on the inverse relationship observed between the consumption of these long-chain n-3 PUFAs (primarily from fish and fish oils) and a lower risk of coronary artery disease. Such recommendations range from 200 mg to 500 mg per day (EFSA, 2005, 2009; EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2010). Most recent evidence derived from meta-analyses of randomised trials and large prospective studies shows that, when only healthy subjects are considered, the intake of EPA plus DHA is negatively related to coronary heart disease mortality in a dose-dependent way up to about 250 mg per day (1–2 servings of oily fish per week), with little additional

benefit observed at higher intakes (Mozaffarian and Rimm, 2006; Mozaffarian, 2008; Harris et al., 2008, 2009a, b; EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2010).

EPA and DHA intakes could reduce the risk of coronary heart disease mortality by different (but often overlapping) mechanisms (e.g. through antiarrhythmic and antithrombotic effects, by reducing blood pressure, heart rate and plasma concentrations of triglycerides), and the doses of EPA and DHA (100->2,500 mg/d) as well as the time required to observe clinical effects and/or alter clinical events (weeks to years) through each mechanism may vary widely (Mozaffarian and Rimm, 2006).

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

### **3.2. Maintenance of normal blood glucose concentrations (ID 566)**

Three references were provided for the scientific substantiation of this claim. One was a narrative review on n-3 fatty acids and the metabolic syndrome, one reported on an intervention study on the effects of a hypocaloric low-fat dietary intervention limiting intake of fatty fish and fish oil supplements on membrane fatty acid composition and insulin sensitivity, and the third reference reported on an intervention study investigating the acute effects of n-3 long-chain polyunsaturated fatty acids on dexamethasone-induced insulin resistance in healthy human volunteers. No measures of blood glucose control were reported in any of these studies. 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 EPA and DHA and long-term maintenance of normal blood glucose concentrations.

### **3.3. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 506, 527, 538, 1317, 1324, 1325)**

A claim on EPA and DHA and the maintenance of normal (fasting) blood concentrations of triglycerides has been already assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009). The Panel considered that intakes of EPA and DHA of about 2-4 g per day were required to obtain the claimed effect.

The Panel is aware of a recently published meta-analysis which aimed to investigate dose-response relationships between the intake of EPA and DHA and changes in blood concentrations of triglycerides to estimate the effects of doses between 200-500 mg per day (Musa-Veloso et al., 2010). A total of 15 studies published between 2002 and 2007 were considered. The reason given to exclude publications prior to 2002 was "to avoid duplication of previously reported findings". Of these, only 12 studies conducted statistical comparisons between intervention and placebo groups. Average intakes of EPA and DHA were 2.3 g per day (range 209 mg to 5.6 g per day). The Panel notes that four studies were conducted with DHA only (Maki et al., 2003, 2005; Stark and Holub, 2004; Wu et al., 2006). The Panel also notes that only two studies were included using doses of DHA or EPA plus DHA in the range for which an effect on blood triglycerides was aimed for, that neither of these found a significant decrease in blood triglycerides in the intervention group compared to controls (Maki et al., 2003; Castro et al., 2007), and that one of them is considered as "flawed" by the authors of the meta-analysis (Castro et al., 2007). The Panel notes that exclusion of pertinent studies published before 2002 is scientifically unjustified. The Panel considers that no scientific conclusions can be drawn from this meta-analysis to establish conditions of use for the claim.

In addition to Maki et al. (2003) and Castro et al. (2007), only one study included in the meta-analysis used doses of EPA plus DHA <1 g per day (0.860 mg per day). In this study, additional intakes in the intervention and placebo groups of about 1,200 mg per day from dietary sources were estimated but were not taken into account in the analysis (Hamazaki et al., 2003). A further two studies using EPA

and DHA at doses of 1 and 1.6 g per day were included in the meta-analysis (Goyens and Mensink, 2006; Murphy et al., 2007), none of these reported statistically significant differences between the intervention and control groups with respect to changes in blood concentrations of triglycerides.

With reference to its previous opinion, the Panel considers that intakes of EPA and DHA of 2 g per day are required to obtain the claimed effect.

### **3.4. Protection of the skin from photo-oxidative (UV-induced) damage (ID 530)**

Among the 26 references provided for the scientific substantiation of this claim, most reported on food constituents (e.g. vitamin E) and/or health effects (e.g. coronary heart disease, sudden cardiac death, blood lipids, blood glucose control, infertility, pregnancy, inflammation, psoriasis, non-melanoma skin cancer) unrelated to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

Two of the references are general reviews on the role of n-3 fatty acids on the pathogenesis of skin cancer (Black and Rhodes, 2006) and photo-protection (Rhodes, 1998) but did not provide original data for the scientific substantiation of the claimed effect.

An open label intervention study in humans on the effects of fish oil supplementation on the minimal erythral dose of UVB irradiation, and on the threshold UVB irradiation dose for papule provocation in patients with polymorphic light eruption, was presented (Rhodes et al., 1995). The Panel notes that no conclusions can be drawn from this uncontrolled study for the scientific substantiation of the claimed effect.

A double-blind, placebo controlled intervention study was presented on the effects of EPA alone (4 g per day) on a range of indicators of ultraviolet radiation (UVR)-induced responses and damage in humans, as well as on basal and post-UVR oxidative status (Rhodes et al., 2003). The Panel considers that no conclusions can be drawn from this study on EPA alone for the scientific substantiation of a claim on the combination of EPA and DHA.

The Panel concludes that a cause and effect relationship has not been established between the consumption of EPA and DHA and the protection of the skin from photo-oxidative (UV-induced) damage.

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

### **4.1. Maintenance of normal cardiac function (ID 504, 506, 516, 527, 538, 703, 1128, 1317, 1324, 1325)**

The Panel considers that the following wording reflects the scientific evidence: "EPA and DHA contribute to the normal function of the heart".

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

### **5.1. Maintenance of normal cardiac function (ID 504, 506, 516, 527, 538, 703, 1128, 1317, 1324, 1325)**

The Panel considers that intakes of EPA and DHA of about 250 mg per day are required to obtain the claimed effect. Such an amount can be consumed as part of a balanced diet. The target population is the general population.

## **5.2. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 506, 527, 538, 1317, 1324, 1325)**

The Panel considers that intakes of EPA and DHA of 2 g per day are required to obtain the claimed effect. Such an amount can be consumed as part of a balanced diet. The target population is adult men and women.

### **CONCLUSIONS**

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

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

#### **Maintenance of normal cardiac function (ID 504, 506, 516, 527, 538, 703, 1128, 1317, 1324, 1325)**

- The claimed effects are “cardiovascular system: maintenance and promotion of heart health and healthy circulation”, “normal cardiovascular function”, “eye, brain and heart health”, “cardiovascular health” and “heart health”. The target population is assumed to be the general population. Maintenance of normal cardiac function is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of EPA and DHA and maintenance of normal cardiac function.
- The following wording reflects the scientific evidence: “EPA and DHA contribute to the normal function of the heart”.
- Intakes of EPA and DHA of about 250 mg per day are required to obtain the claimed effect. Such an amount can be consumed as part of a balanced diet. The target population is the general population.

#### **Maintenance of normal blood glucose concentrations (ID 566)**

- The claimed effect is “carbohydrate metabolism and insulin sensitivity”. The target population is assumed to be the general population. Long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of EPA and DHA and long-term maintenance of normal blood glucose concentrations.

#### **Maintenance of normal blood pressure (ID 506, 516, 703, 1317, 1324)**

- The claimed effects are “cardiovascular health”, “heart health”, “normal cardiovascular function” and “heart health”. The target population is assumed to be the general population.
- A claim on EPA and DHA and the maintenance of normal blood pressure has already been assessed with a favourable outcome.

#### **Maintenance of normal blood HDL-cholesterol concentrations (ID 506)**

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

### **Maintenance of normal (fasting) blood concentrations of triglycerides (ID 506, 527, 538, 1317, 1324, 1325)**

- The claimed effects are “normal cardiovascular function”, “cardiovascular health”, “heart health”, “for cardiovascular system metabolism (cholesterol, triglycerides)” and “decrease triglycerides”. 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 claim on EPA and DHA and the maintenance of normal (fasting) blood concentrations of triglycerides has been already assessed with a favourable outcome.
- Intakes of EPA and DHA of 2 g per day are required to obtain the claimed effect. Such an amount can be consumed as part of a balanced diet. The target population is adult men and women.

### **Maintenance of normal blood LDL-cholesterol concentrations (ID 527, 538, 1317, 1325, 4689)**

- The claimed effects are “cardiovascular health”, “heart health”, “cholesterol-lowering” and “for cardiovascular system metabolism (cholesterol, triglycerides)”. The target population is assumed to be the general population.
- A claim on EPA and DHA and the maintenance of normal blood LDL-cholesterol concentrations has already been assessed with an unfavourable outcome and the references cited for this claim did not provide any additional scientific data that could be used to substantiate the claim.

### **Protection of the skin from photo-oxidative (UV-induced) damage (ID 530)**

- The claimed effect is “skin health”. The target population is assumed to be the general population. Protection of the skin from photo-oxidative (UV-induced) damage is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of EPA and DHA and protection of the skin from photo-oxidative (UV-induced) damage.

### **Improved absorption of EPA and DHA (ID 522, 523)**

- The claimed effects are “intake of emulsified fish oil improves the digestion and absorption of omega-3 fatty acids” and “intake of emulsified cod liver oil improves the digestion and absorption of omega-3 fatty acids”. The target population is assumed to be the general population.
- The claimed effects relate to the bioavailability of the food constituents (EPA and DHA) rather than to the relationship between a food constituent and health as required by Regulation (EC) No 1924/2006.

### **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)**

- The claimed effects are “immune function” and “normal immune system function”. The target population is assumed to be the general population. It is assumed that the claimed effect refers to supporting a normal/healthy immune function in the context of decreasing the level or production of eicosanoids, arachidonic acid-derived mediators and pro-inflammatory cytokines. The evidence provided does not define the context whereby decreasing the level or production of eicosanoids, arachidonic acid-derived mediators and pro-inflammatory cytokines might be a beneficial physiological effect in the general healthy population.
- A cause and effect relationship has not been established between the consumption of DHA and EPA and a beneficial physiological effect related to the contribution to the normal

function of the immune system by decreasing the levels of eicosanoids, arachidonic acid-derived mediators and pro-inflammatory cytokines.

#### **“Immunomodulating agent” (ID 4690)**

- The claimed effect is “immunomodulating agent due to EPA and DHA”. 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.

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

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1291, EFSA-Q-2008-1293, EFSA-Q-2008-1303, EFSA-Q-2008-1307, EFSA-Q-2008-1309, EFSA-Q-2008-1310, EFSA-Q-2008-1314, EFSA-Q-2008-1317, EFSA-Q-2008-1325, EFSA-Q-2008-1353, EFSA-Q-2008-1490, EFSA-Q-2008-1867, EFSA-Q-2008-2054, EFSA-Q-2008-2061, EFSA-Q-2008-2062, EFSA-Q-2008-3647, EFSA-Q-2010-00642, EFSA-Q-2010-00643). 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 EPA/DHA/DPA, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
504	Eicosapentaenoic acid (EPA; C20:5 n-3) + docosahexaenoic acid (DHA; C22:6 n-3) or long-chain n-3 (omega 3) polyunsaturated fatty acids (LC n-3 PUFA, LC omega 3 PUFA)	Cardiovascular System : maintenance and promotion of heart health and healthy circulation	Eating 3g weekly, or 0.45g daily, long-chain omega 3 polyunsaturated fatty acids, as part of a healthy lifestyle, helps maintain heart health
		<u>Clarification provided</u> Contributes to maintain a healthy heart and cardiovascular system/ Helps maintain a healthy blood-circulation	
		<b>Conditions of use</b> - Providing no less than 0.2g LC n-3 PUFA per serving - Daily consumption of omega-3 polyunsaturated fatty acids (EPA and DHA) has to be at least 0,45gr or weekly consumption has to be 3gr. Maximum daily uptake 3gr as safety limit. - Providing no less than 0,2g LC n-3 PUFA per serving	
<b>Comments from Member States</b> Providing no less than 0.2g LC n-3 PUFA per serving Improves blood lipids profile (GR))			
ID	Food or Food constituent	Health Relationship	Proposed wording
506	Omega 3 fatty acids	Normal cardiovascular function	Omega 3 fatty acids help to maintain a healthy cardiovascular system.
		<u>Clarification provided</u> Omega 3 fatty acids help to support a healthy cardiovascular system because they contribute to regulate blood pressure, blood triglycerides level, to modulate hearth rhythm and because they are precursors of components which have anti-inflammatory properties and promote the formation of high density lipoproteins (HDL).	
<b>Conditions of use</b> - Amount of consumption: mind. 300 mg langkettige n-3-Fettsäuren (EPA + DHA) / d - Käitleja andmetel pika ahelaga oomega-3 rasvhapete (EPA+DHA) sisaldus 30 mg/100 g; portsjonis suurusega 250 g sisaldus 75 mg, mis on umbes 38% pika ahelaga oomega-3 rasvhapete (EPA+DHA) päevasest soovitatavast kogusest 200 mg. - 'le produit alimentaire est "source d'acides gras omega 3" ou est "riche en acides gras omega			

	<p>3" et le rapport LA/équivalent ALA est inférieur ou égal à 5; et le produit apporte des lipides en quantités raisonnables (apport &lt;33 % de l'apport énergétique total du produit) ou bien le produit est riche en lipides (apport &gt;33 %) mais apporte des quantités raisonnables d'acides gras saturés (apport &lt;30 %); et le produit contient au plus 150 mg de cholestérol pour 100 g ou 100 ml</p> <p>- 1600 mg of oils, corresponding to 242 mg of EPA and 161 mg of DHA, per day</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
516	Long chain omega-3 fatty acids EPA and DHA	<p>Heart Health</p> <p><u>Clarification provided</u></p> <p>Omega-3 fatty acids play an important role in maintaining endothelial functions. Endothelial dysfunction – recognized as a major pathogenic factor in atherogenesis – develops with an increased and chronic activation of the endothelium and is characterized by an increased expression of adhesion molecules, changes in leukocyte and platelet adhesion, and decreased production of the vasodilator nitrogen monoxide, among other things. Consumption of the Omega-3 fatty acids EPA and DHA increases the likelihood of normal cardiovascular function.</p> <p>Long chain Omega-3 fatty acids EPA and DHA help maintain healthy cardiovascular function.</p> <p>Improves oxygen supply to heart by influencing blood pressure (hence reduced demand on the heart), thereby helping to maintain a healthy heart.</p> <p>Modulation of heart functioning by reduction of leukocyte mediated proinflammatory cytokine production</p>	<p>Long-chain omega-3 fatty acids EPA and DHA help maintain a healthy heart. Long-chain omega-3 fatty acids EPA and DHA are important for cardiovascular health.” Long-chain omega-3 fatty acids EPA and DHA help keep the heart and blood vessels healthy.</p>
	<p><b>Conditions of use</b></p> <p>- Food supplement with 500-3000 mg of fish oil omega-3-fatty acids (EPA and DHA) in the daily dose.</p>		



	<ul style="list-style-type: none"> <li>- The anticipated daily intake is 2 x capsules containing 270 mg of DHA and 75 mg of EPA. This gives a daily dose of 540 mg of DHA and 150 mg of EPA. Pregnant or lactating women should consult a doctor before taking this supplement. Consult with a doctor before taking this supplement if under medical supervision. If adverse effects occur, stop using the product immediately and consult a doctor.</li> <li>- Food supplement with 450-900 mg of EPA and 200-400 mg of DHA in the daily dose.</li> <li>- The effective dose required to maintain heart health is estimated to be 500 mg n-3 LC-PUFAs per day. To carry the claim, a product should contain =30 mg n-3 LC-PUFAs per 100 g or 100 kcal, in accordance with the Update of the ANNEX of the Regulation 1924/2006 (eg., 1% or 2% DHA milk provides 740 mg DHA per 100 g and 77 mg DHA per 100 kcal, and so would qualify to carry the claim). 5-10ml per day General Population. Minimum 15% RDI per 100g or 100kcal. (RDI for EPA+DHA assumed as 200mg/day) General population 15% of RDI; RDI assumed as 200mg/day</li> <li>- amount_consumption_value 30 Gramm (g) amount_consumption_plaintext 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>- Food supplement with 580 mg of EPA and 83 mg of DHA in the daily dose.</li> <li>- The claim relates only to very long chain polyunsaturated fatty acids (of chain length 20 carbons or above) including EPA, DPA and DHA (i.e. 20:3n-3, 20:4n-3, 20:5n-3, 22:5n-3 and 22:6n-3), and not all long chain polyunsaturated fatty acids, such as alpha-linolenic acid (i.e. 18:3n-3 and 18:4n-3). The ratio of EPA and DHA should reflect that which occurs naturally in oily fish. Must be accompanied by a statement to the effect that 3g must be consumed weekly, or 0.45g daily, as part of a healthy lifestyle. When a product is presented as a stand alone serving, then each serving must contain no less than 0.2g LC n-3 PUFA. When a product carries a recommendation for a number of portions per day or week then the total LC n-3 PUFA content of the daily recommendation (daily serving) must be greater than 0.2g. Not personalise the claim to the individual, e.g. "provides half your daily needs". State the proportion (i.e. a 'quarter', 'third', 'half' etc) of the 0.45g daily intake, or 3g weekly intake, in each serving or portion. Clarify to consumers when products have been fortified with LC n-3 PUFA and make clear to consumers the origin of the oil. Products containing significant amounts of contaminants (identified by the SACN/COT Inter-Committee Subgroup to be marlin, swordfish, shark and, to a lesser extent, tuna) carrying the claim should also carry a warning for pregnant women and children</li> <li>- Rainbow trout fillets and products made from them. The required amount was not indicated.</li> <li>- amount_consumption_value 30 Gramm (g) amount_consumption_plaintext 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>- General population. Minimum 15% RDI per 100g or 100kcal (RDI for EPA+DHA assumed as 200mg/day)</li> </ul>		
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ID	Food or Food constituent	Health Relationship	Proposed wording
520	Long Chain Fatty Acids (EPA/DHA)	Immune Function  <u>Clarification provided</u>  Decreased levels of inflammatory eicosanoids and lowering of proinflammatory cytokines to support normal immune functioning	A diet rich in long chain fatty acids may help normal immune system function.

	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 5-10ml per day</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> <li>- Amount of consumption: 2 Gramm (g). Upper limit: 4 Gramm (g).</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
522	Emulsified Fish Oil	<p>Intake of emulsified Fish Oil improves the digestion and absorption of Omega-3 Fatty Acids.</p> <p><u>Clarification provided</u></p> <p>Emulsification process significantly improves the absorption of omega-3 Fatty Acids.</p> <p>Intake of emulsified Fish Oil results in significantly higher levels of DHA and EPA when compared with intake of non emulsified fish oil.</p>	<p>The Wisdom-3 Emulsification process improves the digestion and absorption of Omega-3 Fatty Acids. The Wisdom-3 emulsification process doubles the absorption of Omega 3 Fatty Acids The Wisdom-3 emulsification process significantly improves the absorption</p>
		<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 5-10ml per day</li> </ul>	
ID	Food or Food constituent	Health Relationship	Proposed wording
523	Emulsified Cod Liver Oil	<p>Intake of emulsified Cod Liver Oil improves the digestion and absorption of Omega-3 Fatty Acids.</p> <p><u>Clarification provided</u></p> <p>Higher levels of long chain polyunsaturated fatty acids are detected following intake of emulsified rather than non emulsified oils.</p>	<p>The Wisdom-3 emulsification process doubles the absorption of Omega 3 Fatty Acids The Wisdom-3 emulsification process significantly improves the absorption of Omega 3 Fatty Acids The Wisdom-3 Emulsification process improves the digestion and absorption of Omega 3 Fatty Acids</p>
		<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 5-10ml per day</li> </ul>	
ID	Food or Food constituent	Health Relationship	Proposed wording
527	Omega-3 stable fish body oil	<p>Cardiovascular/Heart Health</p> <p><u>Clarification provided</u></p> <p>Cardiovascular/Heart health: Helps maintain healthy triglyceride and cholesterol levels. Antioxidant activity helps</p>	<p>Natural stable omega-3 fatty acids help to maintain a healthy heart.</p>

		reduce oxidation of LDL.	
<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- Upper limit 300 Milligramm (mg)</li> <li>- Daily intake of 1.5g of stabilised omega-3 fish oil from the flesh of the fish and not the liver.</li> </ul>			
ID	Food or Food constituent	Health Relationship	Proposed wording
530	Omega-3 fatty acids (EPA/DHA)	Skin health	Omega-3 fatty acids protect skin from UV damage and keep the skin healthy
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- 200-500mg EPA, 50-250mg DHA per day</li> <li>- Food supplement with 0.5-1.2 g of omega-3 fatty acids in the daily dose.</li> <li>- 2g, upper limit 4g</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
538	Omega-3 fatty acids (incl. DHA)	For cardiovascular system, metabolism (cholesterin, triglycerides)  <u>Clarification provided</u>  It helps proper blood circulation, by helping to release fats that are deposited in blood vessels walls (it improves endothelial function),  It helps to keep normal levels of blood fat, such as e.g. cholesterol and triglycerides	To protect the cardiovascular system/It promotes heart health To support the fat metabolism
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- Amount of consumption: 300 Milligramm (mg)</li> <li>- Amount of consumption: mind. 300 mg langkettige n-3-Fettsäuren (EPA + DHA) / d</li> <li>- 75-150 mg, 125 - 500 mg</li> <li>- 125 - 500 mg</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
566	EPA and DHA fatty acids	Carbohydrate metabolism and insulin sensitivity	-Helps to regulate the blood sugar level
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- Food supplement with 590 mg of eicosapentaenoic acid (EPA) and 83 mg of docosahexaenoic acid (DHA) in the daily dose</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
703	Long chain Omega 3 fatty acids (EPA/DPA/DHA)	Cardiovascular/ heart health  <u>Clarification provided</u>	-a diet rich in long chain omega 3 fatty acids keeps the arteries healthy; -a diet rich in long chain omega 3 fatty acids promotes a healthy heart. Contributes

		<p>Long-chain omega 3 fatty acids maintain cardiovascular function. Maintains elasticity of arteries/arterial lining. Helps to prevent build up of fat and cholesterol deposits on the artery walls/helps avoid/mitigate against high levels of fat and cholesterol being deposited on artery walls. Helps maintain normal blood pressure therefore reducing potential for tearing/lrsions/damage in the arteries.</p>	<p>to cardiovascular health Eating 3g weekly, or 0.45g daily long chain omega-3 polyunsaturated fatty acids, as part of a healthy lifestyle helps maintain heart health.</p>
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Vegetable fat spread and margarines (60-70% fat) containing 41-47 g/100 g, 2-2.4 g/ tsp (=5 g) of soft, unsaturated fat (67.5-73% of the total fat).Vegetable fat spread and margarines (30-40% fat) containing 22-27g/100 g, 1.1-1.4g/ tsp (=5 g) of soft, unsaturated fat (68-84% of the total fat).Food preparation fraiches containing 7 g/100 g of soft, unsaturated fat (70% of the total fat).Light unripened cheese-type vegetable fat products containing 10 g/100 g, 0.5 g/tsp (=5 g) of soft, unsaturated fat (71% of the total fat).Unripened cheese-type vegetable fat products containing 19g/100 g, 1g/tsp (=5 g) of soft, unsaturated fat (73% of the total fat).Vegetable fat mixture containing 10 g/100 g of soft, unsaturated fat (83% of the total fat) and 2 g/100 g of omega-3 fatty acids.Liquid rapeseed oil product containing 74 g/100 g, 11 g/tbsp (=15 g) of soft, unsaturated fat (93% of the total fat).Rapeseed oil containing 94g/100 g, 14g/tbsp (=15 g) of soft, unsaturated fat (94% of the total fat).</li> <li>- 3 - 4g pro Tag</li> <li>- &gt;1.5g per day (BNF CVD 2005 p.217); Min 10% fat ( product basis), min 70% UFA(fat basis) and max 2% TFA(fat basis) and &gt;1.5g per day VLC Omega 3 (BNF CVD 2005 p.217) (EDA)</li> <li>- 1-2 energy % (around. 2-4 g/day), from which EPA+DHA should be of 200-500 mg.;The product shall contain a significant amount of n-3 PUFA compared to the recommended daily allowance. ;Health claims can be applied on foods complying with requirements of nutrition claims „Source/high omega-3 fatty acids”.;;</li> <li>- Yoghurt or milk-based drink (fat 0.2-2.2 g/100 g) with a 100 mg/100 g, 150 mg/serving of omega-3 fatty acids.Vitamin was added to the product, and this prevents oxidation of omega-3 fatty acids.</li> <li>- 2 Gramm (g/Tag)</li> <li>- 0.43g per day (serving - 1/3 to 1/4 of this)</li> <li>- &gt;1.5g täglich</li> <li>- 0.43g per day (serving - 1/3 to 1/4 of this) 3g weekly or .45g daily min 10% fat (product basis), min 70% UFA (fat basis), max 2% TFA (fat basis); min 30mg very long chain omega 3 100g/ml and 100kcal (product basis), based on 15% of 200mg GDA for Omega3 (VLC)</li> <li>- 200 Milligramm (mg) 200mg/Tag Min 10% fat ( product basis), min 70% UFA(fat basis) and max 2% TFA(fat basis) and &gt;1.5g per day VLC Omega 3(BNF CVD 2005 p.217)(EDA)</li> </ul>			
<p><b>Comments from Member States</b></p> <p>FI noted that the claim Ref.Nr 60872 under the main entry claim ID 703 is dealing with ALA</p>			

	omega-3 fatty acids, not long chain omega-3 fatty acids as the claim ID 703. That is why the claim Ref.nr 60872 should be placed under some unsaturated fat claim / soft fat claim such as the claim ID 621 and not under the claim ID 703.)			
ID	Food or Food constituent	Health Relationship	Proposed wording	
1128	Fish (fresh/ frozen)	Heart health <u>Clarification provided</u> Promotes heart health through omega 3 and keeps an adequate level of cholesterol, blood pressure, platelet aggregation, inflammatory response and plasma triacylglycerol.  In addition UK, NO and HU include 'contributes to the stabilization of arrhythmias and influences inflammatory response' in Health Relationship.  Finally NO also include 'Promotes growth, development and function of the brain through the content of omega 3, iodine and vitamin D'	Fish is an important part of a balanced/ healthy diet.	
		<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Two portions per week, at least one portion fatty fish</li> <li>- Fish consumption 2-3-times/week or 1 g fish oil containing n-3 fatty acids/day.</li> <li>- Fish consumption should be at least 2 servings per week, one of which should be oily (JHCI Expert Committee 2004, WHO 2003, SACN 2004, AHA Scientific Statement 2006). No maximum limitation has been stated.</li> </ul>		
		<p><b>Comments from Member States</b></p> <p>GR and ES believe that 'contributes to the stabilization of arrhythmias and influences inflammatory response' is outside the scope of Article 13.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording	
1317	Food Category: Fish Food: Cultured Sea bass and Gilthead Sea bream Food Component / Nutrient: EPA & DHA Omega 3 Highly Unsaturated fatty acids	Cultured Sea bass and Gilthead sea bream are rich in Eicosapentaenoic acid (EPA, C20:5 ω-3) and Docosahexaenoic acid (DHA, C22:6 ω-3) providing more than 1,2 g per 100g of edible muscle (fillet). EPA and DHA are proven to have very important cardio-protective properties reducing the risk from Coronary Heart Disease (CHD) both	Eating cultured sea bass and gilthead sea bream twice a week, as a rich source of omega-3 highly unsaturated fatty acids and part of a healthy lifestyle, has been shown to help maintain heart health	

		<p>reducing mortalities among people that have already survived at least one heart attack but also by protecting from heart death in apparently healthy populations.</p> <p><u>Clarification provided</u></p> <p>Eating cultured sea bass and gilthead sea bream twice a week, as a rich source of omega-3 highly unsaturated fatty acids and part of a healthy lifestyle, has been shown to help maintain normal levels of blood lipids (cholesterol/triglycerides), normal blood pressure as well as normal heart rhythm.</p>	
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Quantity of food that brings the nutritious result: 0,5 to 1g of EPA and DHA / Day is the recommended daily dose Daily quantity: 1,2 g EPA and DHA in 100g of edible muscle (fillet) of cultured sea bass and Gilthead sea bream Period required to see the desired effect: Immediate vs long systematic consumption Inclusion of Cultured sea bass and sea bream twice a week as part of a healthy diet helps maintain heart health Safety Max Limits for active ingredient: FDA (2000): 3g EPA and DHA / day, AHA (2007) for CHD patients: 2-4g EPA and DHA / day AHA limit refers to consumption of 330g fillet of cultured sea bass or gilthead sea bream (or daily consumption of a fish of mean weight 660 to 800 g), Special active ingredient characteristics: Eicosapentaenoic acid (EPA, C20:5 ω-3) and Docosahexaenoic acid (DHA, C22:6 ω-3), Interaction with other components of the same food: Not applicable, Bioavailability effect (Ca vit D):Not applicable</li> </ul>			
ID	Food or Food constituent	Health Relationship	Proposed wording
1324	Fish (fresh/ frozen)	Système circulatoire, Source d'oméga 3, hypotenseur, réduit les risques de maladie, coronarienne, anti-athérosclérose, diminue les triglycérides, hypolipidémiant	Soutient la circulation Stimule la circulation Favorise le bon cholestérol Aide à maîtriser le cholestérol Harmonise les fonctions cardio-vasculaires
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Huile, 6x500mg/jour</li> </ul>			
<p><b>No clarification provided by Member States</b></p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
1325	Salmon	Système circulatoire, Source d'oméga 3, diminue les triglycérides, hypolipidémiant	Soutient la circulation Aide à maîtriser le cholestérol Harmonise les fonctions cardio-vasculaires

<b>Conditions of use</b>			
Huile, 6x515mg/jour			
<b>No clarification provided by Member States</b>			
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
<b>2914</b>	Long chain Omega 3 fatty acids	Normal immune system function <u>Clarification provided</u> Inflammation and immunity: Decreased production of arachidonic acid-derived mediators/ Reduced production of pro-inflammatory cytokines	-long chain Omega 3 fatty acids are important for a healthy immune system; -LC n3 PUFA help reduce inflammation.
<b>Conditions of use</b>			
- No conditions of use provided			
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
<b>4689</b>	Omega 3-Fatty acids containing eicosapentaenoic acid-EPA and docosahexaenoic acid (DHA)	Hypolypemic agent due to EPA and DHA <u>Clarification provided</u> blood lipid concentrations	Decreases lipid levels / Function in regulation of lipid metabolism / Reduces lipids and LDL-cholesterol levels.
<b>Conditions of use</b>			
Adults and children: 500 - 1000 mg Omega 3 per day			
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
<b>4690</b>	Omega 3-Fatty acids containing eicosapentaenoic acid-EPA and docosahexaenoic acid (DHA)	Immunomodulating agent due to EPA and DHA	Contributes to the good functioning of the immunity system. /
<b>Conditions of use</b>			
- Adults and children: 500 - 1000 mg Omega 3 per day.			

**GLOSSARY AND ABBREVIATIONS**

DHA	Docosahexaenoic Acid
DPA	Docosapentaenoic Acid
EPA	Eicosapentaenoic Acid
HDL	High-Density Lipoprotein
LDL	Low-Density Lipoprotein
n-3 LCPUFA	Long-Chain n-3 Polyunsaturated Fatty Acids
UVR	Ultraviolet Radiation
VLDL	Very Low-Density Lipoprotein