

## SCIENTIFIC OPINION

### Scientific Opinion on health claims already evaluated (ID 215, 568, 674, 712, 1398, 1633, 1974, 4191, 4192, 4193, 4236, 4335, 4698, 4704) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>

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

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to vitamin D and normal absorption of calcium; protein and growth or maintenance of muscle mass; protein and maintenance of normal bone; calcium and maintenance of normal bone; plant stanols and maintenance of normal blood cholesterol concentrations; alpha-linolenic acid (ALA) and maintenance of normal blood cholesterol concentrations; replacement of mixtures of saturated fatty acids (SFAs) as present in foods or diets with mixtures of polyunsaturated fatty acids (PUFAs) and maintenance of normal blood LDL-cholesterol concentrations; lactase and breaking down lactose; ethanol-water extract of *Caralluma fimbriata* and reduction in waist circumference; ethanol-water extract of *Caralluma fimbriata* and reduction of body weight; ethanol-water extract of *Caralluma fimbriata* and reduction of appetite; pectins and maintenance of normal blood cholesterol concentrations; chromium and maintenance of normal blood glucose concentrations; choline and maintenance of normal liver function. 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 Panel concludes that the following health claims have already been assessed with a favourable outcome:

- Vitamin D and normal absorption of calcium (ID 215).

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-1499, EFSA-Q-2008-2369, adopted on 25 March 2011. Question No EFSA-Q-2008-1002, EFSA-Q-2008-1355, EFSA-Q-2008-1461, EFSA-Q-2008-2135, EFSA-Q-2008-2707, EFSA-Q-2008-4902, EFSA-Q-2008-4903, EFSA-Q-2008-4904, EFSA-Q-2008-4946, EFSA-Q-2010-00288, EFSA-Q-2010-00651, EFSA-Q-2010-00657, adopted on 08 April 2011.

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- Protein and growth or maintenance of muscle mass (ID 1398).
- Protein and maintenance of normal bone (ID 4704).
- Calcium and maintenance of normal bone (ID 4704).
- Plant stanols and maintenance of normal blood cholesterol concentrations (ID 568).
- Alpha-linolenic acid (ALA) and maintenance of normal blood cholesterol concentrations (ID 568).
- Replacement of mixtures of saturated fatty acids (SFAs) as present in foods or diets with mixtures of polyunsaturated fatty acids (PUFAs) and maintenance of normal blood LDL-cholesterol concentrations (ID 674, 4335).
- Lactase and breaking down lactose (ID 1974).
- Pectins and maintenance of normal blood cholesterol concentrations (ID 4236).
- Chromium and maintenance of normal blood glucose concentrations (ID 4698).
- Choline and maintenance of normal liver function (ID 712, 1633).

The Panel concludes that the following health claims have already been assessed with an unfavourable outcome and that the references cited did not provide any additional scientific data which could be used to substantiate the claims:

- Ethanol-water extract of *Caralluma fimbriata* and reduction in waist circumference (ID 4191).
- Ethanol-water extract of *Caralluma fimbriata* and reduction of body weight (ID 4192).
- Ethanol-water extract of *Caralluma fimbriata* and reduction of appetite (ID 4193).

#### **KEY WORDS**

Food, constituent, already evaluated, health claims.

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**BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION**

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

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**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

#### 1.1. Vitamin D (ID 215)

The food constituent that is the subject of the health claim is vitamin D. Vitamin D is a well recognised nutrient and is measurable in foods by established methods.

The Panel considers that the food constituent, vitamin D, which is the subject of the health claim, is sufficiently characterised (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009a).

#### 1.2. Protein (ID 1398, 4704)

The food constituent that is the subject of the health claims is protein.

The Panel considers that the food constituent, protein, which is the subject of the health claims, is sufficiently characterised (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010a).

#### 1.3. Calcium (ID 4704)

The food constituent that is the subject of the health claim is calcium. Calcium is a well recognised nutrient and is measurable in foods by established methods.

The Panel considers that the food constituent, calcium, which is the subject of the health claim, is sufficiently characterised (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009b).

#### 1.4. Plant stanols (ID 568)

The food constituent that is the subject of the health claim is plant stanols.

The Panel considers that the food constituent, plant stanols, which is the subject of the health claim, is sufficiently characterised (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010b).

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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> EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

### 1.5. Alpha-linolenic acid (ALA) (ID 568)

The food constituent that is the subject of the health claim is “omega-3 fatty acids”.

From the proposed conditions of use and the references provided, the Panel assumes that the food constituent, which is the subject of the health claim, is alpha-linolenic acid (ALA).

The Panel considers that the food constituent, alpha-linolenic acid (ALA), which is the subject of the health claim, is sufficiently characterised (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009c).

### 1.6. Replacement of mixtures of saturated fatty acids (SFAs) as present in foods or diets with mixtures of polyunsaturated fatty acids (PUFAs) (ID 674, 4335)

The food constituent that is the subject of the health claims is “polyunsaturated fatty acids”.

In the context of the proposed wordings, the Panel assumes that the food constituent, which is the subject of the health claim, is saturated fatty acids (SFAs), which should be replaced by *cis*-polyunsaturated fatty acids (*cis*-PUFAs) in foods or diets in order to obtain the claimed effect.

The Panel considers that the food constituent, saturated fatty acids as present in foods or diets, and the food constituent, mixtures of *cis*-PUFAs, which should replace SFAs in foods, and which are the subject of the health claim, are sufficiently characterised (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011a).

### 1.7. Lactase (ID 1974)

The food constituent that is the subject of the health claim is lactase (beta-D-galactohydrolase).

The Panel considers that the food constituent, lactase, which is the subject of the health claim, is sufficiently characterised (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009d).

### 1.8. Ethanol-water extract of *Caralluma fimbriata* (ID 4191, 4192, 4193)

The food constituent that is the subject of the health claims is an ethanol-water extract of *Caralluma fimbriata*.

From the proposed conditions of use, the Panel assumes that the ethanol-water extract of *Caralluma fimbriata* is identical to the food/constituent (Slimaluma<sup>®</sup>) submitted under Article 13.5 of Regulation (EC) No 1924/2006 (Question No EFSA-Q-2010-00027, EFSA-Q-2010-00028, EFSA-Q-2010-00029, EFSA-Q-2010-00030, EFSA-Q-2010-00031).

The Panel considers that the food constituent, ethanol-water extract of *Caralluma fimbriata*, which is the subject of the health claims, is sufficiently characterised (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010c, 2010d, 2010e).

### 1.9. Pectins (ID 4236)

The food constituent that is the subject of the health claim is pectins.

The Panel considers that the food constituent, pectins, which is the subject of the health claim, is sufficiently characterised (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010f).

### **1.10. Chromium (ID 4698)**

The food that is the subject of the health claim is “*Saccaromyces cerevisiae*-brewer’s yeast”.

From the references provided the Panel assumes that the food which is the subject of the health claim is chromium-enriched *Saccharomyces cerevisiae*, as a source of trivalent chromium Cr(III). Trivalent chromium is a well recognised nutrient and is measurable in foods by established methods.

The Panel considers that the food constituent, trivalent chromium, which is the subject of the health claim, is sufficiently characterised (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010g).

### **1.11. Choline (ID 712, 1633)**

The food that is the subject of the health claims is “phospholipids (phosphatidyl choline, phosphatidyl ethanolamine, phosphatidyl inositol, lysophosphatidyl cholin)”.

Phospholipids are a major component of all cell membranes. Most phospholipids contain a diglyceride, a phosphate group, and a simple organic molecule such as choline.

From the conditions of use, the Panel assumes that the food, which is the subject of the health claim, is phosphatidylcholine, and that the food constituent responsible for the claimed effect is choline. Choline is measurable in foods by established methods.

The Panel considers that the food constituent, choline, which is the subject of the health claim, is sufficiently characterised (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011b)

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

### **2.1. Vitamin D and normal absorption of calcium (ID 215)**

The claimed effect is “vitamin D<sub>3</sub> enhances the calcium-absorption from the gut by inducing formation of calcium-binding proteins within the small intestinal mucosa”. The Panel assumes that the target population is the general population.

A claim on vitamin D and absorption of calcium and phosphorus and maintenance of normal blood calcium concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009a).

### **2.2. Protein and growth or maintenance of muscle mass (ID 1398)**

The claimed effect is “contribution to the assembly of muscles”. 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 growth or maintenance of muscle mass.

A claim on protein and growth or maintenance of muscle mass has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010a).

### **2.3. Protein and maintenance of normal bone (ID 4704)**

The claimed effect is “yogurt is a source of calcium and proteins, indispensable for bone development, mineralization, density and strength”. The Panel assumes that the target population is the general population.

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

### **2.4. Calcium and maintenance of normal bone (ID 4704)**

The claimed effect is “yogurt is a source of calcium and proteins, indispensable for bone development, mineralization, density and strength”. The Panel assumes that the target population is the general population.

A claim on calcium and maintenance of normal bone has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009b).

### **2.5. Plant stanols and maintenance of normal blood cholesterol concentrations (ID 568)**

The claimed effect is “cardiovascular system”. 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 cholesterol concentrations.

A claim on plant sterols and plant stanols and maintenance of normal blood cholesterol concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010b).

### **2.6. Alpha-linolenic acid (ALA) and maintenance of normal blood cholesterol concentrations (ID 568)**

The claimed effect is “cardiovascular system”. 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 cholesterol concentrations.

A claim on ALA and maintenance of normal blood cholesterol concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009c).

### **2.7. Replacement of mixtures of saturated fatty acids (SFAs) as present in foods or diets with mixtures of polyunsaturated fatty acids (PUFAs) and maintenance of normal blood LDL-cholesterol concentrations (ID 674, 4335)**

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

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal blood LDL-cholesterol concentrations.

A claim on the replacement of mixtures of SFAs with *cis*-MUFAs and/or *cis*-PUFAs in foods or diets and maintenance of normal blood LDL-cholesterol concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011a).

### **2.8. Lactase and breaking down lactose (ID 1974)**

The claimed effect is “lactose digestion”. The target population is individuals whose own lactase production is insufficient for breaking down lactose.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers to breaking down lactose (i.e. enzymatic hydrolysis of lactose).

A claim on lactase and breaking down lactose has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009d).

### **2.9. Ethanol-water extract of *Caralluma fimbriata* and reduction in waist circumference (ID 4191)**

The claimed effect is “helps reduce size of waist”. The Panel assumes that the target population is individuals who wish to reduce their waist circumference.

A claim on ethanol-water extract of *Caralluma fimbriata* and a reduction in waist circumference, if accompanied by an improvement in the adverse health effects of an excess abdominal fat, has already been assessed with an unfavourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010e), and the references cited for this claim did not provide any additional scientific data that could be used to substantiate the claim.

### **2.10. Ethanol-water extract of *Caralluma fimbriata* and reduction of body weight (ID 4192)**

The claimed effect is “helps reduce body weight”. The Panel assumes that the target population is overweight individuals in the general population who wish to reduce their body weight.

A claim on ethanol-water extract of *Caralluma fimbriata* and reduction of body weight, has already been assessed with an unfavourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010c), and the references cited for this claim did not provide any additional scientific data that could be used to substantiate the claim.

### **2.11. Ethanol-water extract of *Caralluma fimbriata* and reduction of appetite (ID 4193)**

The claimed effect is “helps reduce appetite”. The Panel assumes that the target population is the general population.

A claim on ethanol-water extract of *Caralluma fimbriata* and a reduction of appetite leading to a reduction in subsequent energy intake, has already been assessed with an unfavourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010d), and the references cited for this claim did not provide any additional scientific data that could be used to substantiate the claim.

### **2.12. Pectins and maintenance of normal blood cholesterol concentrations (ID 4236)**

The claimed effect is “weight management and lipid control (via fiber)”. The Panel assumes that the target population is the general population.

No references on weight management were provided in the consolidated list. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the maintenance of normal blood cholesterol concentrations.

A claim on pectins and maintenance of normal blood cholesterol concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010f).

### **2.13. Chromium and maintenance of normal blood glucose concentrations (ID 4698)**

The claimed effect is “sanguine 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 glucose concentrations.

A claim on trivalent chromium and maintenance of normal blood glucose concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010g).

### **2.14. Choline and maintenance of normal liver function (ID 712, 1633)**

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

In the context of the proposed wordings and the clarifications provided by Member States, the Panel assumes that the claimed effects refer to the maintenance of normal liver function.

A claim on choline and maintenance of normal liver function has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011b)

## **CONCLUSIONS**

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

- The following health claims have already been assessed with a favourable outcome: vitamin D and normal absorption of calcium (ID 215); protein and growth or maintenance of muscle mass (ID 1398); protein and maintenance of normal bone (ID 4704); calcium and maintenance of normal bone (ID 4704); plant stanols and maintenance of normal blood cholesterol concentrations (ID 568); alpha-linolenic acid (ALA) and maintenance of normal blood cholesterol concentrations (ID 568); replacement of mixtures of saturated fatty acids (SFAs) as present in foods or diets with mixtures of polyunsaturated fatty acids (PUFAs) and maintenance of normal blood LDL-cholesterol concentrations (ID 674, 4335); lactase and breaking down lactose (ID 1974); pectins and maintenance of normal blood cholesterol concentrations (ID 4236); chromium and maintenance of normal blood glucose concentrations (ID 4698); choline and maintenance of normal liver function (ID 712, 1633).
- The following health claims have already been assessed with an unfavourable outcome and the references cited did not provide any additional scientific data that could be used to substantiate the claims: ethanol-water extract of *Caralluma fimbriata* and reduction in waist circumference (ID 4191); ethanol-water extract of *Caralluma fimbriata* and reduction of body weight (ID 4192); ethanol-water extract of *Caralluma fimbriata* and reduction of appetite (ID 4193).

## DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1002, EFSA-Q-2008-1355, EFSA-Q-2008-1461, EFSA-Q-2008-1499, EFSA-Q-2008-2135, EFSA-Q-2008-2369, EFSA-Q-2008-2707, EFSA-Q-2008-4902, EFSA-Q-2008-4903, EFSA-Q-2008-4904, EFSA-Q-2008-4946, EFSA-Q-2010-00288, EFSA-Q-2010-00651, EFSA-Q-2010-00657). 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>.

## REFERENCES

- EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009a. Scientific Opinion on the substantiation of health claims related to vitamin D and maintenance of bone and teeth (ID 150, 151, 158), absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations (ID 152, 157), cell division (ID 153), and thyroid function (ID 156) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 7(9):1227, 19 pp.
- EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009b. Scientific Opinion on the substantiation of health claims related to calcium and maintenance of bones and teeth (ID 224, 230, 231, 354, 3099), muscle function and neurotransmission (ID 226, 227, 230, 235), blood coagulation (ID 230, 236), energy-yielding metabolism (ID 234), function of digestive enzymes (ID 355), and maintenance of normal blood pressure (ID 225, 385, 1419) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 7(9):1210, 27 pp.
- EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009c. Scientific Opinion on the substantiation of health claims related to alpha-linolenic acid and maintenance of normal blood cholesterol concentrations (ID 493) and maintenance of normal blood pressure (ID 625) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 7(9):1252, 17 pp.
- EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009d. Scientific Opinion on the substantiation of health claims related to lactase enzyme and breaking down lactose (ID 1697, 1818) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 7(9):1236, 13 pp.
- EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010a. Scientific Opinion on the substantiation of health claims related to protein and increase in satiety leading to a reduction in energy intake (ID 414, 616, 730), contribution to the maintenance or achievement of a normal body weight (ID 414, 616, 730), maintenance of normal bone (ID 416) and growth or maintenance of muscle mass (ID 415, 417, 593, 594, 595, 715) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 8(10):1811, 24 pp.
- EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010b. Scientific Opinion on the substantiation of health claims related to plant sterols and plant stanols and maintenance of normal blood cholesterol concentrations (ID 549, 550, 567, 713, 1234, 1235, 1466, 1634, 1984, 2909, 3140), and maintenance of normal prostate size and normal urination (ID 714, 1467, 1635) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 8(10):1813, 22 pp.
- EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010c. Scientific Opinion on the substantiation of a health claim related to ethanol-water extract of *Caralluma fimbriata* (Slimaluma®) and helps to reduce body weight pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal, 8(5):1604, 11 pp.
- EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010d. Scientific Opinion on the substantiation of a health claim related to ethanol-water extract of *Caralluma fimbriata*

(Slimaluma®) and helps to control hunger/appetite pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal, 8(5):1606, 10 pp.

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010e. Scientific Opinion on the substantiation of a health claim related to ethanol-water extract of *Caralluma fimbriata* (Slimaluma®) and helps to reduce waist circumference pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal, 8(5):1602, 11 pp.

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010f. Scientific Opinion on the substantiation of health claims related to pectins and reduction of post-prandial glycaemic responses (ID 786), maintenance of normal blood cholesterol concentrations (ID 818) and increase in satiety leading to a reduction in energy intake (ID 4692) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 8(10):1747, 17 pp.

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010g. Scientific Opinion on the substantiation of health claims related to chromium and contribution to normal macronutrient metabolism (ID 260, 401, 4665, 4666, 4667), maintenance of normal blood glucose concentrations (ID 262, 4667), contribution to the maintenance or achievement of a normal body weight (ID 339, 4665, 4666), and reduction of tiredness and fatigue (ID 261) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 8(10):1732, 23 pp.

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011a. Scientific Opinion on the substantiation of health claims related to the replacement of mixtures of saturated fatty acids (SFAs) as present in foods or diets with mixtures of monounsaturated fatty acids (MUFAs) and/or mixtures of polyunsaturated fatty acids (PUFAs), and maintenance of normal blood LDL-cholesterol concentrations (ID 621, 1190, 1203, 2906, 2910, 3065) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 9(4):2069, 18 pp.

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011b. Scientific Opinion on the substantiation of health claims related to choline and contribution to normal lipid metabolism (ID 3186), maintenance of normal liver function (ID 1501), contribution to normal homocysteine metabolism (ID 3090), maintenance of normal neurological function (ID 1502), contribution to normal cognitive function (ID 1502), and brain and neurological development (ID 1503) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 9(4):2056, 23 pp.

## 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.

<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 health claims already evaluated, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
215	Vitamin D3	Vitamin D3 steigert die Resorption von Calcium aus dem Darm, indem es in der Dünndarmschleimhaut die Bildung eines calciumbindenden Proteins induziert	[In german : ] Vitamin D3 steigert die Resorption von Kalzium aus dem Darm.
		<u>Clarification provided</u> vitamin D3 enhances the Calcium-absorption from the gut by inducing formation of calcium-binding prteins within the small intestinal mucosa	<u>Clarification provided</u> Vitamin D3 can increase absorption of calcium from the gut.
<b>Conditions of use</b> - None provided			
ID	Food or Food constituent	Health Relationship	Proposed wording
568	Plant stanol + omega-3 fatty acids	Cardiovascular system	Contains/enriched with plant stanol, which effectively reduces cholesterol.
			Omega-3 fatty acids are good for the heart.
			Symbol included in the claim: Benecol (see previous)
<b>Conditions of use</b> - Vegetable fat spreads with 32% fat and containing. 7.2 g/100 g, 0.4 g/serving (1 tsp) of plant stanols and 4 g /100 g, 0.2 g/serving of omega-3 fatty acids/alpha-linoleic acid.Omega-3 fatty acids and plant stanol are not altered during processing.			
<b>No clarification provided by Member States</b>			
ID	Food or Food constituent	Health Relationship	Proposed wording
674	Polyunsaturated fatty acids	Cardio-vascular system	Replacement of saturated fatty acids by polyunsaturated fatty acids in the diet is beneficial for the blood total cholesterol and LDL cholesterol levels.
			<b>Conditions of use</b> - 6-10 energy % (around 13-22 g/day). The product shall contain a significant amount of PUFA compared to the recommended daily allowance. Health claims can be applied on foods complying with requirements of nutrition claims. High polyunsaturated fatty acids”

<b>Comments from Member States</b>			
This health relationship can be classified as a general dietary guideline, but as a part of commercial communication it should be handled under Reg. 1924/2006/EK.			
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
<b>712</b>	Phospholipids (Phosphatidyl choline, Phosphatidyl ethanolamine, Phosphatidyl inositol, Lysophosphatidyl cholin)	Liver health <u>Clarification provided</u> Phospholipids have positive effects on the parameters of hepatocyte integrity: Improve enzymatic function of liver Improve detoxifying function of liver	Contributes to the normal functioning of the liver
		<b>Conditions of use</b> - Min 1 g per day	
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
<b>1398</b>	Milch <u>Clarification provided</u> milk - high quality proteins	Beitrag zum Muskelaufbau <u>Clarification provided</u> contribution to the assembly of muscles	[In german : ] Sportler sollten auf eine eiweißreiche Ernährung achten - vor allem nach dem Sport. Hochwertige Proteine aus Molkegetränke, Buttermilch oder fettarmen Milchprodukten sorgen dafür, dass die Muskeln schnell wieder aufgebaut werden. <u>Clarification provided</u> Sportsmen should look after an albuminous alimentation mailly after sport activities. High quality proteins from whey drinks, buttermilk or low-fat milk products care for a rapid assembly of muscles
		<b>Conditions of use</b> - Milch ist meine Stärke im Sinne von Schönheit / Leistungsfähigkeit/ Energie/ Intelligenz	
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
<b>1633</b>	Phospholidips (Phosphatidyl choline, Phosphatidyl ethanolamine, Phosphatidyl inositol, Lysophosphatidyl cholin)	Liver health <u>Clarification provided</u> Liver health Clarification: Phospholipids have positive effects on the parameters of hepatocyte integrity	Contributes to the normal functioning of the liver

	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Food supplement with phospholipid content of 2500mg/100 g = dose. This is an animal lecithin water emulsion derived from the brain tissue of domestic pig. Active ingredients include linoleic acid (= fatty acid), alpha-linoleic acid (= fatty acid) and choline (= phosphatidylcholine).</li> <li>- Min 1 g per day</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1974	Lactase (bêta D galactohydrolase) as food complement	Lactose digestion <u>Clarification provided</u> enhance gastrointestinal digestion of lactose	Contributes to have better lactose digestion
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Oral ingestion (9900 FCC/50g lactose) before consumption of lactose containing product. remark: activity expressed in FCC according to method defined in Food Chemical Codex</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
4191	Water-ethanol extract of Caralluma fimbriata	Helps reduce size of waist	Natures solution to help reduce you reduce your waist size
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- The recommended dosage for the water-ethanol extract of Caralluma fimbriata (Gencor Pacific) is 1000 (2 x 500) mg per day. No adverse effects reported. Women who are pregnant or planning a pregnancy should consult a healthcare professional before taking any food supplements.</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
4192	Water-ethanol extract of Caralluma fimbriata	Helps reduce body weight	Natures solution to help reduce your body weight
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- The recommended dosage for the water-ethanol extract of Caralluma fimbriata (Gencor Pacific) is 1000 (2 x 500) mg per day. No adverse effects reported. Women who are pregnant or planning a pregnancy should consult a healthcare professional before taking any food supplements.</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
4193	Water-ethanol extract of Caralluma fimbriata	Helps reduce appetite	Natures solution to help reduce your appetite as part of a healthy lifestyle
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- The recommended dosage for the water-ethanol extract of Caralluma fimbriata (Gencor Pacific) is 1000 (2 x 500) mg per day. No adverse effects reported. Women who are pregnant or planning a pregnancy should consult a healthcare professional before taking any food supplements.</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
4236	Pectine de pomme : Dry extract of Pirus malus (apple pectin)	Weight management and lipid control (via fiber)	Fruits pectin helps to manage appetite (satiety-feeling enhancer effect). Fruits pectin helps to improve bowel transit.

			<p>Fruits pectin helps to improve lipids control (total and LDL-cholesterol).</p> <p>Fruits pectin takes part in the regulation of the absorption of fat.</p>
<p><b>Conditions of use</b></p> <p>- the equivalent of 20 g substance</p>			
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
4335	Polyunsaturated fatty acids	Cardio-vascular system	Replacement of saturated fatty acids by polyunsaturated fatty acids in the diet is beneficial for the blood total cholesterol and LDL cholesterol levels.
<p><b>Conditions of use</b></p> <p>- 6-10 energy % (around 13-22 g/day).;The product shall contain a significant amount of PUFA compared to the recommended daily allowance. Health claims can be applied on foods complying with requirements of nutrition claims "High polyunsaturated fatty acids"</p>			
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
4698	Saccaromyces cerevisiae- Brewer's Yeast	Sanguine health	Help to maintain a normal blood glucose level as part of a healthy life style / Contributes to normal glucose – insulin metabolism
<p><b>Conditions of use</b></p> <p>- Powder / 200 mg brewer's yeast / 1 tablet 3 times per day</p>			
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
4704	yogurt-calcium and proteins	yogurt is a source of calcium and proteins, indispensable for bone development, mineralization, density and strength	Yogurt is a source of calcium and proteins, indispensable for strong bones
<p><b>Conditions of use</b></p> <p>- source of protein and Calcium, as per the annex to Regulation CE 1924/2006</p>			

## **GLOSSARY AND ABBREVIATIONS**

ALA	Alpha-linolenic acid
LDL	Low density lipoprotein
MUFA	Monounsaturated fatty acid
PUFA	Polyunsaturated fatty acid
SFA	Saturated fatty acid