

**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to: dairy products (ID 1140, 1141, 1191), raw or processed food products of animal origin, plus bread and panification products (ID 1193, 1194), herbal yeast plasmolysate (ID 1815, 1816), apple polyphenols (ID 2713), rye flour (ID 1266), tomato juice (ID 1202), whey protein and alphasalactalbumin (ID 424, 430, 432, 725, 1433) and “brocco shoots”, “broccoli sprout powder” and “Brassica oleracea var. italica (broccoli)” (ID 1362, 1481, 2844, 2845), honey (ID 1159, 1160, 1318, 4678, 4679), and Cucurbita pepo L. (pumpkin) seed and seed extracts (ID 2029, 2365) pursuant to Article 13(1) of Regulation (EC) No 1924/2006**

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## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to: dairy products (ID 1140, 1141, 1191), raw or processed food products of animal origin, plus bread and panification products (ID 1193, 1194), herbal yeast plasmolysate (ID 1815, 1816), apple polyphenols (ID 2713), rye flour (ID 1266), tomato juice (ID 1202), whey protein and algalactalbumin (ID 424, 430, 432, 725, 1433), “brocco shoots”, “broccoli sprout powder” and “*Brassica oleracea* var. *italica* (broccoli)” (ID 1362, 1481, 2844, 2845), honey (ID 1159, 1160, 1318, 4678, 4679), and *Cucurbita pepo* L. (pumpkin) seeds and seed extracts (ID 2029, 2365) 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

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-1211, EFSA-Q-2008-1217, EFSA-Q-2008-1219, EFSA-Q-2008-1512, EFSA-Q-2008-1879, EFSA-Q-2008-1880, EFSA-Q-2008-1898, EFSA-Q-2008-1899, EFSA-Q-2008-1930, EFSA-Q-2008-1932, EFSA-Q-2008-1933, EFSA-Q-2008-1941, EFSA-Q-2008-2004, EFSA-Q-2008-2055, EFSA-Q-2008-2099, EFSA-Q-2008-2170, EFSA-Q-2008-2218, EFSA-Q-2008-2548, EFSA-Q-2008-2549, EFSA-Q-2008-2762, EFSA-Q-2008-3098, EFSA-Q-2008-3446, EFSA-Q-2008-3577, EFSA-Q-2008-3578, EFSA-Q-2010-00631, EFSA-Q-2010-00632, adopted on 25 March 2011.

<sup>2</sup> Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: [nda@efsa.europa.eu](mailto:nda@efsa.europa.eu)

<sup>3</sup> Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Gut/Immune: Jean-Louis Bresson, Maria Carmen Collado, Miguel Gueimonde, Daisy Jonkers, Martinus Løvik, Bevan Moseley, Maria Saarela, Seppo Salminen, Yolanda Sanz, Stephan Strobel, Daniel Tomé and Hendrik van Loveren. The members of the Claims Sub-Working Group on Cardiovascular Health/Oxidative Stress: Antti Aro, Marianne Geleijnse, Marina Heinonen, Ambroise Martin, Wilhelm Stahl and Henk van den Berg. The members of the Claims Sub-Working Group on Weight Management/Satiety/Glucose and Insulin Control/Physical Performance: Kees de Graaf, Joanne Harrold, Mette Hansen, Mette Kristensen, Anders Sjödin and Inge Tetens. The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain, and Peter Willatts.

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Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to: dairy products; raw or processed food products of animal origin, plus bread and panification products; herbal yeast plasmolysate; apple polyphenols; rye flour; tomato juice; whey protein and alphasalactalbumin; “brocco shoots”, “broccoli sprout powder” and “*Brassica oleracea* var. *italica* (broccoli)”; honey; and *Cucurbita pepo* L. (pumpkin) seeds and seed extracts. 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 foods/food constituents that are the subject of this opinion are:

- Dairy products related to the following claimed effects: weight management and maintenance of tooth mineralisation (ID 1140, 1141, 1191).
- Raw or processed food products of animal origin, plus bread and panification products related to the following claimed effects: maintenance of blood cholesterol concentrations and blood glucose control (ID 1193, 1194).
- Herbal yeast plasmolysate related to the following claimed effects: physical performance and concentration (ID 1815, 1816).
- Apple polyphenols related to the following claimed effect: blood glucose control (ID 2713).
- Rye flour related to the following claimed effect: low glycaemic index (ID 1266).
- Tomato juice related to the following claimed effect: blood glucose control (ID 1202).
- Whey protein and alphasalactalbumin related to the following claimed effects: immune defence against pathogens, cognitive function, mood, and blood pressure (ID 424, 430, 432, 725, 1433).
- “Brocco shoots”, “broccoli sprout powder” and “*Brassica oleracea* var. *italica* (broccoli)” related to the following claimed effect: protection of cells and molecules, including cells of the immune system, against oxidative damage (ID 1362, 1481, 2844, 2845).
- Honey related to the following claimed effects: protection of cells and molecules from oxidative damage, defence against pathogens, and maintenance of blood cholesterol concentrations (ID 1159, 1160, 1318, 4678, 4679).
- *Cucurbita pepo* L. (pumpkin) seeds and seed extracts related to the following claimed effect: maintenance of normal prostate size and normal urination (ID 2029, 2365).

The information given in the consolidated list and in the references provided did not allow the Panel to sufficiently characterise the foods/food constituents which are the subject of this opinion.

The Panel considers that the foods/food constituents which are the subject of this opinion are not sufficiently characterised, or are not sufficiently characterised in relation to the proposed claimed effects.

On the basis of the data presented, the Panel concludes that a cause and effect relationship cannot be established between the foods/food constituents which are the subject of this opinion and the claimed effects.

**KEY WORDS**

Foods, constituents, characterisation, 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

The approach used in the evaluation of Article 13(1) health claims is explained in the general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims<sup>6</sup>.

In assessing each specific food/health relationship that forms the basis of a health claim the NDA Panel considers the extent to which:

1. the food/constituent is defined and characterised;
2. the claimed effect is defined and is a beneficial physiological effect (“beneficial to human health”);
3. a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use).

Substantiation of the claim is dependent on a favourable outcome of the assessment of 1, 2 and 3 above. Thus, a cause and effect relationship is considered not to be established if the outcome of any one of these assessments is unfavourable.

For a claim, each relationship between a food/constituent and a claimed effect is assessed separately, and individual assessments are combined, as appropriate, to form coherent opinions.

### 1. Characterisation of the food/constituent

#### 1.1. Dairy products (ID 1140, 1141, 1191)

The food that is the subject of the claim is: “dairy (low fat dairy), dairy refers to cow’s milk, yogurt and cheese”, “(cow’s) milk and dairy products for which milk is the principle ingredient and no sugar has been added – e.g. yogurt, cheese”, and “fat free dairy products with reduced sugars or without added sugars” related to the following claimed effects: weight management and maintenance of tooth mineralisation.

From the information provided, the Panel assumes that the food refers to dairy products (milk, yogurt and cheese) from cow’s milk which are low in fat or fat free with no added sugars. The Panel notes

<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.

<sup>6</sup> See footnote 5

that dairy products include solid, semi-solid and liquid food products with different energy density, and that no information has been provided with respect to other nutritional characteristics (e.g. protein content, and added fibre) which could have an effect on body weight. The Panel also notes that lactose, the content of which may vary widely from one dairy product to another, is fermented by oral bacteria, and that the effect of different dairy products on tooth mineralisation may vary depending on whether they are chewed (e.g. cheese) or not, and on the frequency of consumption.

The Panel considers that the food category, dairy products, which is the subject of the health claims, is not sufficiently characterised in relation to the claimed effects considered in this section.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of dairy products and the claimed effects considered in this section.

### **1.2. Raw or processed food products of animal origin, plus bread and panification products (ID 1193, 1194)**

The food that is the subject of the health claims is “raw or processed food products of animal origin, plus bread and panification products” related to the following claimed effects: maintenance of blood cholesterol concentrations and blood glucose control.

The information provided in relation to these claims defines these foods as “rich in omega 3”. However, the Panel notes that the energy density, fatty acid profile, and the nature and amount of carbohydrates contained in these foods, all of which could have an impact on the claimed effects, are not specified and may be highly variable from one food product to another.

The Panel considers that the foods, “raw or processed food products of animal origin, plus bread and panification products”, which are the subject of the claim, are not sufficiently characterised in relation to the claimed effects considered in this section.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of “raw or processed food products of animal origin, plus bread and panification products” and the claimed effects considered in this section.

### **1.3. Herbal yeast plasmolysate (ID 1815, 1816)**

The food constituent that is the subject of the health claims is “herbal yeast plasmolysate (*Saccharomyces cerevisiae*)” related to the following claimed effects: physical performance and concentration.

In the context of the references provided, the Panel assumes that the claim refers to a specific commercial preparation of herbal yeast plasmolysate where *Saccharomyces cerevisiae* Meyen (not further specified) is cultivated in a medium containing specific but unidentified plant extracts, and is washed and subjected to plasmolysis by fermentation. *Saccharomyces cerevisiae* Meyen refers to a group of yeast strains that were re-classified by taxonomists (Molina et al., 1992).

The Panel notes that neither the identity of the yeast strain nor the composition of the plant extract in which the yeast is cultivated have been provided. The Panel also notes that no studies on the consumption of herbal yeast plasmolysate in relation to the claimed effects were available, and therefore the food constituents in herbal yeast plasmolysate which could be relevant for the claimed effects are unclear.

The Panel considers that the food, herbal yeast plasmolysate, which is the subject of the claim, is not sufficiently characterised in relation to the claimed effects considered in this section.



The Panel concludes that a cause and effect relationship cannot be established between the consumption of herbal yeast plasmolysate and the claimed effects considered in this section.

#### **1.4. Apple polyphenols (ID 2713)**

The food constituent that is the subject of the health claim is “*Pyrus malus* (common name apple) extract powder containing polyphenols” related to the following claimed effect: post-prandial glycaemic responses.

Polyphenols include a wide range (thousands) of compounds belonging to subgroups of flavanones, flavonols, flavan-3-ols, such as proanthocyanidins, as well as flavonones, isoflavonoids and anthocyanins. Apples typically contain hydroxycinnamic acid derivatives, flavan-3-ols (monomeric and oligomeric), flavonols and their conjugates, and dihydrochalcones such as phlorizin (Shahidi and Naczki, 2004). In addition, anthocyanins are found in the skin of some red apple varieties.

The Panel notes that the nature and amount of different polyphenol compounds in the apple extract powder has not been specified in the information provided.

Two of the three references provided for the scientific substantiation of the claim were a narrative review on the health effects of phlorizin, which included no original data, and one unpublished *in vitro* study for which only an abstract was available. The third reference reported on a human intervention study on the effects of clear and cloudy apple juices characterised on the basis of their content in single polyphenols (e.g. phlorizin, chlorogenic acids, phloretin xyloglucoside and (+)-catechin) and sugars on post-prandial glycaemic and insulinaemic responses as compared to a control beverage containing the same amount of sugars (Johnston et al., 2002). The Panel notes that the pectin content in the apple juices is not reported, and that therefore none of them are sufficiently characterised with respect to all of the components which could have an impact on the claimed effect (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010).

The Panel considers that the food constituent, apple polyphenols, which is the subject of the claim, is not sufficiently characterised in relation to the claimed effect considered in this section.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of apple polyphenols and the claimed effect considered in this section.

#### **1.5. Rye flour (ID 1266)**

The food constituent that is the subject of the health claims is rye flour related to the following claimed effect: low glycaemic index.

Rye flour is obtained through milling of rye (*Secale cereale* L.) grain. Rye flour is typically used to prepare rye bread and sourdough bread, and other products that are generally darker and denser than other types of similar products made from wheat. The milling of rye results in rye flour of different extraction rates varying from around 65 to 100 % (whole grain).

The chemical composition of rye flour varies considerably with the extraction rate, and thus with the degree of milling. As the milling process advances, progressive decreases in starch,  $\beta$ -glucans (indicator of rye bran) and moisture content, as well as increase in protein content, are observed (Gómez et al., 2009). The content of rye dietary fibre with arabinoxylan as the dominating fibre component varies considerably with the milling, and with both the genotype and the environment (Hansen et al., 2004). A variety of specific and non-specific methods for the analysis of various carbohydrate fractions in rye flour is available. Nutritionally, it is important to differentiate between two broad categories of carbohydrates: those digested and absorbed in the human small intestine

providing carbohydrates to body cells (commonly referred to as digestible, available or glycaemic carbohydrates), and those passing to the large intestine forming substrate for the colonic microflora (commonly referred to as nondigestible, “unavailable” or non-glycaemic carbohydrates).

The claimed effect is a low glycaemic index. The concept of glycaemic index (GI) was originally introduced to classify carbohydrate-rich foods (usually having an energy content of >80 % from carbohydrates), according to the differences in effects on post-meal glycaemia (Brouns et al., 2005). The GI, which is a nutritional property of a carbohydrate-rich food, is defined as the incremental area under the blood glucose response curve following a 50 g glycaemic carbohydrate portion of a test food expressed as a percentage of the response to the same amount of carbohydrates from a standard reference product taken by the same subject (FAO/WHO, 1998). Carbohydrate-rich foods can be classified according to their GI values (glucose as the standard): high GI >70; normal GI 55-70; low GI 40-55 and very low <40 (Brand-Miller, 2003). However, the GI of a carbohydrate-containing food depends on several factors (e.g. amount and type of dietary fibre, amount of dietary fat, energy density, physical properties, and mode of preparation) other than the amount of available (glycaemic) carbohydrates present.

Taking into account that the chemical nature and processing of the rye flour, which is the subject of the claim, has not been defined, that the GI of rye flour and food products made from rye flour depends on the chemical and physical properties, and preparation, of the particular type of rye flour under consideration, and that low GI carbohydrates have not been defined in the information provided, the Panel considers that the food constituent, rye flour, which is the subject of the health claim, is not sufficiently characterised in relation to the claimed effect considered in this section.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of rye flour and the claimed effect considered in this section.

#### **1.6. Tomato juice (ID 1202)**

The food that is the subject of the health claim is tomato juice related to the following claimed effect: blood glucose control.

From the conditions of use and the only reference provided no information on the composition and/or manufacturing process of the tomato juice which is the subject of the health claim was provided.

The Panel considers that the food, tomato juice, which is the subject of the claim, is not sufficiently characterised.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of tomato juice and the claimed effect considered in this section.

#### **1.7. Whey protein and alpha-lactalbumin (ID 424, 430, 432, 725, 1433)**

The food constituents that are the subject of the health claims are whey protein and alpha-lactalbumin related to the following claimed effects: immune defence against pathogens, cognitive function, mood, and blood pressure.

Whey protein is a mixture of globular proteins isolated from whey, a by-product obtained during the manufacturing of cheese from cow's milk. Beta-lactoglobulin (approximately 50 %), alpha-lactalbumin (approximately 20 %), bovine serum albumin (approximately 10 %) and immunoglobulins are the major protein fractions in whey. The composition and amino acid profile of whey protein preparations may vary depending on the enrichment of one of these fractions, such as alpha-lactalbumin (Markus et al., 2002). Whey can be treated and processed in different ways

depending on the type of whey protein and products to be obtained. The main commercial forms are concentrates (29-89 % protein by weight), isolates (about 90 % protein by weight) and hydrolysates (partially pre-digested). Differences in composition between different whey protein products may exist depending on the manufacturing processes applied (Onwulata et al., 2004). The products generally have a high content of essential amino acids, with especially high proportions of available lysine, cysteine and tryptophan. Whey protein composition also differs between breeds of cow (Haug et al., 2007; Meisel and FitzGerald, 2003).

In relation to ID 430, 432 and 1433, the Panel notes that the composition of whey protein is variable, especially with regard to constituents such as alpha-lactalbumin, which is claimed to have psychoactive properties. Alpha-lactalbumin is a protein which occurs naturally in mammalian milk, and is measurable in foods by established methods. Alpha-lactalbumin is composed of 123 amino acids, including tryptophan which is a precursor of the neurotransmitter serotonin. The tryptophan content of alpha-lactalbumin preparations is variable, and can range from 1.2 g/100 g (Markus et al., 2002; Merens et al., 2005) to 4.8 g/100 g (Markus et al., 2005). The Panel notes that the references provided for these IDs refer to different food products containing various commercial whey protein or alpha-lactalbumin preparations, and that the composition of these food products is variable, in particular with respect to their amino acid profile, which may have an impact on the claimed effects. The Panel notes that from the information provided it is not possible to determine the food constituent(s) which are the subject of the claims.

In relation to ID 725, the Panel notes that from the conditions of use and references provided it is not possible to determine the particular whey protein peptides which are the subject of the claim.

In relation to ID 424, the Panel notes that in the references provided different commercial whey protein products were used, and that no information has been given on the composition, or on the standardisation of the manufacturing process, of these products. The Panel notes that from the information provided it was not possible to determine the specific “whey protein” product which is the subject of the claim.

The Panel considers that the food constituents, whey protein and alphas-lactalbumin, which are the subject of the claim, are not sufficiently characterised in relation to the claimed effects considered in this section.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of whey protein and alphas-lactalbumin and the claimed effects considered in this section.

#### **1.8. “Brocco shoots”, “broccoli sprout powder” and “*Brassica oleracea* var. *italica* (broccoli)” (ID 1362, 1481, 2844, 2845)**

The foods that are the subject of the health claims are “brocco shoots”, “broccoli sprout powder” and “*Brassica oleracea* var. *italica* (broccoli)” related to the following claimed effect protection of cells and molecules, including cells of the immune system, from oxidative damage.

Broccoli is the common name of the *Italica* cultivar group of the *Brassica oleracea* species in the *Brassicaceae* (belonging to *Cruciferae*) family, whose large flower head is used as a vegetable. Broccoli sprouts are 3-4 day old broccoli plants. Different varieties of *Brassica oleracea* *Italica* (e.g. sprouting broccoli, purple cauliflower, orange cauliflower and green cauliflower), some of which are produced by selective breeding, are available on the market.

The nutritional composition of broccoli flowers and sprouts depends on a variety of factors, including climate, season, horticultural practices, and the variety and age of the plant.

The Panel notes that for ID 2845 the conditions of use refer to sulphoraphane, but no references on sulphoraphane in broccoli have been provided in relation to the claimed effect. The Panel also notes that ID 2844 and 2845 specify in the conditions of use “broccoli seed or sprout or vegetable extract equivalent to 30 mg of glucoraphanin per day”. Glucoraphanin is a glucosinolate found in vegetables of the *Brassicaceae* family which can be hydrolysed to the isothiocyanate sulforaphane.

The vast majority of the references provided for the scientific substantiation of these claims were animal and *in vitro* studies which addressed the effects of glucosinolates (including glucoraphanin) or its isothiocyanate metabolites, sulforaphane, (and its N-acetylcysteine conjugates), sulforaphane nitrile and/or phenethyl-, allyl- or benzyl-isothiocyanate on cancer-related outcomes which are unrelated to the claimed effects considered in this section, or addressed the composition of different cruciferous vegetables in relation to these compounds. The few human studies provided (mostly epidemiological observations) investigated the association between consumption of cruciferous vegetables (including broccoli) and the urinary excretion of isothiocyanates and cancer-related outcomes. One human intervention study on the acute effects of one-week consumption of broccoli sprouts, for which no characterisation was available, on markers of oxidative stress (Murashima et al., 2004), and one human intervention study on the effects of 4-week consumption of *Brassica* vegetables in general on markers of oxidative stress were also provided. From the information provided in relation to the claims evaluated in this section, the foods which are the subject of the claim were not sufficiently characterised in relation to the claimed effect.

The Panel considers that the foods, “brocco shoots”, “broccoli sprout powder” and “*Brassica oleracea* var. *italica* (broccoli)”, which are the subject of the claims, are not sufficiently characterised in relation to the claimed effects considered in this section.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of “brocco shoots”, “broccoli sprout powder” and “*Brassica oleracea* var. *italica* (broccoli)” and the claimed effects considered in this section.

### **1.9. Honey (ID 1159, 1160, 1318, 4678, 4679)**

The food that is the subject of the health claims is honey related to the following claimed effects: protection of cells and molecules from oxidative damage, defence against pathogens, and maintenance of blood cholesterol concentrations.

Honey is a sweet food made by honey bees (genus *Apis*, many subspecies); less common is honey made by non-stinging bees. Honey is usually made from the nectar (sugar-rich secretions) of flowers by a process of regurgitation, and can be monofloral, polyfloral, or blended; there are regional honeys, and classifications according to processing, colour and optical density. Honey can also be made from honeydew (sweet secretions from aphids and some scale insects).

According to Council Directive 2001/110/EC<sup>7</sup> and the Codex Standard for honey (Codex Alimentarius, 1981), honey is defined as “the natural sweet substance produced by bees from the nectar of plants or from secretions of living parts of plants or excretions of plant-sucking insects on the living parts of plants, which the bees collect, transform by combining with specific substances of their own, deposit, dehydrate, store and leave in honeycombs to ripen and mature”.

About 95 % of honey dry matter is composed of carbohydrates, mainly fructose and glucose but also around 25 different oligosaccharides. Different types of honey induce variable glycaemic responses, reflecting the differences in composition and botanical source. Honey contains small amounts of proteins, enzymes, amino acids, minerals and trace elements, vitamins, aroma compounds and

<sup>7</sup> Council Directive 2001/110/EC of 20 December 2001 relating to honey. OJ L 10, 12.1.2002, p. 47-52.

polyphenols. Compositional criteria include the sugar content, moisture content, water-insoluble solid content, electrical conductivity, free acids, diastase activity and hydroxymethylfurfural (HMF) content. Composition varies substantially depending on the floral source and geographical location (Bogdanov et al., 2008).

For ID 1160, fructooligosaccharides (FOS) and “antioxidant phytochemicals” present in honey were specified as “active” substances. FOS in honey differ in composition as well as in degree of polymerisation. FOS content in honey is variable and is dependent on the floral source of the honey. The references cited did not specify the composition or the content of these substances.

The Panel notes that according to the references provided the composition of honey is variable and depends on the floral origin, the geographic location, the season and the processing conditions, that honeys produced in different regions were mentioned, and that it was not possible to characterise the specific honey for which the claims are made.

The Panel considers that the food, honey, which is the subject of the health claims, is not sufficiently characterised in relation to the claimed effects considered in this section.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of honey and the claimed effects considered in this section.

#### **1.10. *Cucurbita pepo* L. (pumpkin) seeds and seed extracts (ID 2029, 2365)**

The food that is the subject of the health claims is *Cucurbita pepo* L. (pumpkin) seeds and seed extracts related to the following claimed effects: maintenance of normal prostate size and normal urination.

The pumpkin (*Cucurbita pepo* L.) is native to America, but is cultivated worldwide in warm and temperate regions. Pumpkin seeds are small, rather flat and oval-shaped, sometimes white but usually vibrant orange. Hull-less seeds contain 41 to 59 wt% fat, approximately 35 wt% protein, with albumin and globulin being the most prominent proteins, 5 to 7 wt% water, and minor amounts of carbohydrates, fibre and ash (Fruhwirt and Hermetter, 2007). Pumpkin seeds also contain a variety of phytosterols, minerals and carotenoids. Because of the wide variety of pumpkin species, the fatty acid composition of the oil obtained from them can vary significantly. The fatty acid pattern of *Cucurbita pepo* subsp. *pepo* var. *styriaca*, a variety which is used by some manufacturers as a source for pumpkin seed oil or pumpkin seed extracts, has been provided. Various pumpkin seed compounds (phytosterols, fatty acids, minerals and vitamins) have been postulated to have an effect on maintenance of normal prostate size and normal urination in males.

Two human studies were conducted with a specific preparation of pumpkin seeds, which contained 500 mg of a (15-25:1) pumpkin seed extract derived from a 92 % alcohol extraction of seeds from *Cucurbita pepo* subsp. *pepo* var. *styriaca* (Bach, 2000; Friederich et al., 2000). No compositional data were provided for this extract.

No human study was provided which evaluated the effect of pumpkin seeds as such on the claimed effect.

The Panel considers that the food, *Cucurbita pepo* L. (pumpkin) seeds and seed extracts, which is the subject of the claims, is not sufficiently characterised in relation to the claimed effects considered in this section.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of *Cucurbita pepo* L. (pumpkin) seeds and seed extracts and the claimed effects considered in this section.

## CONCLUSIONS

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

- The following foods/food constituents are not sufficiently characterised, or are not sufficiently characterised in relation to the claimed effects:
  - Dairy products related to: weight management and maintenance of tooth mineralisation (ID 1140, 1141, 1191).
  - Raw or processed food products of animal origin, plus bread and panification products related to: maintenance of blood cholesterol concentrations and blood glucose control (ID 1193, 1194).
  - Herbal yeast plasmolysate related to: physical performance and concentration (ID 1815, 1816).
  - Apple polyphenols related to: blood glucose control (ID 2713).
  - Rye flour related to: low glycaemic index (ID 1266).
  - Tomato juice related to: blood glucose control (ID 1202).
  - Whey protein and alphas-lactalbumin related to: immune defence against pathogens, cognitive function, mood and blood pressure (ID 424, 430, 432, 725, 1433).
  - “Brocco shoots”, “broccoli sprout powder” and “*Brassica oleracea* var. *italica* (broccoli)” related to: protection of cells and molecules, including cells of the immune system, from oxidative damage (ID 1362, 1481, 2844, 2845).
  - Honey related to: protection of cells and molecules from oxidative damage, defence against pathogens, and maintenance of blood cholesterol concentrations (ID 1159, 1160, 1318, 4678, 4679).
  - *Cucurbita pepo* L. (pumpkin) seeds and seed extracts related to: maintenance of normal prostate size and normal urination (ID 2029, 2365).
- A cause and effect relationship cannot be established between the foods/food constituents which are the subject of this opinion and the claimed effects.

## DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1211, EFSA-Q-2008-1217, EFSA-Q-2008-1219, EFSA-Q-2008-1512, EFSA-Q-2008-1879, EFSA-Q-2008-1880, EFSA-Q-2008-1898, EFSA-Q-2008-1899, EFSA-Q-2008-1930, EFSA-Q-2008-1932, EFSA-Q-2008-1933, EFSA-Q-2008-1941, EFSA-Q-2008-2004, EFSA-Q-2008-2055, EFSA-Q-2008-2099, EFSA-Q-2008-2170, EFSA-Q-2008-2218, EFSA-Q-2008-2548, EFSA-Q-2008-2549, EFSA-Q-2008-2762, EFSA-Q-2008-3098, EFSA-Q-2008-3446, EFSA-Q-2008-3577, EFSA-Q-2008-3578, EFSA-Q-2010-00631, EFSA-Q-2010-00632). 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>8</sup> (hereinafter "the Regulation") entered into force on 19th 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>9</sup>

Foods are commonly involved in many different functions<sup>10</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>8</sup> OJ L12, 18/01/2007

<sup>9</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>10</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 not sufficiently characterised foods/food constituents, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
424	Whey protein	Supports a healthy immune system	Whey protein helps athletes maintain a healthy immune system by increasing the levels of glutathione in the body. Glutathione is an antioxidant required for a healthy immune system and exercise and resistance training may reduce glutathione levels.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.</li> <li>- 20 grams per day Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
430	Whey protein	Cognitive function <u>Clarifications provided:</u> Cognitive Health - Whey protein rich in alpha lactalbumin increases availability of plasma tryptophan, a precursor to brain serotonin, which maintains optimal cognitive function	Whey protein improves cognitive performance
	<p><b>Conditions of use</b></p> <p>Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
432	Whey protein	Stress and mental health <u>Clarifications provided:</u> Stress and mental health - Whey protein rich in alpha lactalbumin leads to higher tryptophan availability resulting in increased brain serotonin synthesis which supports mental health and improves mood, particularly in stress vulnerable people	Whey protein enhances mood and mental well-being

<p><b>Conditions of use</b></p> <p>Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
725	Whey protein peptides	<p>Maintaining vascular health</p> <p><u>Clarification provided</u></p> <p>Whey proteins are a source of bioactive peptides that can aid/support healthy blood circulation.</p>	Helps maintain a healthy vascular system
<p><b>Conditions of use</b></p> <p>Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.</p>			
ID	Food or Food component	Health Relationship	Proposed wording
1140	<p>Dairy (low fat dairy)</p> <p>*Dairy refers to cow's milk, yogurt and cheese</p> <p><u>Clarification provided</u></p> <p>"Low fat dairy" - studies refer to low fat milk and low fat dairy products (yogurt) for which low fat milk is the principle ingredient.</p> <p>Low fat milk and low fat dairy foods (yogurt) will be a source of calcium as per annex to regulation 1924/2006.</p> <p>The nutritional composition of low fat milk and low fat dairy products (yogurt) should reflect that stated in food composition tables.</p>	<p>Weight loss</p> <p>Fat loss</p> <p>Weight maintenance</p>	<p>Dairy in an energy restricted diet helps weight loss.</p> <p>Consuming dairy foods, as part of your weight loss diet, will help weight loss.</p> <p>Consuming dairy foods, as part of your weight loss diet, will help weight maintenance.</p>
<p><b>Conditions of use</b></p> <p>kalorienreduzierte Diät;</p> <p>-low fat, As part of a healthy balanced diet and lifestyle</p>			
ID	Food or Food component	Health Relationship	Proposed wording
1141	<p>(Cow's) Milk</p> <p>And dairy products for which milk is the principle ingredient and no sugar has been added – e.g. yogurt, cheese.</p> <p><u>Clarification provided</u></p> <p>(Cow's) Milk And dairy</p>	Dental Health	<p>(Cow's) Milk products help support dental health.</p> <p>(Cow's) Milk helps support the normal and healthy development of teeth.</p> <p>(Cow's) Milk contributes to dental health.</p>

	<p>products for which milk is the principle ingredient and no sugar has been added – e.g. yogurt, cheese (Hard).</p> <p>Milk and dairy foods will be a source of calcium as per annex to regulation 1924/2006.</p> <p>Dairy foods are consumed as part of a healthy and balanced diet.</p> <p>The nutritional composition of milk and dairy foods should reflect that stated in food composition tables.</p>		<p>(Cow's) Milk helps maintain healthy teeth</p> <p>(Cow's) Milk helps keep teeth healthy.</p>
<p><b>Conditions of use</b></p> <p>(Cow's) Milk (to which no sugar has been added)</p>			
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
<b>1159</b>	Honey (as defined by The Honey Regulations 2003 (as amended)).	Antioxidant properties Plus Antimicrobial properties.	<p>Helps maintain your natural defences.</p> <p>Honey antioxidants contribute to the total antioxidative capacity of the body.</p> <p>Honey contains naturally-occurring antioxidants.</p> <p>Honey helps to support the digestion with a natural antimicrobial action.</p> <p>Honey helps contribute to the natural defences of the body.</p> <p>Honey helps to support the digestion.</p> <p>Honey polyphenols help ensure our antioxidant capacity.</p> <p>Honey has a natural antimicrobial action.</p>
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Internal use: 20-30 g per day.</li> <li>- 15g per day.</li> <li>- Honey (the required amount is not indicated). Heating honey to a temperature of over +60 degrees for more than 10 minutes reduces its enzymes by approximately 50%.</li> </ul>			
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
<b>1160</b>	Honey.	Digestive health through presence of	Helps support and maintain a healthy digestive system.



		<p>fructooligosaccharides and antioxidant phytochemicals.</p> <p><u>Clarification provided</u></p> <p>Helps maintain healthy skin/epithelial layer of the digestive tract and thus helps to maintain a healthy digestive tract.</p> <p>Increases growth of probiotic bacteria.</p> <p>Increases growth of Lactobacillus spp.</p>	
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 12.5g half an hour before food 4 times daily. Advisory Statement: Honey contains natural sugars.</li> <li>- Honey (the required amount is not indicated). Heating honey to a temperature of over +60 degrees for more than 10 minutes reduces its enzymes by approximately 50%.</li> </ul>		
ID	Food or Food component	Health Relationship	Proposed wording
1191	<p>Fat free dairy products with reduced sugars or without added sugars</p> <p><u>Clarification provided</u></p> <p>Fat-free (1) dairy products (2) with no added sugars or with reduced sugars (3) (4).</p> <p>(1): fat free, i.e. containing less than 0.5 g of fat per 100 g of product as defined per Regulation EC N°1924/2006 on Nutrition and</p> <p>Health Claims made on foods.</p> <p>(2): as defined in the COUNCIL REGULATION (EC) No 1234/2007 of 22 October 2007</p> <p>establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products.</p> <p>Dairy products, which would include but not be limited to the following: milks, fermented milks (including yoghurts), fresh cheeses (including "petits suisses").</p>	Body weight control	<p>1 - Main wording</p> <p>In French:</p> <ul style="list-style-type: none"> <li>- Les produits laitiers à 0% de matière grasse et à teneur réduite en sucres (ou sans sucres ajoutés) aident à contrôler le poids corporel dans le cadre d'une alimentation équilibrée.</li> </ul> <p>In English :</p> <ul style="list-style-type: none"> <li>- Fat free dairy products with reduced sugars or without added sugars help control body weight as part of a balanced diet.</li> </ul> <p>2 - Other examples of wordings</p> <p>In French :</p> <ul style="list-style-type: none"> <li>- aide à maintenir le poids corporel</li> <li>- aide à garder la ligne</li> <li>- partenaire nutritionnel de votre ligne</li> </ul> <p>In English :</p> <ul style="list-style-type: none"> <li>- help maintain body weight</li> </ul>

	<p>(3): with no added sugars or reduced in sugar as defined per Regulation EC N°1924/2006 on Nutrition and Health Claims made on foods, i.e. containing at least 30% less sugars than a standard product.</p> <p>(4): at least one serving of a fat-free dairy product with no added sugars or with reduced sugars per day instead of the corresponding standard dairy product, as part of a varied and balanced diet and a healthy lifestyle.</p>		<p>- help keep your figure</p> <p>- nutritional partner of your figure</p>
<p><b>Conditions of use</b></p> <p>▪ dairy products; ▪ and fat free(1); ▪ and with reduced sugars or without added sugars(1); ▪ As part of a daily intake by adults; (1)as defined in the 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 (Annex I)</p>			
ID	Food or Food component	Health Relationship	Proposed wording
1193	<p>Raw or processed food products of animal origin, plus bread and panification products (cow's, goat's and ewe's milk and related products ( milk, cream, butter, cheese, yoghurt, fresh dairy products); hen's and quail's eggs; beef's, veal's and lamb's meat; poultry's meat (chicken, pigeon, turkey); rabbit's meat; pork's meat and related products ( ham, pork-butchery), ), bread and panification products. Specifications for each group of products is given in annexes of the dossier Tradilin quoted A4 above ), intended for the general population and whose elaboration strictly respect Tradilin specifications and which consequently have an improved lipid quality, including an enhanced omega 3 content, relatively to standard equivalent product.</p>	<p>Quality of dietary lipids and blood lipid profile</p>	<p>* The Tradilin network makes it possible to obtain products which fit into a diet naturally rich in omega 3, which favors the balance/a good balance of blood lipids</p> <p>La filière Bleu-Blanc-Coeur / Tradilin permet d'obtenir des produits qui s'intègrent dans une alimentation naturellement riche en oméga 3, qui favorise l'équilibre des lipides sanguins</p> <p>* A diet which includes products from the Tradilin network favours a good balance of blood lipids.</p> <p>S'alimenter avec des produits, issus de la filière Tradilin favorise l'équilibre des lipides sanguins</p> <p>* This product participates/ contributes to improve the balance of blood lipids.</p> <p>Ce produit contribue/participe à l'amélioration de l'équilibre des lipides sanguins</p> <p>* This product, from de Tradilin network fits in a diet</p>

			<p>naturally increased in Omega 3, which favors the balance of blood lipids</p> <p>Ce produit, issu de la filière Tradilin s'intègre dans une alimentation naturellement riche en Oméga 3, qui favorise l'équilibre des lipides sanguins</p>
<p><b>Conditions of use</b></p> <p>Using the product in substitution of its standard equivalent and in combination with other Tradilin animal products. Such diet should be kept for at least one month.</p>			
<p><b>No clarification provided by Member States</b></p>			
ID	Food or Food component	Health Relationship	Proposed wording
1194	<p>Raw or processed food products of animal origin, plus bread and panification products (cow's, goat's and ewe's milk and related products ( milk, cream, butter, cheese, yoghurt, fresh dairy products); hen's and quail's eggs; beef's, veal's and lamb's meat; poultry's meat (chicken, pigeon, turkey); rabbit's meat; pork's meat and related products ( ham, pork-butchery), ), bread and panification products.</p> <p>Specifications for each group of products is given in annexes of the dossier Tradilin quoted A4 above ), intended for the general population and whose elaboration strictly respect Tradilin specifications and which consequently have an improved lipid quality, including an enhanced omega 3 content, relatively to standard equivalent product.</p>	<p>Quality of dietary lipids and nutrient (carbohydrates) metabolism</p>	<p>* The Tradilin network makes it possible to obtain products which fit into a diet naturally rich in omega 3 which participates to improve/decrease carbohydrate metabolic disorders</p> <p>La filière Tradilin permet d'obtenir des produits qui s'intègrent dans une alimentation riche en Oméga 3 qui participe diminuer les désordres du métabolisme des carbohydrates</p> <p>* The Tradilin network makes it possible to obtain products which fit into a diet naturally rich in omega 3 which participates in the control of parameters of the metabolic syndrome</p> <p>La filière Tradilin permet d'obtenir des produits qui s'intègrent dans une alimentation riche en Oméga 3 qui participe au contrôle des paramètres du syndrome métabolique</p> <p>* This product participates/contributes/helps to regulate carbohydrate metabolism</p> <p>Ce produit participe à la régulation du métabolisme glucidique</p> <p>* This product, from the</p>

			<p>Tradilin network, helps to better to regulate carbohydrate metabolism/ control the parameters on the metabolic syndrome</p> <p>Ce produit, issu de la filière Tradilin, s'intègre dans une alimentation riche en Oméga 3 qui participe à diminuer les désordres du métabolisme des carbohydrates/à contrôler les paramètres du syndrome métabolique</p>
<p><b>Conditions of use</b></p> <p>Using the product in substitution of its standard equivalent and in combination with other Tradilin animal products. Such diet should be kept for at least one month.</p>			
<p><b>No clarification provided by Member States</b></p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
1202	Tomato juice.	Cardiovascular System.	Tomato juice has a positive Influence on blood sugar level.
	<p><b>Conditions of use</b></p> <p>- 250 ml per day over 3 weeks.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1266	Rye flour	Rye flour's low glycaemic index.	<p>Rukkijahu iseloomustab madal glükeemiline indeks.</p> <p><u>Clarification provided</u></p> <p>Rye flower is characterised by low glycaemic index.</p>
	<p><b>Conditions of use</b></p> <p>Rukkijahust valmistatud leib.</p>		
	<p><b>Comments from Member States</b></p> <p>Rye flower is characterised by low glycaemic index.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1318	Honey.	<p>Antibacterial and antifungal properties.</p> <p>Target Group: For children and adults older than three years old.</p> <p>Excluded Group : Nobody (only person who are allergic).</p> <p><u>Clarification provided</u></p> <p>Contribute to the total antioxidant capacity of the body/Stimulates the body.</p>	Flavonoids contained within the honey contribute to the microbial balance in the body organs and tissues.

<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 20-30 g per day. Safe limits of use: No limits. Warning : Not for people who are allergic to the honey - No interaction to the association of honey with the administration of traditional therapeutic substance, either natural or synthetic, has been observed.</li> <li>- Miel+huile 3x1-2 pastilles/jour.</li> </ul>			
<p><b>Comments from Member States</b></p> <p>LU: Agree with GR proposal. 20-30 g per day. Safe limits of use: No limits. Warning : Not for people who are allergic to the honey - No interaction to the association of honey with the administration of traditional therapeutic substance, either natural or synthetic, has been obser.</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
1362	<p>Name of Food product: Brocco Shoots.</p> <p>Description of food in terms of food legislation categories: food not covered by specific food legislation.</p> <p>Was food on Irish market before 1st July 2007: Yes.</p>	<p>Health benefits of food: Naturally boosts your immune system.</p> <p>Do benefits relate to a disease risk factor: No.</p> <p>Target group: All of the general population including children and adults.</p> <p><u>Clarification provided</u></p> <p>Health benefits of food: natural source of sulforaphane which may help prevent cell damage</p> <p>Do benefits relate to a disease risk factor: No</p> <p>Target group: All of the general population including children and adults</p>	<p>Exact wording of claim as it appears on product: Brocco Shoots naturally boost your immune system.</p> <p>Is claim a picture: No.</p>
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Weight of average daily food serving: 20 gram(s).</li> <li>- Daily amount to be consumed to produce claimed effect: 20 gram(s).</li> <li>- Number of food portions this equates to in everyday food portions: 1.</li> <li>- Are there factors that could interfere with bioavailability: No</li> <li>- Length of time after consumption for claimed effect to become apparent: It is apparent after a period of regular use.</li> <li>- Number of days: 30.</li> <li>- Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No.</li> <li>- Where applicable outline nutritional composition (g per 100g) of food: Total Fat: 1.69, Saturated Fat: .49, Trans Fat: .00, Sugar: 1.36, Salt: .00, Sodium: .02</li> </ul>			
<p><b>Comments from Member States</b></p> <p>Clarification/further information/alternative wording which was provided by the FBO has been included. The FBO includes a document (attached and identified by claim number- additional information) with additional information on the health relationship.</p>			

ID	Food or Food constituent	Health Relationship	Proposed wording
1433	a-Lactalbumin	<p>Functions in neurotransmitter formation</p> <p><u>Clarification provided</u></p> <p>Cognitive function: Increases alertness and attention span and is anxiolytic</p>	a-Lactalbumin increases cognitive function
	<p><b>Conditions of use</b></p> <p>At least 12 g per day</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1481	Broccoli Sprout Powder.	Antioxidant properties.	Helps to protect the bodies cells against oxidative stress.
	<p><b>Conditions of use</b></p> <p>- 1g per day.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1815	Herbal yeast plasmolycate (saccharomyces cerevisiae)	<p>Physical performance and condition</p> <p><u>Clarification provided</u></p> <p>Herbal yeast plasmolysate improves physical and mental performances, increases the concentration, helps against fatigue and nervousness and restores vitality.</p>	Improves performance
	<p><b>Conditions of use</b></p> <p>- Herbal yeast preparation with 2.7-4.5 g of herbal yeast plasmolycate (saccharomyces cerevisiae) in the daily dose</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1816	Herbal yeast plasmolycate (saccharomyces cerevisiae)	Mental state and performance	<p>Adds vigour and activity.</p> <p>Reduces feeling of tiredness.</p> <p>Improves concentration.</p>
	<p><b>Conditions of use</b></p> <p>- Herbal yeast preparation with 2.7-4.5 g of herbal yeast plasmolycate (saccharomyces cerevisiae) in the daily dose.</p> <p>- 5ml to be taken three times daily</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
2029	Cucurbita pepo (Common Name: Pumpkin).	<p>Health of lower urinary tract.</p> <p><u>Clarification provided</u></p> <p>Health of lower urinary tract/</p>	Maintenance of good bladder function and urinary flow/good for normal prostate function.

		<p>Supports/helps to maintain good bladder and prostate function. Maintains normal urinary flow and reduces frequency and urge of urination in men. Helps to maintain good urinary flow. Good for normal bladder function. Good for normal urinary flow. Helps to reduce need for continuous need to urinate. Helps to reduce need for repeated need to urinate.</p>	
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- nasiona/ równowartość 190- 600 mg oleju lub 30-60 g pestek na dzień.</li> <li>- 400 mg pro Tag.</li> <li>- Kürbiskernextrakt 7:1600 mg pro Tag.</li> <li>- 400mg Kürbiskonzentrat, 2.222mg Kürskerne (als Extrakt).</li> <li>- 2 EL = 20 g täglich.</li> <li>- 500 mg Nahrungsergänzung.</li> <li>- &lt;60 bis 120mg <math>\beta</math>-Sterole 3x täglich—Erwachsene.</li> <li>- Kerne/Männer und Frauen—Tagesdosis Extrakt: entspr. 400-500 mg Kürbiskernextrakt – Tagesdosis Droge: entspr. 8-10 g Kürbsikerne —Speziell für die Blase der Frau: – Tagesdosis: entspr. 400 mg Kürbiskernextrakt und 30 mg Sojaextrakt (entspr. mind. 12 mg Isoflavone).</li> <li>- Seed / The Equivalent of 190-600 ml oil or 30-60g ground seeds per day.</li> <li>- Food supplement with 525 mg of EFLA 940 pumpkin seed extract and 100 mg of soy extract in the daily dose. Two tablets in which the EFLA extract is equivalent to 10.5 g of pumpkin seed and 0.7 g of dried soy bean.</li> <li>- Huile 4x420mg/jour.</li> </ul>			
<p><b>Comments from Member States</b></p> <p>Men: health of bladder and prostate (Irritable bladder, miction complaints), Women:health of bladder, strengthening pelvic floor muscles, irritable bladder, stress incontinence AT.</p> <p>New scientific references:</p> <p>Sogabe H, Terado T. Open Clinical Study of Effects of Pumpkin Seed Extract/Soybean Germ Extract Mixture-containing Processed Food on Nocturia. Jpn J Med Pharm Sci. 2001 Nov;46(5):727-37.</p> <p>Yanagisawa E et al. Study of Effectiveness of Mixed Processed Food Containing Cucurbita Pepo Seed Extract and Soybean Seed Extract on Stress Urinary Incontinence in Women. Jpn J Med Pharm Sci. 2003 14; No.3:313-322.</p> <p>Terado T et al. Clinical Study of mixed processed foods containing pumpkin seed extract and soybean germ extract on pollikiuria in night in elderly men. Jpn Med Pharm Sci. 2004 52(4):551-561.</p> <p>Hata K et al. Effects of Pumpkin Seed Extract on urinary bladder function in anesthetized rats.</p>			

Jpn J Med Pharm. Sci. 2005 54 (3):339-345. (Animal study) (Translations from Japanese into English) - FI			
ID	Food or Food constituent	Health Relationship	Proposed wording
2365	Pumpkin seed (Cucurbita pepo).	Prostate/uri-nary tract. <u>Clarification provided</u> Prostate/urinary tract; health of urogenital system/the healthy prostate function/the normal miction and the normal urinary flow.	Contributes to maintain healthy prostate function.
ID	Food or Food constituent	Health Relationship	Proposed wording
2713	Pyrus malus (Common Name Apple) extract powder containing polyphenols.	Blood glucose control.	Can help to moderate the postprandial blood glucose level.  Can help to decrease the blood glucose level.
ID	Food or Food constituent	Health Relationship	Proposed wording
2844	Brassica oleracea var italica (broccoli).	Immune system. <u>Clarification provided</u> Supports the immune system by through antioxidant activity.	Helps maintain a healthy immune system.
ID	Food or Food constituent	Health Relationship	Proposed wording
2845	Brassica oleracea var italica (broccoli).	Antioxidant properties and cell protection.	Helps to protect cells from oxidation.  Supports cell health & function.  Well known source of antioxidants.  Natural defense against free radicals.  Helps the body to safely neutralize & excrete free radicals.



	Brokkoli Konzentrat: 500 mg –Erwachsene. - Broccoli seed or sprout or vegetable extract equivalent to 30mg of Glucoraphanin per day.		
ID	Food or Food constituent	Health Relationship	Proposed wording
4678	Honey.	Helps heart health and to maintain a balanced level of cholesterol and lipids in the body.	Promotes a good heart functioning and a balanced level of blood lipids.
	<b>Conditions of use</b> - 20 - 40 g/day or the equivalent of 1 spoonful.		
ID	Food or Food constituent	Health Relationship	Proposed wording
4679	Honey.	Energy metabolism.	Reminalizing of the organism.
	<b>Conditions of use</b> - Usual consumption as traditional foodstuff in a normal diet / 5-10 g daily.		

## GLOSSARY AND ABBREVIATIONS

FOS Fructooligosaccharides

HMF Hydroxymethylfurfural