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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to: anthocyanidins and proanthocyanidins (ID 1787, 1788, 1789, 1790, 1791); sodium alginate and ulva (ID 1873); vitamins, minerals, trace elements and standardised ginseng G115 extract (ID 8, 1673, 1674); vitamins, minerals, lysine and/or arginine and/or taurine (ID 6, 1676, 1677); plant-based preparation for use in beverages (ID 4210, 4211); *Carica papaya* L. (ID 2007); "fish protein" (ID 651); acidic water-based, non-alcoholic flavoured beverages containing calcium in the range of 0.3 to 0.8 mol per mol of acid with a pH not lower than 3.7 (ID 1170); royal jelly (ID 1225, 1226, 1227, 1228, 1230, 1231, 1326, 1328, 1329, 1982, 4696, 4697); foods low in cholesterol (ID 624); and foods low in *trans*-fatty acids (ID 672, 4333) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

[1] On request from the European Commission, Question No EFSA-Q-2008-1411, EFSA-Q-2008-1459, EFSA-Q-2008-1909, EFSA-Q-2008-1963, EFSA-Q-2008-1964, EFSA-Q-2008-1965, EFSA-Q-2008-1966, EFSA-Q-2008-1968, EFSA-Q-2008-1969, EFSA-Q-2008-2063, EFSA-Q-2008-2065, EFSA-Q-2008-2066, EFSA-Q-2008-2715, EFSA-Q-2010-00286, EFSA-Q-2010-00649, EFSA-Q-2010-00650, adopted on 28 January 2011. EFSA-Q-2008-793, EFSA-Q-2008-795, EFSA-Q-2008-1438, EFSA-Q-2008-2409, EFSA-Q-2008-2410, EFSA-Q-2008-2412, EFSA-Q-2008-2413, EFSA-Q-2008-2520, EFSA-Q-2008-2521, EFSA-Q-2008-2522, EFSA-Q-2008-2523, EFSA-Q-2008-2524, EFSA-Q-2008-2606, EFSA-Q-2008-2740, EFSA-Q-2008-4920, EFSA-Q-2008-4921, adopted by written procedure on 17 February 2011.

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[3] Acknowledgement: 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.

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SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to: anthocyanidins and proanthocyanidins; sodium alginate and ulva; vitamins, minerals, trace elements and standardised ginseng G115 extract; vitamins, minerals, lysine and/or arginine and/or taurine"; plant-based preparation for use in beverages; *Carica papaya* L.; "fish protein"; acidic water-based, non-alcoholic flavoured beverages containing calcium in the range of 0.3 to 0.8 mol per mol of acid with a pH not lower than 3.7; royal jelly; foods low in cholesterol; and foods low in *trans*-fatty acids. 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:

- Anthocyanidins and proanthocyanidins related to the following claimed effects: "cardiovascular system", "blood fat levels", "carbohydrate metabolism and insulin sensitivity", "gut health" and "eyes" (ID 1787, 1788, 1789, 1790, 1791).

- Sodium alginate and ulva related to the following claimed effect: "alginate and ulva bind toxins, mutagens and heavy metals, they can also stimulate and increase colonic mucin production and thicken the colonic mucosa and protect the colon from harmful substances" (ID 1873).

- Vitamins, minerals, trace elements and standardised ginseng G115 extract related to the following claimed effects: "to cover increased needs of vitamins, minerals, trace elements and ginseng G115 extract specifically in cases of exhaustion, tiredness, feeling of weakness, decreasing concentration as well as decreasing mental alertness", "mental performance" and "energy metabolism" (ID 8, 1673, 1674).

- Vitamins, minerals, lysine and/or arginine and/or taurine related to the following claimed effects: "nutritional support during the period of growth for physical development", "nutritional support after illness" and "nutritional support to help mental performance" (ID 6, 1676, 1677).

- Plant-based preparation for use in beverages related to the following claimed effects: "aide à la prise de décisions chez les personnes hésitantes" and "aide à se libérer des petites manies" (ID 4210, 4211).

- *Carica papaya* L. related to the following claimed effect: "antioxidant activity" (ID 2007).

- "Fish protein" related to the following claimed effect: "skin, hair and nail health" (ID 651).

- Acidic water-based, non-alcoholic flavoured beverages containing calcium in the range of 0.3 to 0.8 mol per mol of acid with a pH not lower than 3.7 related to the following claimed effect: maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 1170).

- Royal jelly related to the following claimed effects: "natural defence/immune system", "metabolism", "vascular function", "glands function", "skin health", "tonus/vitality", "anti-asthénique, immunostimulant", "ménopause, effet oestrogénique", hypolipidémiant", "vitalité physique et intellectuelle" and "helps heart health and to maintain a balanced level of cholesterol and lipids in the body" (ID 1225, 1226, 1227, 1228, 1230, 1231, 1326, 1328, 1329, 1982, 4696, 4697).

- Foods low in cholesterol related to the following claimed effect: maintenance of normal blood cholesterol concentrations (ID 624).

- Foods low in *trans*-fatty acids related to the following claimed effect: maintenance of normal blood cholesterol concentrations (ID 672, 4333).

The information given in the consolidated list and the references provided did not allow the Panel to 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 in relation to the 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 proposed claimed effects.

KEY WORDS

Anthocyanidins, proanthocyanidins, alginate, ulva, vitamins, minerals, ginseng, lysine, arginine, taurine, plant-based preparation, *Carica papaya* L., fish protein, non-alcoholic flavoured beverages, royal jelly, cholesterol, saturated fatty acids, trans fatty acids, health claims.

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[4] 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[5]. 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 briefing document for stakeholders[6] published by EFSA.

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. Anthocyanidins and proanthocyanidins (ID 1787, 1788, 1789, 1790, 1791)

The food constituents that are the subject of the claim are anthocyanidins and proanthocyanidins related to the following claimed effects: "cardiovascular system", "blood fat levels", "carbohydrate metabolism and insulin sensitivity", "gut health" and "eyes".

Both anthocyanins and proanthocyanidins belong to the group of phenolic constituents known as flavonoids, which are naturally present in vegetables, fruits, and their products. Anthocyanins exist in nature as glycosylated forms of anthocyanidins. Proanthocyanidins are a group of flavan-3-ols ranging

[4] 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.

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

[6] See footnote 5

from dimers to polymers. Monomeric flavan-3-ols (such as catechin and epicatechin) are not considered proanthocyanidins. There are also differences in the linkages (A- or B-type) between the monomeric units of proanthocyanidins. The anthocyanin and proanthocyanidin content in different types of berries, fruits and other plants is measurable, but anthocyanin and proanthocyanidin profiles vary widely depending on the food source, and may have an impact on the claimed effects.

The references provided for the scientific substantiation of the claims included narrative reviews, animal and human intervention studies, and *in vitro* experiments on anthocyanosides/anthocyanidins, cyaniding-3-glucoside and pure anthocyanidin compounds, anthocyanoside oligomer, blackcurrant (*Ribes nigrum* L.) anthocyanins, bilberry (*Vaccinium myrtillus* L.) anthocyanosides, anthocyanins and anthocyanidins in fruits, berry polyphenols, black raspberries (*Rubus occidentalis* L.), chokeberry (*Aronia melanocarpa* (Michx.) Elliott) juice, Cornelian cherry (*Cornus mas* L.), red wine, and proanthocyanidins extracted from grape seed on various health outcomes, most of them unrelated to the claimed effects.

The Panel notes that no information has been provided on the source or composition of anthocyanidins or proanthocyanidins. From the references provided it is unclear which type of anthocyanidins or proanthocyanidins are the subject of the claims.

The Panel considers that the food constituents, anthocyanidins and proanthocyanidins, 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 anthocyanidins and proanthocyanidins and the claimed effects considered in this section.

1.2. Sodium alginate and ulva (ID 1873)

The food constituents that are the subject of the claim are sodium alginate and ulva related to the following claimed effect: "alginate and ulva bind toxins, mutagens and heavy metals, they can also stimulate and increase colonic mucin production and thicken the colonic mucosa and protect the colon from harmful substances".

Sodium alginate is the sodium salt of alginic acid. Sodium alginate is extracted from the cell walls of brown algae. It is used as a thickener and emulsifier, and it is authorised for use as a food additive[7]. Alginate is an anionic polysaccharide, a linear copolymer with homopolymeric blocks of (1-4)-linked β-D-mannuronate (M) and its epimer α-glucuronate (G) residues, which are linked covalently in different sequences. Commercial varieties of sodium alginate are extracted from *Marocystis pyrifera*, *Ascophyllum nodosum* and various types of *Laminaria*. Different sources yield alginates that differ in monomeric composition and block structure, and a given alginate has its own characteristic calcium reactivity and gelation properties. Alginates are usually referred to as high M or high G, depending on the proportions of M and G they contain. The references provided did not allow an identification of the monomeric composition and block structure of the specific sodium alginate that is the subject of the claim.

Ulva is a group of edible green algae. Several species of ulva exist worldwide and the species that is the subject of the health claim has not been specified in the information provided.

[7] European Parliament and Council Directive 95/2/EC of 20 February 1995, on food additives other than colours and sweeteners. OJ L 61, 18.3.1995, p. 1–40.

The references provided reported on the use of *Ulva ohnoi* Hiraoka & Shimada, *Ulva reticulata* Forsskål and *Ulva fasciata* Delile, as well as ulvan, a sulphated algal polymer extracted from the Ulva species, which did not allow determining the specific ulva species, or the specific preparation of ulva, which is the subject of the claim.

The Panel considers that the food constituents, sodium alginate and ulva, which are the subject of the claim, are 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 sodium alginate and ulva and the claimed effect considered in this section.

1.3. Vitamins, minerals, trace elements and standardised ginseng G115 extract (ID 8, 1673, 1674)

The food that is the subject of the claim is a combination of vitamins, minerals, trace elements and standardised ginseng G115 extract related to the following claimed effects: "to cover increased needs of vitamins, minerals, trace elements and ginseng G115 extract specifically in cases of exhaustion, tiredness, feeling of weakness, decreasing concentration as well as decreasing mental alertness", "mental performance" and "energy metabolism".

The Panel notes that the conditions of use refer to a number of ingredients which may or may not be included in the formulation of the food, and that the references provided referred to foods of various compositions. It is not possible, therefore, to determine which combination is the subject of the claims.

The Panel considers that the food, a combination of vitamins, minerals, trace elements and standardised ginseng G115 extract, 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 a combination of vitamins, minerals, trace elements and standardised ginseng G115 extract and the claimed effects considered in this section.

1.4. Vitamins, minerals, lysine and/or arginine and/or taurine (ID 6, 1676, 1677)

The food that is the subject of the claim is a combination of vitamins, minerals, lysine and/or arginine and/or taurine related to the following claimed effects: "nutritional support during the period of growth for physical development", "nutritional support after illness" and "nutritional support to help mental performance".

The Panel notes that the conditions of use refer to a number of ingredients which may or may not be included in the formulation of the food, and that the references provided referred to foods of various compositions. It is not possible, therefore, to determine which combination is the subject of the claims.

The Panel considers that the food, a combination of vitamins, minerals, lysine and/or arginine and/or taurine, 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 a combination of vitamins, minerals, lysine and/or arginine and/or taurine and the claimed effects considered in this section.

1.5. Plant-based preparation for use in beverages (ID 4210, 4211)

The food that is the subject of the claims is a plant-based preparation for use in beverages related to the following claimed effects: "aide à la prise de décisions chez les personnes hésitantes" and "aide à se libérer des petites manies".

The plant species used in the preparation that is the subject of the claims have not been further specified in the information provided. No clarifications have been provided by Member States.

The Panel considers that the food, a plant-based preparation for use in beverages, 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 a plant-based preparation for use in beverages and the claimed effects considered in this section.

1.6. *Carica papaya* L. (ID 2007)

The food that is the subject of the claim is *Carica papaya* L. related to the following claimed effect: "antioxidant activity".

Carica papaya L. is a tropical tree-like plant which is cultivated for food use, mainly for its fruits which can be consumed either mature or green. Papain, a proteolytic enzyme, is produced from the green papaya fruit.

The proposed conditions of use for this claim refer to fermented fruits as well as papain as the food/food constituent which is the subject of the claim.

The references provided were related to different fermented papaya preparations, papaya juice and papain. In the one human intervention study provided from which conclusions could be drawn for the scientific substantiation of the claimed effect (Marotta et al., 2006), a fermented papaya preparation was used; the composition or nature of this preparation was not reported.

The Panel notes that from the information provided in the consolidated list and the references cited it is unclear to which specific preparation of *Carica papaya* L. the claim refers.

The Panel considers that the food, *Carica papaya* L., 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 *Carica papaya* L. and the claimed effect considered in this section.

1.7. "Fish protein" (ID 651)

The food that is the subject of the health claim is "fish protein" related to the following claimed effect: "skin, hair and nail health".

Fish protein, like all animal proteins, is a high quality protein containing all the indispensable amino acids, with a true protein digestibility of around 95 % (Torun, 2005).

From the references provided, the Panel assumes that the food refers to a specific commercial preparation containing special protein fractions of marine fish and glycosaminoglycans. The protein fractions and the glycosaminoglycans have not been specified further in the references provided.

The Panel considers that the food, a preparation of special protein fractions of marine fish and glycosaminoglycans, 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 "fish protein" and the claimed effect considered in this section.

1.8. Acidic water-based, non-alcoholic flavoured beverages containing calcium in the range of 0.3 to 0.8 mol per mol of acid with a pH not lower than 3.7 (ID 1170)

The food that is the subject of the health claim is "acidic water-based, non alcoholic flavoured beverages" related to the following claimed effect: "Dental health – low erosion".

In the context of the clarifications provided, the Panel assumes that the food which is the subject of the claim is acidic water-based, non-alcoholic flavoured beverages containing calcium in the range of 0.3 to 0.8 mol per mol of acid with a pH not lower (i.e. not more acidic) than 3.7.

In the context of the information given in the consolidated list and the references provided, the Panel assumes that the claim relates to the maintenance of tooth mineralisation by decreasing tooth demineralisation through the consumption of these beverages as a replacement for soft drinks. The Panel notes that no information was provided on the sugar content of the acidic beverages, which might also contribute to tooth demineralisation, or on the composition of soft drinks to be used as a comparator for the claim.

The Panel considers that the food, acidic water-based, non-alcoholic flavoured beverages containing calcium in the range of 0.3 to 0.8 mol per mol of acid with a pH not lower than 3.7, which is the subject of the claim, is not sufficiently characterised in relation to the maintenance of tooth mineralisation by decreasing tooth demineralisation.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of acidic water-based, non-alcoholic flavoured beverages containing calcium in the range of 0.3 to 0.8 mol per mol of acid with a pH not lower than 3.7 and maintenance of tooth mineralisation by decreasing tooth demineralisation.

1.9. Royal jelly (ID 1225, 1226, 1227, 1228, 1230, 1231, 1326, 1328, 1329, 1982, 4696, 4697)

The food that is the subject of the claims is royal jelly related to the following claimed effects: "natural defence/immune system", "metabolism", "vascular function", "glands function", "skin health", "tonus/vitality", "anti-asthénique, immunostimulant", "ménopause, effet oestrogénique", hypolipidémiant", "vitalité physique et intellectuelle", and "helps heart health and to maintain a balanced level of cholesterol and lipids in the body".

Royal jelly is a creamy, whitish, strongly acidic secretion from the mandibular and hypopharyngeal (cephalic) glands of *Apis mellifera* (Hymenoptera, Apidae) nurse bees, and is important in the sexual differentiation and longevity of the queen bee. Pure royal jelly is usually presented in the form of cream, capsules, or powder/flakes (freeze-dried); additionally, it is an ingredient in many products.

Royal jelly contains sugars, proteins, fatty acids, amino acids, vitamins, salts and trace elements. The average water content of royal jelly is 60-70 %. Crude protein (49-87 kDa) constitutes 12-15 % (or about 50 % of the dry mass), sugars 10-16 % and lipids 3-7 %. Proteins in royal jelly largely belong to one protein family designated MRJP (major royal jelly proteins, about 90 % of proteins) (apalbumins). Components of royal jelly reported to be biologically active include various proteins and peptides, the fatty acid 10-hydroxy-2-decenoic acid (10-HDA), and unidentified components with

oestrogenic activity. The composition of royal jelly is reported to vary with seasonal and regional conditions (Bincoletto et al., 2005; Fontana et al., 2004; Sver et al., 1996).

In the human studies provided which addressed outcomes related to the claimed effects the origin and composition of the royal jelly used was not specified.

The Panel notes that from the references provided it was not possible to characterise royal jelly in general, nor the specific components of royal jelly mediating the functions for which the claims were made.

The Panel considers that royal jelly, 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 royal jelly and the claimed effects considered in this section.

1.10. Foods low in cholesterol (ID 624)

The food constituent that is the subject of the health claims is "cholesterol".

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the foods which are the subject of the health claims are "foods low in cholesterol", and that the claimed effect is maintenance of normal blood cholesterol concentrations.

Cholesterol is a sterol found in all foods of animal origin, whereas foods of plant origin are almost cholesterol-free. Methods are available for the measurement of cholesterol in foods.

The Panel notes that the effects of foods on blood cholesterol may depend on various factors other than the cholesterol content, and, in particular, are dependent on the fatty acid composition of such foods.

The conditions of use for the claim specify "min 10 % fat (product basis), min 70 % UFAs (fat basis), max 2 % TFAs (fat basis) and max 0,02 g cholesterol per 100 g (product basis)" and "2.8-5.8 g DHA and/or EPA per day/up to 20 g fish oil daily". However, the Panel notes that a wide range of foods available on the market could meet one or the other composition specification and still be very variable with respect to the fatty acid profile, and therefore with respect to the effects on blood cholesterol concentrations.

The Panel considers that "foods low in cholesterol", which are the subject of the claim, are not sufficiently characterised in relation to the maintenance of normal blood cholesterol concentrations.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of "foods low in cholesterol" and maintenance of normal blood cholesterol concentrations.

1.11. Foods low in *trans*-fatty acids (ID 672, 4333)

The food constituent that is the subject of the health claims is "decrease of *trans*-fatty acids".

In the context of the proposed wordings, the Panel assumes that the foods which are the subject of the health claims are "foods low in *trans*-fatty acids", and that the claimed effect is maintenance of normal blood cholesterol concentrations.

Unsaturated fatty acids are aliphatic monocarboxylic acids with one (monounsaturated fatty acids, MUFAs) or more (polyunsaturated fatty acids, PUFAs) double bonds which can be liberated by hydrolysis of triacylglycerols from fats and oils. Most unsaturated fatty acids in the diet have the *cis* configuration, but *trans*-fatty acids (TFAs) are also present. These fatty acids originate from several sources and *trans*-MUFAs are the most common TFAs in the diet. *Trans*-PUFAs are also present. *Trans*-PUFAs have at least one *trans* double bond and may also have double bonds in the *cis* configuration.

The Panel notes that the effects of foods on blood cholesterol may depend on various factors other than the content in TFAs, and, in particular, are dependent on the fatty acid composition of such foods.

No reference to the fatty acid profile of "foods low in *trans*-fatty acids", which are the subject of the claim, is made in the information provided.

The Panel considers that "foods low in *trans*-fatty acids", which are the subject of the claim, are not sufficiently characterised in relation to the maintenance of normal blood cholesterol concentrations.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of "foods low in *trans*-fatty acids" and maintenance of normal blood cholesterol concentrations.

CONCLUSIONS

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

- The following foods/food constituents are not sufficiently characterised in relation to the claimed effects:
  - Anthocyanidins and proanthocyanidins related to "cardiovascular system", "blood fat levels", "carbohydrate metabolism and insulin sensitivity", "gut health" and "eyes" (ID 1787, 1788, 1789, 1790, 1791).
  - Sodium alginate and ulva related to "alginate and ulva bind toxins, mutagens and heavy metals, they can also stimulate and increase colonic mucin production and thicken the colonic mucosa and protect the colon from harmful substances" (ID 1873).
  - Vitamins, minerals, trace elements and standardised ginseng G115 extract related to "to cover increased needs of vitamins, minerals, trace elements and ginseng G115 extract specifically in cases of exhaustion, tiredness, feeling of weakness, decreasing concentration as well as decreasing mental alertness", "mental performance" and "energy metabolism" (ID 8, 1673, 1674).
  - Vitamins, minerals, lysine and/or arginine and/or taurine related to "nutritional support during the period of growth for physical development", "nutritional support after illness" and "nutritional support to help mental performance" (ID 6, 1676, 1677).
  - Plant-based preparation for use in beverages related to "aide à la prise de décisions chez les personnes hésitantes" and "aide à se libérer des petites manies" (ID 4210, 4211).
  - *Carica papaya* L. related to "antioxidant activity" (ID 2007).
  - "Fish protein" related to "skin, hair and nail health"(ID 651).

  - Acidic water-based, non-alcoholic flavoured beverages containing calcium in the range of 0.3 to 0.8 mol per mol of acid with a pH not lower than 3.7 related to the maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 1170).

  - Royal jelly related to "natural defence/immune system", "metabolism", "vascular function", "glands function", "skin health", "tonus/vitality", "anti-asthénique, immunostimulant", "ménopause, effet oestrogénique", hypolipidémiant", "vitalité physique et intellectuelle" and "helps heart health and to maintain a balanced level of cholesterol and lipids in the body" (ID 1225, 1226, 1227, 1228, 1230, 1231, 1326, 1328, 1329, 1982, 4696, 4697).

  - Foods low in cholesterol related to the maintenance of normal blood cholesterol concentrations (ID 624).

  - Foods low in *trans*-fatty acids related to the maintenance of normal blood cholesterol concentrations (ID 672, 4333).

- A cause and effect relationship cannot be established between the foods/food constituents, which are the subject of this opinion, and the proposed claimed effects.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-793, EFSA-Q-2008-795, EFSA-Q-2008-1411, EFSA-Q-2008-1438, EFSA-Q-2008-1459, EFSA-Q-2008-1909, EFSA-Q-2008-1963, EFSA-Q-2008-1964, EFSA-Q-2008-1965, EFSA-Q-2008-1966, EFSA-Q-2008-1968, EFSA-Q-2008-1969, EFSA-Q-2008-2063, EFSA-Q-2008-2065, EFSA-Q-2008-2066, EFSA-Q-2008-2409, EFSA-Q-2008-2410, EFSA-Q-2008-2412, EFSA-Q-2008-2413, EFSA-Q-2008-2520, EFSA-Q-2008-2521, EFSA-Q-2008-2522, EFSA-Q-2008-2523, EFSA-Q-2008-2524, EFSA-Q-2008-2606, EFSA-Q-2008-2715, EFSA-Q-2008-2740, EFSA-Q-2008-4920, EFSA-Q-2008-4921, EFSA-Q-2010-00286, EFSA-Q-2010-00649, EFSA-Q-2010-00650). 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 (EC) No 1924/2006 on nutrition and health claims made on foods[8] (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[9]

Foods are commonly involved in many different functions[10] 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.

[8] OJ L12, 18/01/2007
[9] The term 'food' when used in this Terms of Reference refers to a food, the food or the food category.
[10] 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, a positive assessment of its safety, nor a decision on whether the food 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
6	Vitamins, minerals, lysine and/or arginine and/or taurine (Pharmaton Kiddi)	Nutritional support during the period of growth for physical development Clarification provided To cover increased needs of vitamins/minerals/aminoacids, during periods of intense activity when the metabolism is increased or in case of loss of appetite, unbalanced/insufficient nutrition, convalescence. For healthy physical functions (amino acids are necessary to build up proteins which are constituents of body tissues, bones, teeth and muscles) For healthy mental functions (helps the brain and nerves to work properly) Vitamins and minerals are important in metabolism to release energy from carbohydrates, proteins and fats, for the production of new cells structures, for repairing damaged cells, for keeping the nervous system working properly.	It helps to support an adequate vitamins/minerals/lysine supplementation in children, in case of unbalanced or insufficient nutrition To support a healthy growth and development in children. When a child is recovering from illness, or has a loss of appetite.
	Conditions of use - Target groups: children of 1-5 years, schoolchildren, adolescents and adults. Applicable to multivitamin/mineral products which contain the following daily dosage ranges: Beta-carotene: 0.514-1.6 mg, Vitamin A: 715-2145 IU, Vitamin B1: 0.5-3 mg, Vitamin B2: 0.55-3.5 mg, Vitamin B6: 0.55-6 mg, Vitamin B12: 0.6-1.8 mcg, Vitamin C: 22-66 mg, Vitamin D3: 150-600 IU, Vitamin E: 3.5-15 mg, Folic acid: 0.05-0.15 mg, Biotin: 15-45 mcg, Vitamin PP (nicotinamide): 6-20 mg, Dexpanthenol: 5-10 mg, Copper: 0.3-0.9 mg, Calcium: 65-200 mg, Phosphorus: 100-200 mg, Iron: 2.5-7.5 mg, Zinc: 2.5-7.5 mg, Magnesium: 12.5-40 mg, Manganese: 0.5 mg, Lysine (50-500mg/day) and/or Arginine (75 – 150mg/day) and/or Taurine (75 – 150 mg/day)		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**

8	Vitamins, minerals, trace elements and standardized ginseng G115 extract (Pharmaton capsules, film coated tablets, effervescent).	To cover increased needs of vitamins, minerals, trace elements and Ginseng G115 extract specifically in cases of exhaustion, tiredness, feeling of weakness, decreasing concentration as well as decreasing mental alertness. <u>Clarification provided</u> Vitamins, minerals, trace elements and standardised ginseng G115 extract are scientifically proven to maintain energy within the body and to help coping with daily stress symptoms such as tiredness, fatigue, body weakness, decreased concentration and decreased alertness, by: - enhancing oxygen uptake in body cells - reducing the lactate level in body tissues - enhancing the reoxygenation of haemoglobin in the blood circulation system. Improve concentration and alertness, reduced tiredness in subjects exhibiting signs of stress. OR Vitamins, minerals and trace elements support the metabolism to release energy from carbohydrates, proteins and fats Supports mental functions (especially in the elderly) and help the brain and nerves to work properly	Helps to cover nutritional needs in cases of unbalanced diet. Nutritional support to cover increased needs and to maintain optimal/appropriate levels in the body of vitamins, minerals, trace elements and Ginseng G115 extract specifically in cases of exhaustion, tiredness, feeling of weakness, decreasing concentration as well as decreasing mental alertness. Promote maintenance of physical and mental faculties (especially in elderly) and vitality. Help to reduce tiredness and fatigue. Help to prevent deficiency of micronutrients in elderly adults. Help to sustain energy within the body throughout the day and to help coping with stress.

	Conditions of use - Applicable to multivitamin/mineral product which contain following daily dosage ranges:: Vitamin A:2500-4000 IU, Vitamin B1: 1-3 mg, Vitamin B2: 1-3 mg, Vitamin B6: 1-3 mg, Vitamin B12: 1-2 mcg, Vitamin C: 60-90 mg, Vitamin D: 200-600 IU, Vitamin E: 10-15 mg, Vitamin PP: 9-20 mg, Copper: 0.5-2 mg, Calcium: 50-200 mg, Iron: 5-15 mg, Zinc: 0.5-2 mg, Magnesium: 5-40 mg, Manganese: 0.5-3 mg, Ginseng G115 extract standardised to 4% ginsenosides (40-200 mg/day), And/Or:, Beta-carotene: 0.5-1.6 mg, And/Or, Folic acid: 0.010-0.40 mg, And/Or, Biotin: 150-300 mcg, And/Or, Lecithin: 50-150 mg, And/Or:, Calcium Pantothenate: 5-25 mg, And/Or:, 2-Dimethyaminoethanol hydrogentartrate: 15-40mg, And /Or, Potassium: 4-10 mg, And/Or, Fluoride: 0.1-0.5 mg, And/Or, Phosphorus: 30-200 mg, And/Or, Selenium: 40-60 mcg, And/Or, Rutoside:10-30mg - Applicable to multivitamin/mineral product which contain following daily dosage ranges: Vitamin A:2500-4000 IU, Vitamin B1: 1-3 mg, Vitamin B2: 1-3 mg, Vitamin B6: 1-3 mg, Vitamin B12: 1-2 mcg, Vitamin C: 60-90 mg, Vitamin D: 200-600 IU, Vitamin E: 10-15 mg, Vitamin PP: 9-20 mg, Copper: 0.5-2 mg, Calcium: 50-200 mg, Iron: 5-15 mg, Zinc: 0.5-2 mg, Magnesium: 5-40 mg, Manganese: 0.5-3 mg, Ginseng G115 extract standardised to 4% ginsenosides (40-200 mg/day), And/Or:, Beta-carotene: 0.5-1.6 mg, And/Or, Folic acid: 0.010-0.40 mg, And/Or, Biotin: 150-300 mcg, And/Or, Lecithin: 50-150 mg, And/Or:, Calcium Pantothenate: 5-25 mg, And/Or:, 2-Dimethyaminoethanol hydrogentartrate: 15-40mg, And /Or, Potassium: 4-10 mg, And/Or, Fluoride: 0.1-0.5 mg, And/Or, Phosphorus: 30-200 mg, And/Or, Selenium: 40-60 mcg, And/Or, Rutoside:10-30mg, Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
624	Cholesterol	Blood cholesterol and heart health Clarification provided Helps maintain normal cholesteol: Normal blood cholesterol levels are defined in the Guidelines of the EU Soc of Cardiology 2007 as Total serum cholesterol <190mg/dl LDL cholesterol <115mg/dl	Foods low in cholesterol help manage blood cholesterol.
	Conditions of use - 2.8-5.8g DHA and/ or EPA per day/ up to 20g fish oil daily - min 10% fat (product basis), min 70% UFA (fat basis), max 2% TFA (fat basis) and max 0,02g cholesterol per 100g (product basis)		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
651	Fish protein	Skin, hair and nail health Clarification provided helps to maintain elasticity and hydratation of skin	Fish protein is combination of substances for a beautiful skin

	Conditions of use - Use for 90 days		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
672	Decrease of trans fatty acids	Cardio-vascular system.	Reduction of the intake of the trans fatty acids under 1 % of the daily energy intake helps to maintain the normal total cholesterol and LDL cholesterol levels in blood.
	Conditions of use - Less than 1 energy %; (around 2 g/day).		
	Comments from Member States 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.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1170	Acidic water - based, non alcoholic flavoured beverages	Dental health - low erosion Clarification provided In the beverage ready for consumption in accordance with the manufacturer's instructions - calcium is present in the range of 0.3 to 0.8 mol per mol of acid and the amount of calcium and acidulant in the composition being selected so that the pH of the composition is no lower (more acidic) than 3.7 In relation to tooth erosion, helps keep teeth healthy; minimises loss of dental enamel; friendly to teeth; kind to teeth; used as an alternative to soft drinks, helps maintain healthy teeth	poses minimal risk of tooth erosion in relation to tooth erosion, helps keep teeth healthy minimises loss of dental enamel

	Conditions of use - In the beverage ready for consumption in accordance with the manufacturer's instructions - calcium is present in the range of 0.3 to 0.8 mol per mol of acid and the amount of calcium and acidulant in the composition being selected so that the pH of the composition is at least 3.7 - Daily amount to be consumed to produce claimed effect: 200 millilitre(s). Are there factors that could interfere with bioavailability: No. Length of time after consumption for claimed effect to become apparent: effect is maintenance of healthy teeth. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No. Other conditions for use: In the beverage ready for consumption in accordance with the manufacturer's instructions - calcium is present in the range of 0.3 to 0.8 mol per mol of acid and the amount of calcium and acidulant in the composition being selected so that the pH of the composition is at least 3.7		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1225	Royal jelly	Natural defence/immune system <u>Clarification provided</u> Strengthens body's resistance. Possesses body toning properties, increase the overall body tonus. Helps improve activity of the immune system, increases body's adaptation in extreme and stressful situations	1. Acts as a general body restorative substance 2. Strengthens body's resistance against infections 3. Royal jelly helps strengthen your body / strengthens the body 4. Possesses body toning and antispastic properties, strengthens body's defence abilities and resistance against stress, promotes metabolism — use during recovery and postnatal period to improve your appetite and increase the overall body tonus 5. Royal jelly improves feeling of comfort 6. Royal jelly helps improve activity of the immune system/strengthens the immune system/body's defence system 7. A generally restorative product for the maintenance of body's functions — strengthens the immunity, improves the state of cardiovascular system, tones up the body, stimulates mental work capacities, increases body's adaptation in extreme and stressful situations
	Conditions of use - 30mg		

ID	Food or Food constituent	Health Relationship	Proposed wording
1226	Royal jelly	Metabolism	1. Substances contained in royal jelly help normalize metabolism, improve appetite 2. Royal jelly normalizes metabolism 3. Royal jelly is very nourishing, it contains biologically active substances — amino acids (replaceable and irreplaceable), carbohydrates, vitamins, microelements and minerals 4. Royal jelly helps improve tissue breathing
	Conditions of use - 30mg		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1227	Royal jelly	Vascular function	Stimulates blood circulation
	Conditions of use - 30mg		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1228	Royal jelly	Glands function	1. Regulates the function of endocrine glands 2. Royal jelly helps promote milk secretion in breastfeeding mothers
	Conditions of use - 30mg		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1230	Royal jelly	Skin health	1. Royal jelly contains vitamins, fatty acids and hormone substances that promote its beneficial effect on skin 2. Vitamins and other biologically active substances contained in royal jelly beneficially affect the skin
	Conditions of use - 30mg		

	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1231	Royal jelly	Tonus/ vitality Clarification provided Increase resistance against fatigue	Helps in case of fatigue. Helps to support body's vitality. Helps to make you feel more energetic. Enhancement of vitality/energy
	Conditions of use - Secretion from the salivary glands of worker honey bee, Apis mellifera. - At least 150 mg daily - Traditional use of royal jelly - 220 mg per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1326	Gelée Royale	Anti-asthénique Immunostimulant	Tonifie et revitalise l'organisme Entretien l'énergie et le tonus A utiliser en cas de fatigue passagère Soutient le système de défense
	Conditions of use - Gelée Royale 1000mg/jour		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1328	Gelée Royale Clarification provided Royal jelly	Ménopause Effet oestrogénique Clarification provided Royal jelly has estrogenic effects that alleviate menopausal symptoms	Bien-être et équilibre lors de la ménopause A utiliser en cas de symptômes ménopausiques Atténue les désagréments liés à la ménopause Clarification provided Helps to maintain a calm and comfortable menopause/helps women coping with the telltale signs associated with menopause, such as hot flushes, sweating, restlessness and irritability/Royal jelly is an effective dietary supplement for the improvement of quality of life in menopausal women.
	Conditions of use - Gelée Royale 1000mg/jour		

ID	Food or Food constituent	Health Relationship	Proposed wording
1329	Gelée Royale	Hypolipidémiant Clarification provided Royal jelly decreases total serum cholesterol levels and total serum lipids	Soutient la circulation Aide à maîtriser le cholestérol Bon pour le cholestérol Clarification provided Soutient la circulation Aide à maîtriser le cholestérol Bon pour le cholestérol
	Conditions of use - Gelée Royale 50-100mg/jour		
	Comments from Member States Food: Royal jelly/Health relationships: Royal jelly might help the control of blood lipid profiles/regulates blood lipids/Royal jelly can help control serum lipid profiles and promotes healthy cholesterol levels		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1673	Vitamins, minerals, trace elements and standardized ginseng G115 extract (Pharmaton capsules, film coated tablets, effervescent) Clarification provided Vitamins, minerals, trace elements and standardized ginseng G115 extract (Pharmaton capsules, film coated tablets, effervescent): Applicable to multivitamin/mineral product which contain: Vitamin A, B1, B2, B6, C, D, E, PP (nicotinamide), Copper, Calcium, Iron, Zinc, Magnesium, Manganese, Ginseng G115 extract standardised to 4% ginsenosides, and/or betacarotene, and/or folic acid, and/or biotin, and/or lectithin, and/or Calcium Pantothenate, and/or 2-Dimethyaminoethanol hydrogentartrate, and/or Posassium, and/or Fluoride, and/or Phosphorus, and/or Selenium, and/or Rutoside.	Mental performance.	in cases of decreasing concentration as well as decreasing mental alertness. scientifically proven to promote maintenance of mental faculties .

	Conditions of use - Applicable to multivitamin/mineral product which contain following daily dosage ranges::, Vitamin A:2500-4000 IU, Vitamin B1: 1-3 mg, Vitamin B2: 1-3 mg, Vitamin B6: 1-3 mg, Vitamin B12: 1-2 mcg, Vitamin C: 60-90 mg, Vitamin D: 200-600 IU, Vitamin E: 10-15 mg, Vitamin PP: 9-20 mg, Copper: 0.5-2 mg, Calcium: 50-200 mg, Iron: 5-15 mg, Zinc: 0.5-2 mg, Magnesium: 5-40 mg, Manganese: 0.5-3 mg, Ginseng G115 extract standardised to 4% ginsenosides (40-200 mg/day), And/Or:, Beta-carotene: 0.5-1.6 mg, And/Or, Folic acid: 0.010-0.40 mg, And/Or, Biotin: 150-300 mcg, And/Or, Lecithin: 50-150 mg, And/Or:, Calcium Pantothenate: 5-25 mg, And/Or:, 2-Dimethyaminoethanol hydrogentartrate: 15-40mg, And /Or, Potassium: 4-10 mg, And/Or, Fluoride: 0.1-0.5 mg, And/Or, Phosphorus: 30-200 mg, And/Or, Selenium: 40-60 mcg, And/Or, Rutoside:10-30mg		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1674	Vitamins, minerals, trace elements and standardized ginseng G115 extract (Pharmaton capsules, film coated tablets, effervescent)	Energy metabolism Clarification provided Vitamins, minerals, trace elements and standardised ginseng G115 extract are scientifically proven to maintain energy within the body and to help coping with daily stress symptoms such as tiredness, fatigue, body weakness, decreased concentration and decreased alertness, by: - enhancing oxygen uptake in the cells - reducing the lactate level in body tissues - enhancing the reoxygenation of haemoglobin in the blood circulation system. Vitamins, minerals and trace elements support the metabolism to release energy from carbohydrates, proteins and fats.	scientifically proven to help to sustain energy within the body throughout the day and to help coping with stress.

	Conditions of use - Applicable to multivitamin/mineral product which contain following daily dosage ranges::, Vitamin A:2500-4000 IU, Vitamin B1: 1-3 mg, Vitamin B2: 1-3 mg, Vitamin B6: 1-3 mg, Vitamin B12: 1-2 mcg, Vitamin C: 60-90 mg, Vitamin D: 200-600 IU, Vitamin E: 10-15 mg, Vitamin PP: 9-20 mg, Copper: 0.5-2 mg, Calcium: 50-200 mg, Iron: 5-15 mg, Zinc: 0.5-2 mg, Magnesium: 5-40 mg, Manganese: 0.5-3 mg, Ginseng G115 extract standardised to 4% ginsenosides (40-200 mg/day), And/Or:, Beta-carotene: 0.5-1.6 mg, And/Or, Folic acid: 0.010-0.40 mg, And/Or, Biotin: 150-300 mcg, And/Or, Lecithin: 50-150 mg, And/Or:, Calcium Pantothenate: 5-25 mg, And/Or:, 2-Dimethyaminoethanol hydrogentartrate: 15-40mg, And /Or, Potassium: 4-10 mg, And/Or, Fluoride: 0.1-0.5 mg, And/Or, Phosphorus: 30-200 mg, And/Or, Selenium: 40-60 mcg, And/Or, Rutoside:10-30mg		
	Comments from Member States Please also amend, if necessary, the 'food' section using clarifications requested by EFSA for the 'food' in claim 1673. Other claims with the same food type received a code '5' as well as a code'3'.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1676	Vitamins, minerals, lysine and/or arginine and/or taurine (Pharmaton Kiddi)	Nutritional support after illness Clarification provided To provide vitamins, minerals, aminoacids which are necessary to develop and support properly the immune system functions, by strengthening the normal structure of skin and mucous membranes and to build up cells of the natural immune system defence.	When a child is recovering from illness, or has a loss of appetite, Pharmaton Kiddi provides important vitamins, minerals. These are important for developing and supporting proper immune system functions.
	Conditions of use - Target groups: children of 1-5 years, schoolchildren, adolescents and adults. Applicable to multivitamin/mineral products which contain the following daily dosage ranges: Beta-carotene: 0.514-1.6 mg, Vitamin A: 715-2145 IU, Vitamin B1: 0.5-3 mg, Vitamin B2: 0.55-3.5 mg, Vitamin B6: 0.55-6 mg, Vitamin B12: 0.6-1.8 mcg, Vitamin C: 22-66 mg, Vitamin D3: 150-600 IU, Vitamin E: 3.5-15 mg, Folic acid: 0.05-0.15 mg, Biotin: 15-45 mcg, Vitamin PP (nicotinamide): 6-20 mg, Dexpanthenol: 5-10 mg, Copper: 0.3-0.9 mg, Calcium: 65-200 mg, Phosphorus: 100-200 mg, Iron: 2.5-7.5 mg, Zinc: 2.5-7.5 mg, Magnesium: 12.5-40 mg, Manganese: 0.5 mg, Lysine (50-500mg/day) and/or Arginine (75 – 150mg/day) and/or Taurine (75 – 150 mg/day),		
	Comments from Member States Other claims (1675 and 1677) received code 5. Please update the Food category for this claim to match those of the revised aforementioned claims		

ID	Food or Food constituent	Health Relationship	Proposed wording
1677	Vitamins, minerals, lysine and/or arginine and/or taurine (Pharmaton Kiddi) Clarification provided Combination of different vitamins and minerals, lysine and/or arginine and/or taurine (Pharmaton Kiddi) (Beta-carotene, Vitamins A, B1, B2, B6, B12, C, D3, E, Folic Acid, Biotin, Vitamin PP (nicotinamide), Dexpanthenol, Copper, Phosphorus, Iron, Zinc, Magnesium, Manganese, Lysine and/or Arginine and/or Taurine)	Nutritional support to help mental performance	scientifically proven to support attention and mental performance
	Conditions of use - Target groups: children of 1-5 years, schoolchildren, adolescents and adults. Applicable to multivitamin/mineral products which contain the following daily dosage ranges: Beta-carotene: 0.514-1.6 mg, Vitamin A: 715-2145 IU, Vitamin B1: 0.5-3 mg, Vitamin B2: 0.55-3.5 mg, Vitamin B6: 0.55-6 mg, Vitamin B12: 0.6-1.8 mcg, Vitamin C: 22-66 mg, Vitamin D3: 150-600 IU, Vitamin E: 3.5-15 mg, Folic acid: 0.05-0.15 mg, Biotin: 15-45 mcg, Vitamin PP (nicotinamide): 6-20 mg, Dexpanthenol: 5-10 mg, Copper: 0.3-0.9 mg, Calcium: 65-200 mg, Phosphorus: 100-200 mg, Iron: 2.5-7.5 mg, Zinc: 2.5-7.5 mg, Magnesium: 12.5-40 mg, Manganese: 0.5 mg, Lysine (50-500mg/day) and/or Arginine (75 – 150mg/day) and/or Taurine (75 – 150 mg/day),		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1787	Anthocyanidines + proanthocyanidines	Cardiovascular system	Good for the cardiovascular system.
	Conditions of use - Food supplement with 2.4 mg of anthocyanidines and 28 mg of proanthocyanidines in the daily dose (source not indicated).		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1788	Anthocyanidines + proanthocyanidines	Blood fat levels	Can help to normalise blood fat levels.
	Conditions of use - Food supplement with 2.4 mg of anthocyanidines and proanthcyanidines in the daily dose.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1789	Anthocyanidines + proanthocyanidines	Carbohydrate metabolism and insulin sensitivity	Can help to normalise blood sugar levels.

	Conditions of use - Food supplement with 2.4 mg of anthocyanidines and proanthocyanidines in the daily dose.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1790	Anthocyanidines + proanthocyanidines	Gut health	For stomach health.
	Conditions of use - Food supplement with 2.4 mg of anthocyanidines and 28 mg of proanthocyanidines in the daily dose.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1791	Anthocyanidines + proanthocyanidines	Eyes	Especially for the eye health of older people.
	Conditions of use - Food supplement with 2.4 mg of anthocyanidines and 28 mg of proanthocyanidines in the daily dose.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1873	sodium alginate and ulva (product-specific claim)	Alginate and ulva bind toxins, mutagens and heavy metals. They can also stimulate and increase colonic mucin production and thicken the colonic mucosa and protect the colon from harmful substances.	Exact wording of claim as it appears on product: Seaweed fibres support body detoxification Examples of any alternative wording that may be used in relation to claim: Seaweed fibres rid toxins from the body/Seaweed fibres aid colonic health/Seaweed fibres protect the colon/ Seaweed fibres can detox the body/Seaweed fibres help maintain a healthy colon/Seaweed fibres promote healthy conditions in the colon Is claim a picture: No

	Conditions of use - Quantity in Average daily serving: 5 grams Sodium alginate, 5 grams ulva. Weight of average daily food serving: 150 mililitre(s). Daily amount to be consumed to produce claimed effect: 450 mililitre(s). Number of food portions this equates to in everyday food portions: 1. Are there factors that could interfere with bioavailability: No. Length of time after consumption for claimed effect to become apparent: 2-4 weeks. Where applicable outline nutritional composition (g per 100g) of food: Total Fat: .01, Saturated Fat: .00, Trans Fat: .00, Sugar: .31, Salt: .00, Sodium: .01, Target group: Adults aged 18 years and over with some exceptions. Other conditions for use: This beverage should be consumed as part of a varied, balanced and healthy lifestyle. Three beverages are to be consumed daily in order to gain benefit. The entire beverage must be consumed. This product should be avoided by pregnant, lactating women and children and those with calcium deficiency or brittle bones. Reasons for excluding these groups: Alginate may decrease the absorption of calcium if taken concomitantly therefore it should be avoided by pregnant, lactating women and children and those with calcium deficiency or brittle bones.		
	Comments provided by Member States Further clarification to support the use of this claim was not submitted to the Food Safety Authority of Ireland. The FBO involved did submit further information on other claims and remarked in relation to the comment from EFSA that this claim is 'too vague', that they felt that the information they already provided is quite specific		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1982	Gelée royale	Vitalité physique et intellectuelle	Combattre la fatigue intellectuelle et physique, le surmenage
	Conditions of use - Gelée royale fraîche		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2007	Carica papaya (Common Name : Papaya)	Antioxidant activity	Contains antioxidant/s; Is a source of antioxdiant/s. With antioxidant/s. Antioxidant activity '-Contributes to the protection against oxidation; - contributes to the protection against free radicals
	Conditions of use - Fruit / The equivalent of 1500 mg papain per day - Fruit fermenté 6x300mg/jour - owoc/równowartość 1500 mg papainy na dzień - Frucht / Äquivalent von 1500 mg Papain pro Tag		

ID	Food or Food constituent	Health Relationship	Proposed wording
4210	préparation pour boisson à base de plantes	aide à la prise de décisions chez les personnes hésitantes	Décisions :pour ceux qui sont tiraillés, immobilisés ou perdus. Apporte une vision claire et raisonnée du juste choix
	Conditions of use - 12 gouttes par litre d'eau ou 4 gouttes par verre		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4211	préparation pour boisson à base de plantes	aide à se libérer des petites "manies"	Dépendances : pour ceux qui déplorent leurs manies et habitudes nocives. Aide à se libérer et à stimuler la volonté, la motivation
	Conditions of use - 12 gouttes par litre d'eau ou 4 gouttes par verre;		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4333	Decrease of trans fatty acids.	Cardio-vascular system.	Reduction of the intake of the trans fatty acids under 1 % of the daily energy intake helps to maintain the normal total cholesterol and LDL cholesterol levels in blood.
	Conditions of use - Less than 1 energy %; (around 2 g/day).		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4696	Royal jelly	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 the blood lipids
	Conditions of use - 200 – 500 mg per day as fresh product or the equivalent as freeze dried product or other presentation forms, for both children and adults		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4697	Royal jelly	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 the blood lipids
	Conditions of use - 200 – 500 mg per day as fresh product or the equivalent as freeze dried product or other presentation forms, for both children and adults		

GLOSSARY AND ABBREVIATIONS

10-HAD	10-hydroxy-2-decenoic acid
DHA	Docosahexaenoic acid
EPA	Eicosapentaenoic acid
G	α-glucuronate
M	D-mannuronate
MRJP	Major royal jelly proteins
MUFA	Monounsaturated fatty acid
PUFA	Polyunsaturated fatty acid
TFA	*Trans*-fatty acid
UFA	Unsaturated fatty acid