SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to various food(s)/food constituent(s) and health relationships that are not sufficiently defined (ID 9, 377, 531, 555, 560, 569, 582, 583, 584, 585, 589, 590, 675, 692, 847, 1199, 1265, 1267, 1342, 1352, 1357, 1368, 1369, 1379, 1382, 1383, 1399, 1401, 1477, 1480, 1482, 1530, 1625, 1732, 1777, 1792, 1814, 1837, 1998, 2175, 2212, 2223, 2329, 2487, 2504, 2753, 2916, 3076, 3667, 3692, 4241, 4243, 4247, 4248, 4278, 4407); are not referring to a function of the body (ID 1233, 1385, 1406, 1746, 1879, 1950, 3131, 4202); are related to the prevention or treatment of a disease (ID 1859, 2552, 2743, 2773, 3087, 3164, 3687); are not referring to a beneficial physiological effect (ID 544, 545, 648, 773, 782, 1399, 1781, 1795, 1842, 1906, 1944, 2759, 2825, 2886, 3128, 3137, 3153, 3519, 3972, 4112, 4662, 4691) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

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

European Food Safety Authority (EFSA), Parma, Italy[3]

[1] On request from the European Commission, Question No EFSA-Q-2008-2639, adopted on 25 March 2011. Question No EFSA-Q-2008-796, EFSA-Q-2008-1164, EFSA-Q-2008-1318, EFSA-Q-2008-1331, EFSA-Q-2008-1332, EFSA-Q-2008-1347, EFSA-Q-2008-1356, EFSA-Q-2008-1369, EFSA-Q-2008-1370, EFSA-Q-2008-1371, EFSA-Q-2008-1372, EFSA-Q-2008-1376, EFSA-Q-2008-1377, EFSA-Q-2008-1435, EFSA-Q-2008-1462, EFSA-Q-2008-1479, EFSA-Q-2008-1560, EFSA-Q-2008-1569, EFSA-Q-2008-1634, EFSA-Q-2008-1938, EFSA-Q-2008-1971, EFSA-Q-2008-2003, EFSA-Q-2008-2005, EFSA-Q-2008-2079, EFSA-Q-2008-2089, EFSA-Q-2008-2094, EFSA-Q-2008-2105, EFSA-Q-2008-2106, EFSA-Q-2008-2116, EFSA-Q-2008-2119, EFSA-Q-2008-2120, EFSA-Q-2008-2122, EFSA-Q-2008-2136, EFSA-Q-2008-2138, EFSA-Q-2008-2143, EFSA-Q-2008-2214, EFSA-Q-2008-2217, EFSA-Q-2008-2219, EFSA-Q-2008-2267, EFSA-Q-2008-2361, EFSA-Q-2008-2468, EFSA-Q-2008-2479, EFSA-Q-2008-2510, EFSA-Q-2008-2514, EFSA-Q-2008-2525, EFSA-Q-2008-2528, EFSA-Q-2008-2547, EFSA-Q-2008-2570, EFSA-Q-2008-2575, EFSA-Q-2008-2592, EFSA-Q-2008-2612, EFSA-Q-2008-2677, EFSA-Q-2008-2683, EFSA-Q-2008-2731, EFSA-Q-2008-2908, EFSA-Q-2008-2945, EFSA-Q-2008-2956, EFSA-Q-2008-3062, EFSA-Q-2008-3220, EFSA-Q-2008-3237, EFSA-Q-2008-3285, EFSA-Q-2008-3476, EFSA-Q-2008-3486, EFSA-Q-2008-3492, EFSA-Q-2008-3506, EFSA-Q-2008-3558, EFSA-Q-2008-3619, EFSA-Q-2008-3649, EFSA-Q-2008-3808, EFSA-Q-2008-3819, EFSA-Q-2008-3860, EFSA-Q-2008-3863, EFSA-Q-2008-3869, EFSA-Q-2008-3885, EFSA-Q-2008-3896, EFSA-Q-2008-4246, EFSA-Q-2008-4390, EFSA-Q-2008-4410, EFSA-Q-2008-4415, EFSA-Q-2008-4687, EFSA-Q-2008-4823, EFSA-Q-2008-4912, EFSA-Q-2008-4951, EFSA-Q-2008-4953, EFSA-Q-2008-4957, EFSA-Q-2008-4958, EFSA-Q-2010-00231, EFSA-Q-2010-00360, EFSA-Q-2010-00615, EFSA-Q-2010-00644, adopted on 08 April 2011. Question No EFSA-Q-2008-1342, adopted on 13 May 2011.

[2] 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

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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 related to various food(s)/food constituent(s) and "anti-aging properties", "maintenance of urinary tract", "cardiovascular health", "vascular and vein health", "blood flow/vascular function", "hormonal balance", prevention or treatment of prostate cancer, "women's health", "menstrual health", "absorption of nutrients", improvement of the digestion of macronutrients (e.g. carbohydrates, proteins and lipids), "digestive function", "gut health", "intestinal flora", increasing numbers of gastro-intestinal microorganisms, "stomach health", "powerful protectors of the stomach", reduction of gastric acid , treatment of diarrhoea and/or vomiting, "liver health", "nervous system function", "mental energy", "mental health", "physical and mental health", "physical performance", "overtraining and effort prevention", "physical well-being", "skin health", maintenance of normal structure and appearance of hair and nails structure, maintenance of normal structure and elasticity of the skin, prevention or treatment of acne, prevention or treatment of cellulitis, "function of the cell membrane", "mucous membranes", "immune system", increasing non-specific IgA secretion, stimulation of natural killer cell activity, induction of cytokine production, immune defence against pathogens, "essential for the balanced body functions, with special regards to the immune system", decreasing the absorption of alcohol, increase in muscle creatine stores, and "improves mechanical activity of gallbladder". The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

- The Panel considers that the following claimed effects are general and non-specific, and do not refer to any specific health claims as required by Regulation (EC) No 1924/2006: "anti-aging properties" (ID 1352), "maintenance of urinary tract" (ID 1199, 1369), "cardiovascular health" (ID 569, 582, 1382), "vascular and vein health" (ID 1480, 1998, 2212, 2753, 3667, 4278), "blood flow/vascular function" (ID 1265), "hormonal balance" (ID 1837, 2916), "women's health" (ID 531), "menstrual health" (ID 2487), "absorption of nutrients" (ID 1814), "digestive function" (ID 377, 692, 1267, 1357, 1401, 1625, 2329, 3692), "gut health" (ID 585, 2223), "intestinal flora" (ID 3076), "stomach health" (ID 2175), "powerful protectors of the stomach" (ID 1368), "liver health" (ID 583, 2504), "nervous system function" (ID 1383, 1732) "mental energy" (ID 1530), "mental health" (ID 555), "physical and mental health" (ID 9), "physical performance" (ID 560, 4248), "overtraining and effort prevention"(ID 4247), "physical well-being" (ID 4407), "skin health" (ID 584, 590, 1379, 4241, 4243), "function of the cell membrane" (ID 1777), "mucous membranes" (ID 589), "immune system" (ID 675, 847, 1399, 1482, 1792), immune defence against pathogens (ID 1477), "essential for the balanced body functions, with special regards to the immune system" (ID 675), and "improves mechanical activity of gallbladder" (ID 1342).

- The Panel considers that the following claimed effects do not refer to a function of the body as required by Regulation (EC) No 1924/2006: maintenance of normal structure and appearance of

[3] 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.

hair and nails structure (ID 1233, 1385, 1746, 1879, 4202), and maintenance of normal structure and elasticity of the skin (ID 1385, 1406, 1746, 1879, 1950, 3131).

- The Panel considers that the following claimed effects are related to the prevention or treatment of a disease and do not comply with the criteria laid down in Regulation (EC) No 1924/2006: prevention or treatment of prostate cancer (ID 1859, 2773), treatment of diarrhoea and/or vomiting (ID 3087), prevention or treatment of acne (ID 2552, 3164), and prevention or treatment of cellulitis (ID 2743, 3687).

- The Panel considers that macronutrient digestion is not impaired in the general population and that no evidence has been provided that an improvement of the digestion of macronutrients (e.g. carbohydrates, proteins and lipids) (ID 1781, 1842, 2825, 3137, 3519, 3972, 4662, 4691) is a beneficial physiological effect *per se* for the general population. On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to the digestion of carbohydrates, proteins and lipids.

- The Panel considers that the evidence provided does not establish that increasing numbers of gastro-intestinal microorganisms (ID 773, 782, 1399) is a beneficial physiological effect. On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to increasing numbers of gastro-intestinal microorganisms.

- The Panel considers that the evidence provided does not establish that reduction of gastric acid (ID 1795, 1906, 2759, 2886) is a beneficial physiological effect *per se* for the general population. On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to reduction of gastric acid.

- The Panel considers that the evidence provided does not establish that increasing non-specific IgA secretion (ID 1944) is a beneficial physiological effect *per se*. On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to an increase of non-specific IgA secretion.

- The Panel considers that the evidence provided does not establish that stimulation of natural killer cell activity (ID 3128, 3153) is a beneficial physiological effect *per se*. On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to the stimulation of natural killer cell activity.

- The Panel considers that the evidence provided does not establish that induction of cytokine production (e.g. TNF-alpha and IFN-gamma) (ID 4112) is a beneficial physiological effect for the general population *per se*. On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to the induction of cytokine production.

- The Panel considers that the evidence provided does not establish that decreasing the absorption of alcohol (ID 648) is a beneficial physiological effect. On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the

consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to decreasing the absorption of alcohol.

- The Panel considers that from the evidence provided the beneficial physiological effect of increasing muscle creatine stores is unclear (ID 544, 545). On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to an increase in muscle creatine stores.

KEY WORDS

Food, constituent, not defined, not a function, disease, not beneficial, 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 general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims[6].

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. Relevance of the claimed effect to human health

1.1. "Anti-aging properties" (ID 1352)

The claimed effect is "anti ageing properties". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were provided in the proposed wordings. No clarifications were provided by Member States. From the references provided it was not possible to establish the specific effect which is the target for the claim.

[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] 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.

[6] See footnote 5

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

1.2. "Maintenance of urinary tract" (ID 1199, 1369)

The claimed effects are "maintenance of urinary tract" and "urinary tract maintenance (Urinary Calculus)". The Panel assumes that the target population is the general population.

The claimed effects are not sufficiently defined and no further details were provided in the proposed wordings or the clarifications provided by Member States. From the references provided it was not possible to establish the specific effect which is the target for the claim.

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

1.3. "Cardiovascular health" (ID 569, 582, 1382)

The claimed effects are "cardiovascular system" and "cardiovascular health". The Panel assumes that the target population is the general population.

The claimed effects are not sufficiently defined and no further details were provided in the proposed wordings or the clarifications provided by Member States. From the references provided it was not possible to establish the specific effect which is the target for the claim.

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

1.4. "Vascular and vein health" (ID 1480, 1998, 2212, 2753, 3667, 4278)

The claimed effects are "vascular health", "vein health", and "venous system". The Panel assumes that the target population is the general population.

The claimed effects are not sufficiently defined. The Panel notes that either different health outcomes were mentioned in the references provided, and it was not possible to establish the specific effect which is the target of the claim, or that the references provided did not contain original scientific data and it was therefore unclear how the health outcomes cited in the proposed wordings ("normal blood fluidity and vessel patency", "blood vessel walls strength", "blood circulation", "sensation of heavy legs", "good circulation of blood in microvessels", "circulatory well being") could be defined and assessed.

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

1.5. "Blood flow/vascular function" (ID 1265)

The claimed effect is "blood flow/vascular function". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were provided in the proposed wordings. No clarifications were provided by Member States. The Panel notes that the references provided for the substantiation of the claim were either unrelated to the food which is the subject of the claim or referred to different health outcomes (i.e. platelet aggregation, endothelial function,

oxidative stress) and it was not possible to establish the specific effect which is the target for the claim.

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

1.6. "Hormonal balance" (ID 1837, 2916)

The claimed effects are "sexual organs and/or hormone activity" and "cell metabolism – positively affects the fission of cells their immunity and regeneration". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined, and the proposed wordings or the clarifications provided by Member States did not provide further information. From the references provided it was not possible to establish the specific effect which is the target for the claim.

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

1.7. Prevention or treatment of prostate cancer (ID 1859, 2773)

The claimed effects are "sexual organs and/or hormone activity" and "santé de la prostate". The Panel assumes that the target population is adult males.

In the context of the proposed wordings or the clarifications provided by Member States, the Panel assumes that the claimed effect refers to prostate function. Prostate function is not sufficiently defined. From the references provided, the Panel assumes that the claimed effect is related to prevention or treatment of prostate cancer.

The Panel considers that the claimed effect is related to the prevention or treatment of a disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

1.8. "Women's health" (ID 531)

The claimed effect is "women's health". The Panel assumes that the target population is women.

The claimed effect is not sufficiently defined and no further details were provided in the proposed wording or the clarifications provided by Member States. The Panel notes that different health outcomes were mentioned in the references provided and it was not possible to establish the specific effect which is the target for the claim.

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

1.9. "Menstrual health" (ID 2487)

The claimed effect is "menstrual health". The Panel assumes that the target population is women.

The claimed effect is not sufficiently defined and no further details were provided in the proposed wordings. No clarifications were provided by Member States. From the references provided it was not possible to establish the specific effect which is the target for the claim.

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

1.10. "Absorption of nutrients" (ID 1814)

The claimed effect is "absorption of nutrients". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and from the proposed wordings, the references or the clarifications provided by Member States, it was not possible to establish for which nutrients an improved absorption is the target for the claim.

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

1.11. Improvement of the digestion of macronutrients (e.g. carbohydrates, proteins and lipids) (ID 1781, 1842, 2825, 3137, 3519, 3972, 4662, 4691)

The claimed effects are "digestive function", "digestion", "break down of high-molecules compound from food", "pancreas" and "digestive system benefits". The Panel assumes that the target population is the general population.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effects refer to the facilitation of the digestion of macronutrients (e.g. dietary carbohydrates, proteins and lipids) in the gastro-intestinal tract.

The human gastro-intestinal tract capacity for digestion of macronutrients is very high and it is estimated that in physiological situation it exceeds tenfold the biological demand. The Panel considers that macronutrient digestion is not impaired in the general population and that no evidence has been provided that an improvement of the digestion of macronutrients (e.g. carbohydrates, proteins and lipids) is a beneficial physiological effect *per se* for the general population.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to the digestion of carbohydrates, proteins and lipids.

1.12. "Digestive function" (ID 377, 692, 1267, 1357, 1401, 1625, 2329, 3692)

The claimed effects are "joue un rôle dans le processus digestif", "essential fatty acids to aid in digestive tract function", "consumption of bran improves digestive function", "naturally boost your digestive system", "digestion (stimulation)", "gastro-intestinal support" and "digestion". The Panel assumes that the target population is the general population.

The claimed effects are not sufficiently defined and no further details were available in the proposed wordings, the references or the clarifications provided by Member States.

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

1.13. "Gut health" (ID 585, 2223)

The claimed effects are "gut health" and "intestinal health". The Panel assumes that the target population is the general population.

The claimed effects are not sufficiently defined and no further details were provided in the proposed wordings. No clarifications were provided by Member States. From the references provided it was not possible to establish the specific effect which is the target for the claim.

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

1.14. "Intestinal flora" (ID 3076)

The claimed effect is "intestinal flora". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were provided in the proposed wordings. The Panel notes that different health outcomes were mentioned in the references provided and it was not possible to establish the specific effect which is the target for the claim.

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

1.15. Increasing numbers of gastro-intestinal microorganisms (ID 773, 782, 1399)

The claimed effects are "increased inner protection/resistance", "prebiotic/bifidogenic", and "benefits the growth of intestinal bifidus bacteria and stimulates the immune system". The Panel assumes that the target population is the general population.

In the context of the proposed wordings or the clarifications provided by Member States, the Panel assumes that the claimed effects refer to an increase in the number of bacteria that are considered to be beneficial.

The numbers/proportions of bacterial groups that would constitute a "good, balanced, healthy or beneficial intestinal flora" have not been established. Increasing the number of any group of microorganisms including lactobacilli or bifidobacteria, is not in itself considered to be a beneficial physiological effect.

The Panel considers that the evidence provided does not establish that increasing numbers of gastro-intestinal microorganisms is a beneficial physiological effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to increasing numbers of gastro-intestinal microorganisms.

1.16. "Stomach health" (ID 2175)

The claimed effect is "stomach health". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were provided in the proposed wordings. No clarifications were provided by Member States. From the references provided it was not possible to establish the specific effect which is the target for the claim.

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

1.17. "Powerful protectors of the stomach" (ID 1368)

The claimed effect is "more recently, emerging research suggests that cranberries may also be powerful protectors of the stomach". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were provided in the proposed wording. No clarifications were provided by Member States. From the references provided it was not possible to establish the specific effect which is the target for the claim.

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

1.18. Reduction of gastric acid (ID 1795, 1906, 2759, 2886)

The claimed effects are "gut health", "gastrointestinal health", "gastric acidity" and "stomach acid in digestion". The Panel assumes that the target population is the general population.

For ID 1795, 2759, 2886, in the context of the proposed wordings, the Panel assumes that the claimed effect refers to the reduction of gastric acid.

For ID 1906, in the context of the proposed wording, the clarifications provided by Member States, and the references cited for the scientific substantiation of the claim, the Panel assumes that the claimed effect refers to the protection of the mucous membrane of the stomach by reducing gastric acid.

The Panel considers that the evidence provided does not establish that reducing gastric acid is a beneficial physiological effect *per se* for the general population.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to reduction of gastric acid.

1.19. Treatment of diarrhoea and/or vomiting (ID 3087)

The claimed effect is "ORSALIT is given in order to supplement liquids and mineral components during diarrhoea and/or vomiting". The Panel assumes that the target population is individuals who are suffering from diarrhoea and/or vomiting.

The Panel assumes that the claimed effect is related to treatment of a disease (diarrhoea and/or vomiting).

The Panel considers that the claimed effect is related to the treatment of a disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

1.20. "Liver health" (ID 583, 2504)

The claimed effects are "liver" and "liver health". The Panel assumes that the target population is the general population.

The claimed effects are not sufficiently defined and no further details were provided in the proposed wording. No clarifications were provided by Member States. From the references provided it was not possible to establish the specific effect which is the target for the claim.

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

1.21. "Nervous system function" (ID 1383, 1732)

The claimed effect is "nervous system function". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were provided in the proposed wordings. No clarifications were provided by Member States. From the references provided it was not possible to establish the specific effect which is the target for the claim.

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

1.22. "Mental energy" (ID 1530)

The claimed effect is "for mental energy". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were provided in the proposed wordings. No clarifications were provided by Member States. From the reference provided it was not possible to establish the specific effect which is the target for the claim.

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

1.23. "Mental health" (ID 555)

The claimed effect is "mental health". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were provided in the proposed wordings. No clarifications were provided by Member States. From the reference provided it was not possible to establish the specific effect which is the target for the claim.

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

1.24. "Physical and mental health" (ID 9)

The claimed effect is "physical and mental health". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were available in the proposed wordings. The Panel notes that different health outcomes were mentioned in the clarifications provided by Member States or the references provided and it was not possible to establish the specific effect which is the target for the claim.

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

1.25. "Physical performance" (ID 560, 4248)

The claimed effects are "physical performance and condition" and "physical performance". The Panel assumes that the target population is the general population.

The claimed effects are not sufficiently defined and no further details were provided in the proposed wordings. No clarifications were provided by Member States. From the references provided it was not possible to establish the specific effect which is the target for the claim.

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

1.26. "Overtraining and effort prevention" (ID 4247)

The claimed effect is "overtraining and effort prevention". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were provided in the proposed wordings. No clarifications were provided by Member States. From the references provided it was not possible to establish the specific effect which is the target for the claim.

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

1.27. "Physical well-being" (ID 4407)

The claimed effect is "physical well-being". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were provided in the proposed wording. From the reference provided it was not possible to establish the specific effect which is the target for the claim.

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

1.28. "Skin health" (ID 584, 590, 1379, 4241, 4243)

The claimed effects are "skin", "skin health" and "skin care". The Panel assumes that the target population is the general population.

The claimed effects are not sufficiently defined and no further details were provided in the proposed wordings. No clarifications were provided by Member States. From the references provided it was not possible to establish the specific effect which is the target for the claim.

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

1.29. Maintenance of normal structure and appearance of hair and nails (ID 1233, 1385, 1746, 1879, 4202)

The claimed effects are "hair and nails health", "skin health", "essential part of the connective tissues, skin and hair", "hair beauty and health", "healthy hair, skin and nails" and "hair beauty and health". The Panel assumes that the target population is the general population.

In the context of the proposed wordings or the clarifications provided by Member States, the Panel assumes that the claimed effects refer to the maintenance of normal structure and appearance of hair and nails.

The Panel considers that the claimed effects do not refer to a function of the body as required by Regulation (EC) No 1924/2006.

1.30. Maintenance of normal structure and elasticity of the skin (ID 1385, 1406, 1746, 1879, 1950, 3131)

The claimed effects are "skin health", "skin health, in particular skin surface: significant reduction of skin density", "essential part of the connective tissues, skin and hair", "healthy hair, skin and nails" and "helps to keep elasticity of skin". The Panel assumes that the target population is the general population.

In the context of the proposed wordings or the clarification provided by Member States, the Panel assumes that the claimed effects refer to the maintenance of the normal structure and elasticity of the skin. The references provided did not refer to a particular physiological function of the skin.

The Panel considers that the claimed effects do not refer to a function of the body as required by Regulation (EC) No 1924/2006.

1.31. Prevention or treatment of acne (ID 2552, 3164)

The claimed effects are "epiderme, soigne l'acnée" and "skin health". The Panel assumes that the target population is the general population.

In the context of the clarifications provided, the Panel considers that the claimed effects refer to the prevention or treatment of acne, which is a skin disease, characterised by pimples on the face, chest, and back and occurs when the pores of the skin become clogged with oil, dead skin cells, and bacteria.

The Panel considers that the claimed effect is related to the prevention or treatment of a disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

1.32. Prevention or treatment of cellulitis (ID 2743, 3687)

The claimed effect is "skin curves/cellulitis". The Panel assumes that the target population is the general population.

The Panel assumes that the claimed effect is related to the treatment of cellulitis, which is a common skin infection caused by bacteria, most commonly caused by *Streptococcus pyogenes* or *Staphylococcus aureus*.

The Panel considers that the claimed effect is related to the prevention or treatment of a disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

1.33. "Function of the cell membrane" (ID 1777)

The claimed effect is "function of the cell membrane". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined. Cell membranes may have different structures and functions depending on their composition and the cell type they belong to. The Panel notes that several properties of cell membranes were mentioned in the proposed wordings and that a specific effect related to the function of cell membranes has not been identified. No further clarifications were provided by Member States.

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

1.34. "Mucous membranes" (ID 589)

The claimed effect is "mucous membranes". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined. Mucosa is the inner lining tissue of organs e.g. digestive, respiratory and urogenital tracts and the inner surface of the eyes. It acts as protective layer against different environmental detrimental factors. The Panel notes that several mucous membranes were mentioned in the clarifications provided by Member States and that a specific effect related to the function of mucous membranes has not been identified.

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

1.35. "Immune system" (ID 675, 847, 1399, 1482, 1792)

The claimed effects are "essential for the balanced body functions, with special regards to the immune system", "immune health", "stimulation of the immune system", "immune system function" and "immunity". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were available in the proposed wording or the clarifications provided by Member States. Given the multiple roles of the immune system, the specific aspect of immune function, which is the subject of the health claim, needs to be specified but has not been indicated in the information provided.

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

1.36. Increase of non-specific IgA secretion (ID 1944)

The claimed effect is "immune health". The Panel assumes that the target population is the general population.

In the context of the clarifications provided by the Member States, the Panel assumes that the claimed effect refers to "promotes a healthy immune system by notably increasing IgA".

The Panel considers that the evidence provided does not establish that increasing non-specific IgA secretion is a beneficial physiological effect *per se*.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claim and a beneficial physiological effect related to an increase of non-specific IgA secretion.

1.37. Stimulation of natural killer cell activity (ID 3128, 3153)

The claimed effects are "immune system" and "strengthens immune systems". The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers to the stimulation of natural killer cell activity.

The Panel considers that the evidence provided does not establish that stimulation of natural killer cell activity is a beneficial physiological effect *per se*.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to the stimulation of natural killer cell activity.

1.38. Induction of cytokine production (ID 4112)

The claimed effect is "immune support". The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers to supporting immune health by inducing cytokine production (e.g. TNF-alpha and IFN-gamma).

The Panel considers that the evidence provided does not establish that induction of cytokine production (e.g. TNF-alpha and IFN-gamma) is a beneficial physiological effect for the general population *per se*.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to the induction of cytokine production.

1.39. Immune defence against pathogens (ID 1477)

The claimed effect is "antimicrobial/antiviral/innate host defense". The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers to immune defence against pathogens.

The Panel notes that the type of infection has not been specified and the references provided addressed several effects (e.g. related to treatment of tinea pedis (athletes foot), eradication of *Helicobacter pylori*, lower respiratory tract illnesses, the effects of long-term administration of bovine lactoferrin in patients with chronic hepatitis C, effects in post-surgical patients) and it was not possible to establish which of these effects is the target for the claim.

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

1.40. "Essential for the balanced body functions, with special regards to the immune system" (ID 675)

The claimed effect is "essential for the balanced body functions, with special regards to the immune system". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were available in the proposed wordings. The clarifications provided by Member States included several physiological functions and the references provided did not allow the identification of the specific function which is the target for the claim.

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

1.41. Decreasing the absorption of alcohol (ID 648)

The claimed effect is "slows the absorption of alcohol". The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers to decreasing the absorption of alcohol.

The Panel considers that the evidence provided does not establish that decreasing the absorption of alcohol is a beneficial physiological effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to decreasing the absorption of alcohol.

1.42. Increase in muscle creatine stores (ID 544, 545)

The claimed effects are "increased muscle creatine storage" and "enhancing storage & uptake". The Panel assumes that the target population is active individuals in the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to an increase in muscle creatine stores.

The Panel notes that from the references provided the beneficial physiological effect of increasing muscle creatine stores is unclear.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to an increase in muscle creatine stores.

1.43. "Improves mechanical activity of gallbladder" (ID 1342)

The claimed effect is "improves mechanical activity of gallbladder". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were available in the proposed wordings. The Panel notes that is unclear whether the claim refers to an increase or to a decrease in the frequency or the intensity of contraction of the gallbladder wall, and none of the references provided refers to the function of the gallbladder.

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

CONCLUSIONS

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

- The claimed effects: "anti-aging properties" (ID 1352), "maintenance of urinary tract" (ID 1199, 1369), "cardiovascular health" (ID 569, 582, 1382), "vascular and vein health" (ID 1480, 1998, 2212, 2753, 3667, 4278), "blood flow/vascular function" (ID 1265), "hormonal balance" (ID 1837, 2916), "women's health" (ID 531), "menstrual health" (ID 2487), "absorption of nutrients" (ID 1814), "digestive function" (ID 377, 692, 1267, 1357, 1401, 1625, 2329, 3692), "gut health" (ID 585, 2223), "intestinal flora" (ID 3076), "stomach health" (ID 2175), "powerful protectors of the stomach" (ID 1368), "liver health" (ID 583, 2504), "nervous system function" (ID 1383, 1732) "mental energy" (ID 1530), "mental health" (ID 555), "physical and mental health" (ID 9), "physical performance" (ID 560, 4248), "overtraining and effort prevention"(ID 4247), "physical well-being" (ID 4407), "skin health" (ID 584, 590, 1379, 4241, 4243), "function of the cell membrane" (ID 1777), "mucous membranes" (ID 589), "immune system" (ID 675, 847, 1399, 1482, 1792), immune defence against pathogens (ID 1477), "essential for the balanced body functions, with special regards to the immune system" (ID 675), and "improves mechanical activity of gallbladder" (ID 1342), are general and non-specific, and do not refer to any specific health claims as required by Regulation (EC) No 1924/2006.

- The claimed effects are "hair and nails health", "skin health", "essential part of the connective tissues, skin and hair", "hair beauty and health", "healthy hair, skin and nails"; "skin health", "skin health, in particular skin surface: significant reduction of skin density", "essential part of the connective tissues, skin and hair", "healthy hair, skin and nails" and "helps to keep elasticity of skin". Maintenance of the normal structure and elasticity of the skin (ID 1233, 1385, 1746, 1879, 4202), and maintenance of normal structure and elasticity of the skin (ID 1385, 1406, 1746, 1879, 1950, 3131), do not refer to a function of the body as required by Regulation (EC) No 1924/2006.

- The claimed effects are "sexual organs and/or hormone activity", "santé de la prostate"; "ORSALIT is given in order to supplement liquids and mineral components during diarrhoea and/or vomiting"; "epiderme, soigne l'acnée", "skin health"; and "skin curves/cellulitis". Prevention or treatment of prostate cancer (ID 1859, 2773), treatment of diarrhoea and/or vomiting (ID 3087), prevention or treatment of acne (ID 2552, 3164), and prevention or treatment of cellulitis (ID 2743, 3687), are related to the prevention or treatment of a disease and do not comply with the criteria laid down in Regulation (EC) No 1924/2006.

- The claimed effects are "digestive function", "digestion", "break down of high-molecules compound from food", "pancreas" and "digestive system benefits". Macronutrient digestion is not impaired in the general population and no evidence has been provided that an improvement of the digestion of macronutrients (e.g. carbohydrates, proteins and lipids) (ID 1781, 1842, 2825, 3137, 3519, 3972, 4662, 4691) is a beneficial physiological effect *per se* for the general population. A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to the digestion of carbohydrates, proteins and lipids.

- The claimed effects are "increased inner protection/resistance", "prebiotic/bifidogenic", and "benefits the growth of intestinal bifidus bacteria and stimulates the immune system". The evidence provided does not establish that increasing numbers of gastro-intestinal microorganisms

(ID 773, 782, 1399) is a beneficial physiological effect. A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to increasing numbers of gastro-intestinal microorganisms.

- The claimed effects are "gut health", "gastric acidity" and "stomach acid in digestion". The evidence provided does not establish that reduction of gastric acid (ID 1795, 1906, 2759, 2886) is a beneficial physiological effect *per se* for the general population. A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to reduction of gastric acid.

- The claimed effect is "immune health". The evidence provided does not establish that increasing non-specific IgA secretion (ID 1944) is a beneficial physiological effect *per se*. A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to an increase of non-specific IgA secretion.

- The claimed effects are "immune system" and "strengthens immune systems". The evidence provided does not establish that stimulation of natural killer cell activity (ID 3128, 3153) is a beneficial physiological effect *per se*. A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to the stimulation of natural killer cell activity.

- The claimed effect is "immune support". The evidence provided does not establish that induction of cytokine production (e.g. TNF-alpha and IFN-gamma) (ID 4112) is a beneficial physiological effect *per se* for the general population. A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to the induction of cytokine production.

- The claimed effect is "slows the absorption of alcohol". The evidence provided does not establish that decreasing the absorption of alcohol (ID 648) is a beneficial physiological effect. A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to decreasing the absorption of alcohol.

- The claimed effects are "increased muscle creatine storage" and "enhancing storage & uptake". From the evidence provided the beneficial physiological effect of increasing muscle creatine stores is unclear (ID 544, 545). A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claims and a beneficial physiological effect related to an increase in muscle creatine stores.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-796, EFSA-Q-2008-1164, EFSA-Q-2008-1318, EFSA-Q-2008-1331, EFSA-Q-2008-1332, EFSA-Q-2008-1342, EFSA-Q-2008-1347, EFSA-Q-2008-1356, EFSA-Q-2008-1369, EFSA-Q-2008-1370, EFSA-Q-2008-1371, EFSA-Q-2008-1372, EFSA-Q-2008-1376, EFSA-Q-2008-1377, EFSA-Q-2008-1435, EFSA-Q-2008-1462, EFSA-Q-2008-1479, EFSA-Q-2008-1560, EFSA-Q-2008-1569, EFSA-Q-2008-1634, EFSA-Q-2008-1938, EFSA-Q-2008-1971, EFSA-Q-2008-2003, EFSA-Q-2008-2005, EFSA-Q-2008-2079, EFSA-Q-2008-2089, EFSA-Q-2008-2094, EFSA-Q-2008-2105, EFSA-Q-2008-2106, EFSA-Q-2008-2116, EFSA-Q-2008-2119, EFSA-Q-2008-2120, EFSA-Q-2008-2122, EFSA-Q-2008-2136, EFSA-Q-2008-2138, EFSA-Q-2008-2143, EFSA-Q-2008-2214, EFSA-Q-2008-2217, EFSA-Q-

2008-2219, EFSA-Q-2008-2267, EFSA-Q-2008-2361, EFSA-Q-2008-2468, EFSA-Q-2008-2479, EFSA-Q-2008-2510, EFSA-Q-2008-2514, EFSA-Q-2008-2525, EFSA-Q-2008-2528, EFSA-Q-2008-2547, EFSA-Q-2008-2570, EFSA-Q-2008-2575, EFSA-Q-2008-2592, EFSA-Q-2008-2612, EFSA-Q-2008-2639, EFSA-Q-2008-2677, EFSA-Q-2008-2683, EFSA-Q-2008-2731, EFSA-Q-2008-2908, EFSA-Q-2008-2945, EFSA-Q-2008-2956, EFSA-Q-2008-3062, EFSA-Q-2008-3220, EFSA-Q-2008-3237, EFSA-Q-2008-3285, EFSA-Q-2008-3476, EFSA-Q-2008-3486, EFSA-Q-2008-3492, EFSA-Q-2008-3506, EFSA-Q-2008-3558, EFSA-Q-2008-3619, EFSA-Q-2008-3649, EFSA-Q-2008-3808, EFSA-Q-2008-3819, EFSA-Q-2008-3860, EFSA-Q-2008-3863, EFSA-Q-2008-3869, EFSA-Q-2008-3885, EFSA-Q-2008-3896, EFSA-Q-2008-4246, EFSA-Q-2008-4390, EFSA-Q-2008-4410, EFSA-Q-2008-4415, EFSA-Q-2008-4687, EFSA-Q-2008-4823, EFSA-Q-2008-4912, EFSA-Q-2008-4951, EFSA-Q-2008-4953, EFSA-Q-2008-4957, EFSA-Q-2008-4958, EFSA-Q-2010-00231, EFSA-Q-2010-00360, EFSA-Q-2010-00615, EFSA-Q-2010-00644). 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.

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[7] (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[8]

Foods are commonly involved in many different functions[9] 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.

[7] OJ L12, 18/01/2007
[8] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[9] 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 various food(s)/food constituent(s) claiming general and non-specific health effects, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
9	Vitamins, minerals, trace elements and standardized ginseng G115 extract (Pharmaton Activit G effervescent tablets).	Physical and mental health. 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 body cells - reducing the lactate level in body tissues - enhancing the reoxygenation of haemoglobin in the blood circulation system. 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.	Scientifically proven: Helps to sustain energy, performance and concentration throughout the day. Scientifically proven: Helps to maintain mental and physical performance.
	Conditions of use - 600 - 650 g / Tag. - Applicable to multivitamin/mineral product which contains following daily dosage: Beta-carotene 2mg, Vitamin D 5mcg, Vitamin E 10mg, Vitamin C 60mg, Vitamin B1 1.4mg, Vitamin B2 1.6mg, Niacin 18mg, Vitamin B6 2mg, Folic acid 200mcg, Vitamin B12 1mcg,		

	Biotin 150mcg, Calcium 100mg, Iron 10mg, Magnesium 40mg, Zinc 1mg, Copper 1.1mg, Selenium 50mcg, Panax Ginseng extract G115 40mg.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
377	Bicarbonate	Joue un rôle dans le processus digestif	Pendant les repas, elle (NB : l'eau minérale naturelle DIDIER) facilite la digestion grâce à sa teneur en bicarbonate - Le bicarbonate permet une meilleure digestion et aide à lutter contre les maux d'estomac
	Conditions of use - Article 1321-78 du Code de la Santé Publique. Composition minérale moyenne DIDIER (mg/l) : Bicarbonate (1280)		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
531	Omega-3 and Omega-6 fatty acids (GLA)	Women´s health Clarification provided Omega-3 Fatty acids help improve women's emotional and mental wellbeing	Omega-3 fatty acids with GLA support women during menstruation, PMS and menopause
	Conditions of use - 400 – 1000mg DHA + EPA 1-3g EPO per day corresponds to 90-330mg GLA per day		
	Comments from Member States Please change "Food category" to "Omega-3 Fatty Acids"		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
544	Creatine and carbohydrate Clarification provided Creatine and carbohydrate in sports nutrition : products Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC. Sports foods and food supplements providing at least 0.07g creatine per kg body mass and at least 0.26g carbohydrate per kg body mass, per serve OR Sports foods and food supplements providing at least 5g creatine and 18g	Increased muscle creatine storage	Combined creatine and carbohydrate increases muscle creatine stores compared to creatine alone. Helps deliver creatine to the muscle effectively. Creatine retention is increased when consumed with carbohydrate.

	carbohydrate per serve		
	Conditions of use - Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC. Sports foods and food supplements providing 0.08 g/kg body weight per recommended daily consumption. 0.8g creatine /kg body weight		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
545	Creatine plus Carbohydrate (dextrose, sugar) Clarification provided Creatine plus Carbohydrate (dextrose, sugar) Food or food supplement must contain at least 1 gram Creatine and 30 g Dextrose per serving	Enhancing Storage & Uptake	Blend of ingredients clinically shown to help enhance creatine uptake into muscle University tests show that a blend of creatine and high-glycemic carbohydrate promotes creatine uptake and storage in muscle tissue
	Conditions of use - The product must contain at least 1 gram creatine and 30 g dextrose per serving Claim to be used for foods for active individuals		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
555	Fructose	Mental health	Improves well-being after alcohol use
	Conditions of use - 250 ml		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
569	Berry seed oils (supercritical carbon dioxide extract).	Cardiovascular system. Clarification provided Berry seed oils are rich sources of omega-3 alpha-linolenic acid. The omega-3 fatty acids in berry seed oils improve the balance of omega-3 ja omega-6 in the body. Due to the favourable profile of essential fatty acids, berry seed oils support cardiovascular health.	The essential fatty acids in berry seed oils balance fatty acid metabolism in the body. Berry seed oils support the health of the cardiovascular system.
	Conditions of use - Seed oils from wild berries such as lingonberry, bilberry and cranberry and from domestic berries such as strawberry and raspberry and sea buckthorn berry oils. The amount was not indicated. The seed oils are produced by means of supercritical carbon dioxide extraction.		

ID	Food or Food constituent	Health Relationship	Proposed wording
582	Sea buckthorn berry oil (cold-pressed).	Cardiovascular system.	Healthy for the heart and blood vessels.
	Conditions of use - Food supplement with 2 g of cold-pressed sea buckthorn berry oil (pulp oil) in the daily dose.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
583	Sea buckthorn berry oil (cold-pressed).	Liver.	Protects the liver.
	Conditions of use - Food supplement with 2 g of cold-pressed sea buckthorn berry oil (pulp oil) in the daily dose.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
584	Sea buckthorn berry oil (cold-pressed).	Skin.	Healthy for the skin and mucous membranes.
	Conditions of use - Food supplement with 2 g of cold-pressed sea buckthorn berry oil (pulp oil) in the daily dose.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
585	Sea buckthorn berry oil (cold-pressed).	Gut health.	Healthy for the stomach. Protects the gut.
	Conditions of use - Food supplement with 2 g of cold-pressed sea buckthorn berry oil (pulp oil) in the daily dose.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
589	Sea buckthorn seed oil and pulp oil	Mucous membranes <u>Clarification provided</u> Standardised sea buckthorn oil SBA24 manufactured by supercritical CO2 maintains the health of female genital mucosa especially in females of post-menopausal age. Standardised sea buckthorn oil SBA24 manufactured by	Sea buckthorn seed and pulp oil nourish the mucous membranes and help to maintain their normal structure and functioning. Sea buckthorn seed and pulp oil moisturise dry mucous membranes. Sea buckthorn seed and pulp oil strengthen and protect the mucous membranes of the stomach.

		supercritical CO2 maintains the health of gastric mucosa, the mucous membranes of the stomach. Standardised sea buckthorn oil SBA24 manufactured by supercritical CO2 maintains the health of mucosa of eyes and mouth	
	Conditions of use - Food supplement that has 1000-2000 mg of sea buckthorn seed and pulp oil in the daily dose.		
	Comments from Member States Health relationship defined		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
590	Sea buckthorn oil.	Skin.	For skin health / well-being.
	Conditions of use - Serving required for the effect: In clinical studies beneficial effects have been achieved by using 5 g of sea buckthorn seed oil or sea buckthorn seed oil produced by supercritical extraction.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
648	Mix of Glucose-Fructose	slows the absorbtion of alcohol Clarification provided increases blood flow and alcohol elimination in the liver	helps to lower level of the consumed alcohol in the body by decelerating of the absorbin of alcohol
	Conditions of use - at least 6g of Glucose and Fructose / not recommended for diabetics		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
675	Polyunsatu-rated fatty acids: n-3/n-6 (omega 3 / omega 6) ratio	Optimal linolenic / linoleic acid ratio is essential for the balanced body functions, with special regards to the immune system. Clarification provided Optimal linolenic / linoleic acid ratio is	Optimal (1/5-1/8) linolenic / linoleic acid (n-3 / n-6) ratio in the diet is essential for the good balanced function of the body and the immune system.;DHA and EPA are formed from these two essential fatty acids. Transformation is mediated by the same enzymes; therefore adequate precursor ratio (n-3 / n-6 = 1/5 - 1/8) is important for balanced DHA/EPA

		essential for the good balanced body functions, with special regards to the nervous tissue, skin, retina and the immune system. Clarification:'DHA is a component of membrane structural lipids, especially in nervous tissue and the retina. EPA is the precursor for series 3 prostanoids and series 5 leukotrienes, which participate in the regulation of blood pressure, renal function, blood coagulation, inflammatory and immunological reactions.Because of he competition for metabolic enzymes between the fatty acids of n-6 and n-3 series, it is important to maintain a balance between n-6 and n-3 PUFA in the diet.	synthesis.;
	Conditions of use - 1/5 – 1/8 (linolenic / linoleic acid) ratio in the daily diet or in the food.;The product shall comply with the conditions of nutrition claim „High polyunsaturated fat".;;		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
692	Essential Fatty Acids	Essential fatty acids to aid in digestive tract function.	Essential fatty acids to aid in digestive tract function.
	Conditions of use - No RDA / RNI.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
773	Chicory oligofructose	Increased inner protection/ resistance <u>Clarification provided</u> Increased inner protection/ resistance. Improved intestinal function/ digestive health and increased inner protection/ resistance. Increases number of	contributes to your body's natural defences;

		beneficial bacteria in the gut.	
	Conditions of use - 5 bis 9 Gramm (g) - 12 g/Tag. beginnt bei 12g/Tag - Where a daily value is indicated the amount per serving is typicaly 25% unless otherwise stated. 12g/day - beginnt bei 12g pro Tag		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
782	Xylo-oligosaccharides	Prebiotic / bifidogenic	Prebiotic; Stimulate a healthy intestinal flora; Stimulates the growth of bifidobacteria.
	Conditions of use - 3 g/day - 2,6g/ day - Where a daily value is indicated the amount per serving is typicaly 25% unless otherwise stated 2.6g/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
847	Beta-glucan of Saccharomyces cerevisiae	Immune health	Beta glucan from yeast as immunomodulators Beta glucan from yeast support of natural defences
	Conditions of use - 400mg/d - 5 mg per kg body mass per day		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1199	Black Currant juice	Urinary tract maintenance (Urinary Calculus). Clarification provided Alkaline protective effect: increase citric acid excretion and contribute to support the urinary tract immune function.	Blackcurrent juice helps to: - improve the urinary tract immune function. - support the normal functionning of the urinary tract.
	Conditions of use - One time 330 ml.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1233	Brewer's yeast (Saccharomyces cerevisiae)	Hair and nails health Clarification provided	Useful in case of fragile nails. Helps to support the hair's vitality.

		Increase hair and nails resistance	Helps to Improve the structure and appearance of hair and nails. Helps to support hair and nails health.
	Conditions of use - Saccharomyces cerevisiae At least 1g/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1265	Purple Grape Juice	Blood flow/Vascular function	Purple grape juice contributes to healthy arteries/ contributes to a healthy blood flow/ contributes to healthy vascular functions.
	Conditions of use - At least 250 ml per day		
	Comments from Member States Purple grape juice contributes to healthy arteries/contributes to a healthy blood flow/contributes to healthy vascular functions.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1267	Bran.	Consumption of bran improves digestive function.	Soodustab seedimist. Clarification provided Consumption of bran improves digestive function.
	Conditions of use - Küpsiste kliisisaldus on 5 g/100 g, väidet kasutava toidukäitleja poolt esitatud andmete põhjal on kliide päevane soovitatav kogus 31 g.		
	Comments from Member States Consumption of bran improves digestive function.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1342	Water-based product (Water purified by reverse osmosis to monomolecular level, complex of salts)	Improves mechanical activity of gall- bladder	Improves gallbladder mechanoactivity
	Conditions of use - ab 200 mg/l Sulfat (siehe EG Mineralwasser-Richtlinie) - 200- 400 ml in 30 - 40 min before eating		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1352	Name of Food product: Sqeez Wild Blueberry Juice Drink. Description of food in terms of food legislation	Health benefits of food: Anti aging properties. Do benefits relate to a disease risk factor: No.	Exact wording of claim as it appears on product: Blueberries have a wide range of health benefits including anti-ageing properties and the maintenance of urinary tract and

	categories: food not covered by specific food legislation. Was food on Irish market before 1st July 2007: Yes.	Target group: All of the general population including children and adults.	vision health. Is claim a picture: No.
	Conditions of use - Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance. Number of nutrients/other substances that are essential to claimed effect: 1. Names of nutrient/other substances and Quantity in Average daily serving: 200ml blueberry juice. Weight of average daily food serving: 200 mililitre(s). Daily amount to be consumed to produce claimed effect: 200 mililitre(s). Number of food portions this equates to in everyday food portions: 1.00. Are there factors that could interfere with bioavailability: Yes. Please give reason: Storage beyond its shelf life. Length of time after consumption for claimed effect to become apparent: It is apparent immediately. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No.		
	Comments from Member States Further clarification to support the use of this claim was not submitted to the Food Safety Authority of Ireland.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1357	Name of Food product: Lentil & Bean Shoots. Description of food in terms of food legislation categories: food not covered by specific food legislation. Was food on Irish market before 1st July 2007: Yes.	Health benefits of food: Naturally boost your digestive system. Do benefits relate to a disease risk factor: Yes. Target group: All of the general population including children and adults. <u>Clarification provided</u> Health benefits of food: High in fibre which helps maintain a healthy digestive system. Do benefits relate to a disease risk factor: Yes. Target group: All of the general population including children and adults.	Exact wording of claim as it appears on product: Lentil & Bean Shoots naturally boost your digestive system. Is claim a picture: No.
	Conditions of use - Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance. Number of nutrients/other substances that are essential to claimed effect: 1. Names of nutrient/other substances and Quantity in Average daily serving: 4.4 g fibre. Weight of average daily food serving: 40 gram(s). Daily amount to be consumed to produce claimed effect: 40 gram(s). Number of food portions this equates to in everyday food portions: 1.00. Are there factors that could		

	interfere with bioavailability: No. Length of time after consumption for claimed effect to become apparent: It is apparent after a period of regular use. Number of days: 30 . Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No. Where applicable outline nutritional composition (g per 100g) of food: Total Fat: 1.10. Saturated Fat: .20. Trans Fat: .00. Sugar: 17.00. Salt: .00. Sodium: .02.		
	Comments from Member States Clarification/ further information/alternative wording which was provided by the FBO has been included. This FBO also includes information on the nutritional composition of the product carried out by an accredited laboratory - this is enclosed in a separate file identified by claim number - additional information.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1368	Name of Food product: Sqeez Cranberry and Orange Juice Drink, Sqeez Light Cranberry Juice Drink. Description of food in terms of food legislation categories: food not covered by specific food legislation. Was food on Irish market before 1st July 2007: Yes.	Health benefits of food: More recently, emerging research suggests that cranberries may also be powerful protectors of the stomach. Do benefits relate to a disease risk factor: No. Target group: All of the general population including children and adults.	Exact wording of claim as it appears on product: More recently, emerging research suggests that cranberries may also be powerful protectors of our health in other areas of the body, such as the stomach, gums and even the heart. Is claim a picture: No.
	Conditions of use - Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance. Number of nutrients/other substances that are essential to claimed effect: 1. Names of nutrient/other substances and Quantity in Average daily serving: 200 millilitres cranberry juice. Weight of average daily food serving: 200 millilitre(s). Daily amount to be consumed to produce claimed effect: 200 millilitre(s). Number of food portions this equates to in everyday food portions: 1.00. Are there factors that could interfere with bioavailability: No. Length of time after consumption for claimed effect to become apparent: It is apparent immediately. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No.		
	Comments from Member States Further clarification to support the use of this claim was not submitted to the Food Safety Authority of Ireland.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1369	Name of Food product: Sqeez Wild Blurberry Juice Drink. Description of food in terms of food legislation categories: food not covered by specific food legislation. Was food on Irish market before 1st July 2007: Yes.	Health benefits of food: Maintenance of urinary tract. Do benefits relate to a disease risk factor: No. Target group: All of the general population including children and adults.	Exact wording of claim as it appears on product: Blueberries have a wide range of health benefits including anti-ageing properties and the maintenance of urinary tract and vision health. Is claim a picture: No.

	Conditions of use - Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance. Number of nutrients/other substances that are essential to claimed effect: 1. Names of nutrient/other substances and Quantity in Average daily serving: 200 millilitres blueberry juice. Weight of average daily food serving: 200 millilitre(s). Daily amount to be consumed to produce claimed effect: 200 millilitre(s). Number of food portions this equates to in everyday food portions: 1. Are there factors that could interfere with bioavailability: Yes. Please give reason: Storage beyond its shelf life. Length of time after consumption for claimed effect to become apparent: It is apparent immediately. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No.		
	Comments from Member States Further clarification to support the use of this claim was not submitted to the Food Safety Authority of Ireland.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1379	Apple cider vinegar.	Skin health.	Helps maintain healthy skin.
	Conditions of use - Powder: 1,2 g.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1382	Brewer`s Yeast.	Cardiovascular health.	Strengthens the cardiovascular system, is necessary for blood formation.
	Conditions of use - 2- 4g.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1383	Brewer`s Yeast	Nervous system function	1. Helps maintain a healthy nervous system 2. Stimulates mental and physical work capacities
	Conditions of use - 2- 4g - Traditional use of ale yeast, 3 table spoon of fresh yeast diluted in water or 4-10g of dried yeast per day		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1385	Brewer`s Yeast	Skin health Clarification provided Improves the skin, hair and nail structure	Improves skin, hair and nail condition

	Conditions of use - 2- 4g		
	Comments from Member States Brewer's yeast (Saccharomyces cerevisiae) contains B group vitamins and minerals (selenium, iron, copper, chromium), organic acids, amino acids, enzymes that improves the structure of skin, hair and nails. (EFSA published list of health claims - Nr.1233)		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1399	Stutenmilch, naturbelassen Clarification provided Mare's milk, natural finish	Stutenmilch fördert die Entwicklung der Bifidusflora im Darm, und stimuliert das Immunsystem. Wirksame Inhaltsstoffe sind u.a. Lactoferrin, Lysozym, Immunglobuline (sIgA, sIgM), weitere Enzyme (Amylase, Katalase, Lipase, Peroxydase, Phosphatase, Malat- u. Clarification provided Mare's milk benefits the growth of intestinal bifidus bacteria and stimulates the immune system. Active components are lactoferrin, lysozyme, immunoglobulins (secretory immunoglobulin A, secretory immunoglobulin M), other enzymes (amylase, catalase, lipase, peroxydase, phosphatase, malat- and lactat-dehydrogenase, lacto-transferrin, acetylcholin), and beta-lactose, linolenic acid, vitamin C, taurine.	[In German:] Stutenmilch kann die Anzahl an Bifidusbakterien im Darm erhöhen. Clarification provided Mare's milk is able to increase the number of intestinal bifidus bacteria.
	Conditions of use - Naturbelassene, nicht erhitzte oder pasteurisierte Stutenmilch, die unter den Bedingungen für Vorzugsmilch erzeugt wurde und besonders keimarm ist. Sie ist bis zur Verwendung bei -18 °C tiefgekühlt 9 Monate lagerfähig. Besonders für Personen mit entzündli.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1401	Mineralwasser/ Kohlensäure	Verdauung/Magen-Darm- funktion (Anregung)	[In german :] regt die Verdauung an Clarification provided

	Clarification provided mineral water/carbonic acid	Clarification provided Digestion (stimulation)	stimulates digestion
	Conditions of use - ab 1 g/l Kohlensäure - ab 2 g/l Kohlensäure		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1406	Natürliches Mineralwasser. Clarification provided Natural mineral water.	Hautgesundheit. Clarification provided Skin health, in particular skin surface: significant reduction of skin density.	[In German:] trägt zur sichtbaren Verbesserung der Hautoberflächenstruktur bei. Clarification provided Contributes to visible improvement of the skin surface structure.
	Conditions of use - 2 Liter (l)/Tag; min. 4 Wochen. - Zusammensetzung des Mineralwassers: Gesamtmineralisation mindestens 2,5 g /l, davon mindestens 1,8 g Hydrogencarbonat / l, mindestens 50 mg Magnesium /l, mindestens 90mg Calcium /l und mindestens 550 mg Natrium /l; Trinkmenge mindestens 2,25 l / Tag üb.		
	Comments from Member States Additional example of wording: Can contribute towards improving skin surface structure; Can lead to a smoother skin surface structure.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1477	Bovine lactoferrin	Antimicrobial / antiviral / innate host defense Clarification provided Antimicrobial / antiviral / innate host defense. Inactivation of bacteria and virusses. Contribution to the aspecific immune defense.	Contributes to the natural defences
	Conditions of use - Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 65 micrograms selenium Daily amount to be consumed to produce claimed effect: 200 microgram(s) Are there factors that could interfere with bioavailability: Don't Know Length of time after consumption for claimed effect to become apparent: Habitual intakeIs there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Don't Know - Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 30mg Bovine Lactoferrin Daily amount to be consumed		

	to produce claimed effect: 200 miligram(s)Are there factors that could interfere with bioavailability: Yes Please give reason: Heat treatment of lactoferrin may result in denaturation of lactoferrin.Length of time after consumption for claimed effect to become apparent: It is apparent after a period of regular use. Number of days: 28 Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: NoOther conditions for use: Suggested intake ~ 30mg bovine lactoferrin/dose for antimicrobial & immune enhancing effects. - 160 mg for 10 day		
	Comments from Member States Italy's proposal is identical to Dutch proposal/ IE proposal is identical to Dutch proposal/ Slovak's proposal is identical to the Dutch proposal		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1480	Bromelain	Vascular health Clarification provided Vascular health. Maintains natural blood fluidity and vessel patency by helping to maintain balance of fibrinogen/plazmin system and to optimise bradikynin level.	helps to maintein natural blood fluidity and vessel patence
	Conditions of use - daily dosage: >/= 200 mg (with activity 5 F 5 F.I.P/mg). - Personen, die eine Operation mit Verlust von Lymphknoten/Lymph-gefäßen hinter sich haben zur Langzeitverhütung von Ödemen—150 mg Bromelain– - 200 mg/Tag. tägl. Dosierung: ≥ 200 mg (5 F.I.P/mg).		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1482	Buckwheat extract containing flavonoid-mineral (troxerutin - zinc) complex (Coldizin)	Immune system function Clarification provided Improves the function of immune system cells	Coldizin helps support the immune system
	Conditions of use - 50mg troxerutin and 25mg zinc gluconate (5 lozenges daily)		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1530	2 - Dimethylaminoethanol hydrogentartrate.	For mental energy.	Helps support mental development.
	Conditions of use - 25-200 mg		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1625	Nucleotides.	Gastro-intestinal support.	Dietary nucleotides help support a

			healthy gastro-intestinal tract.
	Conditions of use - Typical adult dosage: 250 mg - 1000 mg exogenous RNA nucleotides, derived, for example, from Saccharomyces cerevisiae or other dietary sources.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1732	Inositol	Nervous system function	Important for the function of the nervous system.
	Conditions of use - 12-18 g per day		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1746	Para-aminobenzoic Acid	Essential part of the connective tissues, skin and hair	helps maintain hair, nails and skin in optimum condition
	Conditions of use - 12 g daily in 4 to 6 divided doses		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1777	Lecithin	Function of the cell membrane	1. Necessary for normal growth, wholesome mental and physical development 2. Helps maintain functions and structure of the body and organ cell membranes 3. Lecithin is found in every human cell and it participates in various vitally important processes
	Conditions of use - 1,2- 3,6 g		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1781	Pancreatic enzymes	Digestive function	For a better digestive process
	Conditions of use - 425 mg		
	No clarifications provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1792	Beta-glucan (WGP)	Immunity	For immunity. Strengthens immunity.

	Conditions of use - Food supplement with 125-150 mg of WGP beta-glucan (WGP = whole glucan particle) in the daily dose.		
	No clarifications provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1795	Buffering salts (calcium carbonate + magnesium oxide) <u>Clarification provided</u> Food supplement for which health claims are requested: Sugarfree chewing gum with xylitol. The applicant wants to define the previously submitted conditions of use on Buffering salts (calcium carbonate + magnesium oxide), and add sodium bicarbonate to be one of the active ingredient. There are two different compositions of sugarfree chewing gum with xylitol, Composition I and Composition II. The ingredients of these two compositions are otherwise similar but Composition I contains as active ingredients only 1) calcium carbonate and 2) magnesium oxide whereas Composition II contains 1) calcium carbonate, 2) sodium bicarbonate and 3) magnesium oxide. List of ingredients of sugarfree chewing gum with xylitol (both Compositions I and II): - xylitol (35-37 %), chewing gum base, calcium carbonate (Compositions I and II), sodium bicarbonate (only Composition II), magnesium oxide	Gut health	Calms the stomach. In combination with the following sentence * Xylitol chewing gum for post-meal gastric acid attack. (or) * Xylitol gum with a fast and long-lasting neutralising effect on gastric acids. Chewing calms your stomach. In combination with the following sentence: * Xylitol chewing gum for post-meal gastric acid attack. (or) * Xylitol gum with a fast and long-lasting neutralising effect on gastric acids. Fast and long-lasting calming effect on your stomach. In combination with the following sentence * Xylitol chewing gum for post-meal gastric acid attack. * Calms the gastric acid attack * For gastric acid attack * Balances the gastric acids * Fast and long-lasting

	(Compositions I and II), sorbitol/maltitol, flavours, thickener E414, humectant E422, emulcifier E322 (rapeseed lecithin), colour E171, sweeteners E950 and/or sucralose E955, glazing agents E903, E901, E904. One piece of xylitol chewing gum (ca. 1,4 g/piece) will contain active ingredients as following: Composition I: 300 mg of calcium carbonate (CaCO3) and 100 mg of magnesium oxide (MgO) Composition II: 100 mg of calcium carbonate (CaCO3), 150 mg of sodium bicarbonate (NaHCO3) and 50 mg of magnesium oxide (MgO). These ingredients are situated in chewing gum base. Intake of 1-2 pieces of chewing gum just after the meal is recommended. The maximum daily dose is 6 pieces for Composition I and 10 pieces for Composition II. To be chewed for at least 10 minutes is recommended.		
	Conditions of use - Xylitol chewing gum (food supplement) with 300-600 mg of calcium carbonate and 100-200 mg of magnesium oxide in the edible dose (1-2 pieces of chewing gum). The chewing gum is sweetened with xylitol.		
	Comments from Member States Food composition defined		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1814	Herbal yeast plasmolycate (saccharomyces cerevisiae).	Absorption of nutrients. Clarification provided Herbal yeast plasmolysate promotes	Promotes the absorption of nutrients. Helps the body utilise nutrients obtained from food more effectively.

		absorption and helps the body to utilize nutrients obtained from the daily food more effectively.	
	Conditions of use - Herbal yeast preparation with 2.7-4.5 g of herbal yeast plasmolycate (saccharomyces cerevisiae) in the daily dose.		
	Comments from Member States Health relationship defined.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1837	Pollen + Royal Jelly	Sexual organs and/or hormone activity	Balances hormone activity. For menopausal women.
	Conditions of use - Food supplement with 270mg of pollen and 190mg of Royal Jelly in the daily dose.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1842	Protease, lipase and other enzymes that break down carbohydrates <u>Clarification provided</u> Protease, lipase and other enzymes that break down carbohydrates Proteolytic enzyme product, one capsule contains: Protease 4.5 21000 HUT (hemoglobin unit on tyrosine basis) Protease 3.0 40,7 SAPU (spectrophotometric acid protease unit) Protease 6.0 4000 HUT (hemoglobin unit on tyrosine basis) Capsules are taken with meals. Enzyme product with protease, lipase and different carbohydrates breaking enzymes, one capsule contains: Amylase 7500 DU (dextrinizing unit)	Digestion <u>Clarification provided</u> Product with protease enzyme: Promotes digestion. The preparation´s enzymes break down proteins. Product´s protease enzymes split proteins derived from food to complement the weakening secretion of organism´s own enzyme production. Product with protease, lipase and carbohydrate breaking enzymes: Promotes digestion. The preparation´s enzymes break down proteins, fats and carbohydrates. Product´s different enzymes split proteins, fats and carbohydrates derived from food to complement the weakening secretion of organism´s own enzyme production; Diminishes gas production and other symptoms derived from	Promotes digestion The preparation's enzymes break down proteins. A food supplement containing protease enzymes is particularly recommended after heavy meals and, as the years pass, to complement the weakening secretion of enzymes that break down proteins.

	Protease 4.5 18000 HUT (hemoglobin unit on tyrosine basis) Glucoamylase 10 AGU (amyloglucocidase unit) Protease 6.0 5000 HUT (hemoglobin unit on tyrosine basis) Protease 3.0 10 SAPU (spectrophotometric acid protease unit) Lipase RO 437.5 FIP (federatin international pharmaceutique) Cellulase 125 CU (cellulase unit) Malt diastase 250 DP o (degrees diastatic power) Invertase 250 SU (Sumner unit) Capsules are taken with meals.	indigestion.	
	Conditions of use - Food supplement containing protease enzymes (protease 2.5 18000 HUT, protease 3.0 10 SAPU and protease 6.0 4000 HUT units/daily dose and proteases, lipases and enzymes that break down carbohydrates (amylase 7500 DU, glucoamylase 10 AGU, cellulase 125 CU, malt diastase 250 DP and invertase 250 SU, lipase RO 437.5 FIP units/daily dose.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1859	Soy isoflavones + lycopene + zinc + selenium + vitamin D + vitamin E + vitamin C	Sexual organs and/or hormone activity Clarification provided A carefully considered combination of important isoflavones, vitamins and minerals promotes men´s wellbeing.	Good for the prostate gland. A carefully considered combination of important isoflavones, vitamins and minerals for men's well-being. Name of symbol included in the claim: MenBalans®.
	Conditions of use - Preparation with 2.5 g/100g, 40 mg/day of isoflavones, 93.8 mg/100g, 1.5 mg/day of lycopene, 938 mg/100 g, 15 mg/day of zinc, 3125 µg /100g, 50 µg/day of selenium, 313 µg/100 g, 5 µg/day of vitamin D, 625 mg/100g, 10 mg/day of vitamin E and 3750 mg/100 g, 60 mg/day of vitamin C. The amount and quality of microbial flora in the gut can affect the usefulness of the isoflavones.		
	Comments from Member States Health relationship defined		

ID	Food or Food constituent	Health Relationship	Proposed wording
1879	Name of Food product: gelatin & cystine Description of food in terms of food legislation categories: Food supplement Was food on Irish market before 1st July 2007: No	Health benefits of food: healthy hair, skin and nails Do benefits relate to a disease risk factor: No Target group: All adults aged 18 years and over	Exact wording of claim as it appears on product: gelatin, cystine significantly strengthens hair, skin and nails Examples of any alternative wording that may be used in relation to claim: Gelatin and cystine significantly increases hair diameter and the degree of hardness of finger and toe nails. Is claim a picture: No
	Conditions of use - Number of nutrients/other substances that are essential to claimed effect: 2. Names of nutrient/other substances and Quantity in Average daily serving: 100mg Gelatin, 100mg L-cystine. Weight of average daily food serving: 300 miligram(s). Daily amount to be consumed to produce claimed effect: 300 miligram(s). Number of food portions this equates to in everyday food portions: 3. Are there factors that could interfere with bioavailability: Yes. Please give reason: do not store above 25 degrees C. Length of time after consumption for claimed effect to become apparent: It is apparent after a period of regular use. Number of days: 7 Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Don't Know		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1906	Fat-reduced cream powder (rich source of milk phospholipids) Clarification provided Fat-reduced cream powder (rich source of milk phospholipids) ≥ 2g milk phospholipids, corresponding to 10g Lacprodan PL-20, per eating occasion	Gastrointestinal health Clarification provided Gastrointestinal health Protects the stomach lining from excessive stomach acid	• For people with a sensitive stomach; • Soothes a sensitive stomach; • Protects the stomach lining
	Conditions of use - ≥2g milk phospholipids per eating occasion		
	Comments from Member States Additional comment Dutch applicant: Fat-reduced cream powder (Lacprodan PL-20) contains about 20% milk phospholipids (from milk fat globule membranes). It may be used as an ingredient in a variety of foods. In order to not increase the fat intake, it is used preferably as a substitute for other fat components of food. Portugal's proposal and additional comment is identical to the Dutch proposal and comment		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1944	Beta-glucan of Saccharomyces cerevisiae	Immune health Clarification provided	Beta glucan from yeast as immunomodulators

		Promotes a healthy immune system by notably increasing IgA	Beta glucan from yeast support of natural defences
	Conditions of use - 400mg/d		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1950	Collagen	Skin health	Collagen is a natural component of the skin. Helps the skin to preserve its firmness and elasticity. Has beneficial effect in the maintenance of skin firmness and elasticity.
	Conditions of use - At least 30 mg per day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1998	Aronia melanocarpa (Common Name : Chokeberry)	Vein health/Vascular health	Maintenance of blood vessel wals strenght
	Conditions of use - Frucht / Äquivalent zumAnthocyanin - Gehalt von 9-15 g frischer Früchte; täglich (45 – 60 mg Anthocyanine ber. als Cyanidin-3-0-galactosid pro Tag) - Fruit / The equivalence of anthocyanins content of 9-15 g of fresh fruits per day (45 – 60 mg anthocyanins calculated as cyanidin-3-0 galactoside per day)		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2175	Capsicum annum (Common Name : Capsicum)	Stomach health	Helps to protect the stomach in case of intake of irritating substances
	Conditions of use - owoc/ równowartość 90-360mg na dzień - Fruit / The equivalent to 90-360 mg per day		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2212	Ananas comosus - common name : Bromelain, Pineapple	Vascular and Vein Health	"Used for the good circulation of blood in microvessels" "Helps to decrease the sensations of heavy leggs"
	Conditions of use - Traditional use of the fruit / 80-320mg of bromelain two to three times daily for 8 to 10 days / Equivalent quantity in extract - Fruit / 160-960 mg of bromelain daily for 8 to 10 days / Equivalent quantity in extract		

	Comments from Member States claim 1998 has the same relationship and comment 0		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2223	Armoracia rusticana	Intestinal health	Soothes the digestive tract/ /helps support the digestive system /a source of mucilage which support the mucous membranes
	Conditions of use - Root / The equivalent of 6-20 g of root per day		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2329	Raphanus sativus - common name : radish, black radish, Japanese radish, Daikon	Digestion	"Used to facilitate the digestion" "Helps to support normal liver function" "Contributes to the stimulation of the production of the digestive body fluids" "Supports the liver and biliary function" "Contributes to the digestive comfort" "Helps to facilitate fat digestion" "Contributes to better fat digestion" "Helps to support the digestion" "Contributes to support the digestion".
	Conditions of use - Traditional use of the root / 50 - 100 ml of pressed juice daily / Equivalent quantity in extract		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2487	Rubus idaeus (Raspberry)	Menstrual health	A traditional lady's tea, particularly recommended during menopause and menstruation
	Conditions of use - Leaf: 0,2 g / Used as part of a multibotanical combination		
	No clarification provided by Member States		

ID	Food or Food constituent	Health Relationship	Proposed wording
2504	Zea mays (Maize)	Liver health	1. For liver and gallbladder health — beneficially affects the function of liver and gallbladder 2. A beneficial effect in case of acute condition of chronic pancreatitis 3. Beneficially affects digestion and promotes body's detoxification processes
	Conditions of use - Extract: 10 mg / Corn: 60 mg, Stigma: 40 mg / Used as part of a multibotanical combination		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2552	Levure de bière	Epiderme. Soigne l'acnée	Contribue à la beauté de la peau Favorise l'éclat et la vitalité de la peau
	Conditions of use - 750mg/jour		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2743	Papaya (Carica papaya L.)	Skin curves/ Cellulitis	Helps to reduce localized excess fat. - Helps to limit cellulitis thanks to its proteolytic effect.
	Conditions of use - 400 mg per day, documentation do not evidence data supporting the active dose to be specifically recommended. - Leaves or fruit. At least 1g per day leaves powder		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2753	Sureau: Elder berry (dry aqueous extract)	Veinous system	Improves blood circulation. Contributes to improve blood circulation
	Conditions of use - 40 mg of dry aqueous elder berry extract per day.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2759	Brocoli : Dry extract of concentrated Brassica oleracea inflorescences juice	Gastric acidities	Help in case of eructation. Regulating action on gastric acidities/acidities of the stomach.

			Protective role against the gastric aggressions and their nuisances.
	Conditions of use - Plant / 600mg of extract per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2773	Graines de brocoli et extraits de graines de brocoli: Sulforaphane	Santé de la prostate	Le sulforaphane aide à maintenir la fonction de la prostate. Il contribue à la fonction normale de la prostate. Il aide à maintenir votre prostate en forme
	Conditions of use - Graines et extraits de graines de brocoli / équivalent de 100 à 500 mg de sulforaphane par jour		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2825	Papaya	Digestion	Supports pancreas activity and protein break-up. Papaya breaks down proteins and relieves after a heavy meal and when traveling in areas with different food hygiene. The papain enzymes in papaya break down proteins and activates digestive enzymes.
	Conditions of use - Food supplement with 0.78-1.56 g of papaya in the daily dose. - Leaves At least 1 g per day		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2886	Natural mineral water: Hydrogencarbonates as Na-, Mg-, Ca-, salts: NaHCO3, Mg(HCO3)2,Ca(HCO3)2	Stomach acid in digestion	Hydrogencarbonates neutralize stomach acid.
	Conditions of use - 15% RDA per 100 ml		
	Comments from Member States MS clarification to Cou: 'min. 1300 mg HCO3- /L, 200 mL to 350 mL three times during the day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2916	Indole-3-carbinol	Cell metabolism - positively affects the fission of cells their	Indole-3-carbinol supports the defence ability of female reproductive organs (ovaria, uterus,

		immunity and regeneration Clarification provided Support to balance the level of sex hormones in human body needed for correct function of reproductive organs	breasts). Indole-3-carbinol helps to support the healthy development and fission of soft tissues of male and female reproductive organs, stomach, colon and larynx.
	Conditions of use - 150 - 450mg daily		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3076	Beta carota (carrot juice, lactic acid fermented)	Intestinal flora	Supports a healthy intestinal and colon flora
	Conditions of use - At least 1 glass (= 150 ml) lactic acid fermented carrot juice per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3087	Dietary food for special medical purposes - oral rehydrating solution with decreased osmolarity composed according to WHO/UNICEF recommendations - ORSALIT. ORSALIT is available in following versions: - ORSALIT without flavor, - ORSALIT with banana flavor, - ORSALIT with raspberry flavor. • The composition of ORSALIT - in accordance with current WHO/UNICEF recommendations: glucose– 75 mmol/l, sodium– 75 mmol/l, chlorides– 65 mmol/l, potassium– 20 mmol/l,citrate– 10 mmol/l, osmolarity– 245 mOsm/l • 100g of the product in sachets contain: glucose 61,84 g, chlorides 10,55 g, citrate 8,65 g, sodium 7,89	ORSALIT is given in order to supplement liquids and mineral components during diarrhea and/or vomiting	1. ORSALIT is used in all cases when dehydration may occur 2. ORSALIT is hypoosmolar, oral rehydrating solution composed according to WHO and UNICEF recommendations 3. ORSALIT helps to avoid dehydration which may occur in case of diarrhea and/or vomiting 4. ORSALIT uses mechanism of collective adsorption of water, sodium and glucose which is not damaged even during diarrhea 5. ORSALIT is used in order to supplement current losses of water and electrolytes 6. Oral rehydrating solutions are used in every situation when dehydration may occur 7. ORSALIT composition is identical to current recommendations of WHO and UNICEF 8. ORSALIT composition ensures effective rehydration during diarrhea on the contrary of usually given feezy drinks (cola), apple juice or broth 9. ORSALIT rehydrates effectively during diarrhea, on the contrary to traditional methods

	g, potassium 3,58 g. • 100 ml of the product prepared according to the instructions of use contain: glucose1,35 g, chlorides 0,23 g, citrate 0,19 g, sodium 0,17 g, potassium 0,08 g. ORSALIT with raspberry flavor and ORSALIT with banana flavor contain aroma additionally.		10. Oral rehydration is beneficial and well tolerated due to low risk of side effects 11. ORSALIT is used in order to rehydrate 12. ORSALIT is dedicated to infants, children and adults rehydration during diarrhea and/or vomiting 13. ORSALIT is dedicated to supplement body fluids and mineral components 14. ORSALIT is used in case of disturbance of water-electrolyte balance during dehydration due to diarrhea and/or vomiting
	Conditions of use - Jak w oświadczeniu nr 1. - Ilość produktu, dobowa dawka oraz czas stosowania produktów ORSALIT, które wpływają na wywołanie efektu zdrowotnego, są uzależnione od wieku, masy ciała i fazy nawadniania. W zależności od fazy nawadniania przewiduje się następujący schemat nawadniania: a) Faza nawadniania – pierwsze 3-4 godziny nawadniania: • masa ciała do 8 kg (wiek: do 6 miesięcy) – 2 saszetki rozpuszczone zgodnie z zaleceniem (400 ml), • masa ciała od 8 do 12 kg (wiek: od 6 miesięcy do 1 roku) - 3 saszetki rozpuszczone zgodnie z zaleceniem (600 ml), • masa ciała od 12 do 15 kg (wiek: od 1 roku do 2 lat) - 4 saszetki rozpuszczone zgodnie z zaleceniem (800 ml), • masa ciała powyżej 15 kg (wiek: powyżej 2 lat) - 6 saszetek rozpuszczonych zgodnie z zaleceniem (1200 ml), • osoby dorosłe – 4-8 saszetek rozpuszczonych zgodnie z zaleceniem (500-1500 ml); b) Faza nawadniania podtrzymującego (dalsze etapy nawadniania): • masa ciała do 12 kg (wiek: do 1 roku) - 1 saszetka rozpuszczona zgodnie z zaleceniem (200 ml); należy podawać 100 ml po każdym biegunkowym stolcu lub wymiotach, • masa ciała powyżej 12 kg (wiek: powyżej 1 roku) - 1 saszetka rozpuszczona zgodnie z zaleceniem (200 ml); należy podawać po każdym biegunkowym stolcu lub wymiotach. 2. Uwagi dotyczące stosowania preparatów ORSALIT : • powinny być przyjmowane pod nadzorem lekarza, w przypadku wystąpienia biegunki i/lub wymiotów, • nie zawierają białka mleka, laktozy i glutenu, • w trakcie przyjmowania preparatów można kontynuować karmienie piersią lub podawanie standardowych mieszanek mlecznych, • nie można stosować pozajelitowo, • nie powinny być stosowane u osób, u których nie występuje odwodnienie organizmu lub zagrożenie odwodnienia, • przeciwwskazania: wstrząs hemodynamiczny, niedrożność jelit, • mogą być stosowane u niemowląt, dzieci i osób dorosłych, • ORSALIT o smaku neutralnym przeznaczony jest dla niemowląt poniżej 6 miesiąca życia oraz dla dzieci i dorosłych skłonnych do alergii. - 25 mmol/l (460 mg/l) ≤ sód (Na+) ≤ 50 mmol/l (1150 mg/l). Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC Metabolisable carbohydrates: ≥ 75% of total energy. 340kJ/l (80kcal/l) ≤ Energy ≤ 1488kJ/l (350kcal/l). 20 mmol/l (460 mg/lbrazu, a następnie ponowne wstawienie go.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3128	Arabinoxylan	Immune system Clarification provided Contributes to maintain immunological defences	Natural enhancer of immune system. Supports the immune system. Supports the immune response.

		and immune system function, such as the action of Natural Killer cell activity	Support of the body's defence.
	Conditions of use - Arabinoxylan from corn husk or rice bran. Dose range: 15-45 mg/kg.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3131	hyaluronic acid	helps to keep elasticity of skin Clarification provided Hyaluronic is major component of skin, binds water, moisturizes skin from inside out and provides moisture and elasticity of skin.	helps to keep good health of skin helps to keep young look of skin
	Conditions of use - 100 mg per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3137	Digestive enzyme protease, lipase, amylase, glucoamylase, invertase, cellulase, malt diastase	Break down of high-molecules compound from food Clarification provided helps to digest food {in case of deteriorated digest functions} == claim referring to reduction of digest problem risk	Helps to encrease bioavailability of nutritient from food, supports vitality and activity of organism, break down the foods we eat into basic building blocks that our body then absorbs and reassembles to build cells, tissues, organs, glands, and body systems and to reuse for more metabolic process
	Conditions of use - 75 mg of amylase per day, 2,5 mg of invertase per day, 3,13 mg of cellulase per day, 36 mg of protease per day, 8,75 mg of lipase per day, 3,09 mg of malt diastase per day, 22,22 mg of glucoamylasw per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3153	MGN-3 Rice Bran Arabinoxylan compound	Strengthens immune systems Clarification provided Necessary to maintain a strong immune system and to keep optimal NK-cell activity“. Strengthens immune systems Increases NK-cell, T and	Helps the body maintain a strong immune system Supports optimal immune functions.

		B lymphocyte activity	
	Conditions of use - 1000-3000mg daily		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3164	Lactoferrin	Skin health Clarification provided Lactoferrin has been shown to express several properties which are relevant to the prevention and treatment of acne; these properties include anti-microbial, anti-inflammatory and anti-oxidant effects.	Lactoferin favourably affect skin status/improve external skin status
	Conditions of use - 160 mg for 8 weeks		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3519	Pleurotus Eryngii	pancréas	régule la physiologie du pancréas et le métabolisme des graisses
	Conditions of use - 2 gélules le matin avant le repas		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3667	Citrus sinensis - common name : Orange	Vascular and Vein Health	"Traditionally used for the good circulation of blood in microvessels" / "Traditionally used to decrease the sensations of heavy leggs" / "Used for the good circulation of blood in microvessels" / "Helps to decrease the sensations of heavy leggs"
	Conditions of use - Traditional use of the outer peel : 2,5-5 g/d		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3687	Pineapple (Ananas comosus L.)	Skin curves/ Cellulitis	Helps to reduce localized excess fat. - Helps to limit cellulitis thanks to its proteolytic effect.
	Conditions of use - Stem or fruit- at least 1200 mg per day		

ID	Food or Food constituent	Health Relationship	Proposed wording
3692	Prunus cerasus - common name : Sour cherry	Digestion	"Traditionally used to facilitate the digestion" / "Used to facilitate the digestion" / "Contributes to the digestive comfort" / "Helps to support the digestion" / "Contributes to support the digestion".
	Conditions of use - Traditional use of the fruit and pedoncule of fruit : 5-10 g/d		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3972	Aegle marmelos UNRIPE FRUIT	Digestion	Supports digestion and metabolism of carbohydrates and lipids
	Conditions of use - Powder: 1.0-0.10g/day All over 2 years old: 2-4 years ¼ adult dose, 4-10 years half adult dose		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4112	Reishi mushrooms (Ganoderma lucidum) and extracts	Immune support Clarification provided Immune health: induces cytokine production (e.g. TNF-alpha and IFN-gamma)	Reishi mushrooms [Reishi mushroom extracts] may help to support the immune system
	Conditions of use - Typical adult dosages: 2 – 6 g raw fungus daily or 600 – 1800 mg, three times a day. Use cautiously or following advice of a healthcare professional if taking anticoagulant medication (e.g. warfarin).		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4202	Gélatine	Hair beauty and health	Promote keratin formation. Strength hair. Hair is more resistant and thick. Increase hair resistance.
	Conditions of use - 160 mg/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4241	Huile de noisettes: Hazel nut (Corylus avellana) oil	Skin care	Provides an essential fatty acid entering the composition of the scalp. Provides an essential fatty acid entering the composition of the skin.
	Conditions of use - 315 mg/day of Corylus avellana oil		

	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4243	Huile de foie de Morue: Cod liver oil standardized in vitamin A, EPE and HA	Skin care	Maintain the youth capital of the skin. Contribute to the integrity of the skin tissues
	Conditions of use - 550 to 1100 mg of oil		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4247	Corn protein hydrolysate titrated at 29 % glutamine	Overtraining and effort prevention	Can help to prevent the consequences of overtraining in athletes. Can help to prevent the outbreak of the effort
	Conditions of use - 2,2 g dose/physical exercise (= 638 mg glutamine)		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4248	Corn protein hydrolysate titrated at 29 % glutamine	Physical performance	Can help to improve physical performance
	Conditions of use - 2,2 g dose/physical exercise (= 638 mg glutamine)		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4278	Black currant (Ribes nigrum L.)	Vein health	Support of venous circulation - Helps to reduce the feeling of tired and heavy legs - Helps to maintain healthy leg-vein functions - Promotes circulatory well-being - Favourable influence on the blood circulation - For legs relief and to favour comfort
	Conditions of use - Fruit At least 1 g of fruit juice per day or an equivalent extract		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4407	Ganoderma lucidum-Mashroom-Reishi mushroom	Physical Well-being	Stimulates the body in exhaustion
	Conditions of use - 150 – 350 mg a day		

ID	Food or Food constituent	Health Relationship	Proposed wording
4662	Bromelain	Digestive system benefits	Digestive aid, protein digestion
	Conditions of use - Oral administration, capsules or tablets		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4691	Papain	Digestive system benefits	Digestive aid, protein digestion
	Conditions of use - Oral administration, capsules or tablets		