EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion Part II on the substantiation of health claims related to various food(s)/food constituent(s) not supported by pertinent human data (ID 406, 462, 472, 543, 659, 678, 696, 858, 1381, 1403, 1437, 1438, 1513, 1536, 1537, 1538, 1539, 1540, 1543, 1613, 1627, 1855, 1860, 1981, 2126, 2514, 3127, 4038, 4501, 4672, 4712, 4718) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion Part II on the substantiation of health claims related to various food(s)/food constituent(s) not supported by pertinent human data (ID 406, 462, 472, 543, 659, 678, 696, 858, 1381, 1403, 1437, 1438, 1513, 1536, 1537, 1538, 1539, 1540, 1543, 1613, 1627, 1855, 1860, 1981, 2126, 2514, 3127, 4038, 4501, 4672, 4712, 4718) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

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

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to various food(s)/food constituent(s) not supported by pertinent human data. 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 references provided in relation to the claims evaluated in this opinion included studies which assessed the effects of food(s)/food constituent(s) other than the food(s)/food constituent(s) which are the subject of the claims, and/or investigated health outcomes unrelated to the claimed effects. No human studies which investigated the effects of the food(s)/food constituent(s) on appropriate measures of the claimed effects were provided. The Panel considers that no conclusions can be drawn from any of the references provided for the scientific substantiation of the claims evaluated in this opinion.

[1] On request from the European Commission, Question No EFSA-Q-2008-1193, EFSA-Q-2008-1249, EFSA-Q-2008-1259, EFSA-Q-2008-1330, EFSA-Q-2008-1446, EFSA-Q-2008-1465, EFSA-Q-2008-1483, EFSA-Q-2008-1645, EFSA-Q-2008-2118, EFSA-Q-2008-2140, EFSA-Q-2008-2174, EFSA-Q-2008-2175, EFSA-Q-2008-2250, EFSA-Q-2008-2349, EFSA-Q-2008-2363, EFSA-Q-2008-2588, EFSA-Q-2008-2593, EFSA-Q-2008-2714, EFSA-Q-2008-2859, EFSA-Q-2008-3247, EFSA-Q-2008-3859, EFSA-Q-2008-4750, EFSA-Q-2010-00454, EFSA-Q-2010-00625, EFSA-Q-2010-00665, EFSA-Q-2010-00671, adopted on 08 April 2011. Question No EFSA-Q-2008-2273, EFSA-Q-2008-2274, EFSA-Q-2008-2275, EFSA-Q-2008-2276, EFSA-Q-2008-2277, EFSA-Q-2008-2280, adopted on 13 May 2011.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: 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.

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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) and the claimed effects evaluated in this opinion.

KEY WORDS

Muscle mass, joints, bone, energy-yielding metabolism, endurance performance, endurance capacity, protein metabolism, health claims.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

EFSA DISCLAIMER

See Appendix B

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[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. Growth or maintenance of muscle mass (ID 858, 1536, 1540, 4038, 4712)

The claimed effects are "guard against symptoms of fatigue of skeleton muscle cells", "increasing strength", "strength and energy", and "muscle development". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the growth or maintenance of muscle mass by decreasing muscle breakdown, increasing muscle synthesis or both. Failure to increase muscle mass during growth and development, and the loss of muscle mass at any age will reduce muscle strength and power.

[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 growth or maintenance of muscle mass is a beneficial physiological effect.

1.2. Maintenance of normal joints (ID 659, 678, 696, 1513, 1627, 1855, 1981, 2126, 2514, 4501, 4672, 4718)

The claimed effects are "joints", "soigne l'ostéoarthrose", "joint health", "articulations", "muscles and joint health", "shows anti-inflammatory properties", "bones and joints health", and "health of bones and joints, as a structural component of the cartilage". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, clarifications from Member States and references provided for the substantiation of these claims, the Panel assumes that the claimed effects refer to the maintenance of normal joints.

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

1.3. Maintenance of normal bone (ID 1860, 4501, 4672)

The claimed effects are "bone", "bones and joints health", and "health of bones and joints, as a structural component of the cartilage". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, clarifications from Member States and references provided for the substantiation of these claims, the Panel assumes that the claimed effects refer to the maintenance of normal bone.

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

1.4. Contribution to normal energy-yielding metabolism (ID 1381, 1613)

The claimed effects are "energy metabolism" and "muscles/energy". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to energy-yielding metabolism.

The Panel considers that contribution to normal energy-yielding metabolism is a beneficial physiological effect.

1.5. Increase in endurance performance (ID 472, 543, 1403, 1538, 1539, 3127)

The claimed effects are "endurance, enhanced carbohydrate delivery to muscle", "endurance performance and increases carbohydrate availability", "muscles/increase in performance", "enhancing training volume and intensity", "increasing exercise thresholds", and "adaptogen, supports energy level, invigoration of the body, supports immune system". The Panel assumes that the target population is adults performing endurance exercise.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to an increase in endurance performance. Endurance performance relates to the ability to complete certain tasks with higher intensity, faster, or with a higher power output when performing long-term exercise.

The Panel considers that an increase in endurance performance is a beneficial physiological effect.

1.6. Increase in endurance performance during the subsequent exercise bout after strenuous exercise (ID 462, 1437, 1438)

The claimed effects are "recovery, glycogen restoration through ingested carbohydrate, muscle tissue building from the amino acids obtained from protein, muscle lipid reloading by consuming the right amount of dietary fat", "carbohydrate and lipid metabolism", and "carbohydrate metabolism". The Panel assumes that the target population is adults performing endurance exercise.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to an increase in endurance performance during the subsequent exercise bout after strenuous exercise. Endurance performance relates to the ability to complete certain tasks with higher intensity, faster, or with a higher power output when performing long-term exercise.

The Panel considers that an increase in endurance performance during the subsequent exercise bout after strenuous exercise is a beneficial physiological effect.

1.7. Increase in performance during intense and repeated anaerobic exercise bouts (ID 1543)

The claimed effect is "enhancing anaerobic working capacity". The Panel assumes that the target population is individuals performing sports which require intense and repeated exercise bouts.

In the context of the proposed wordings and references provided, the Panel assumes that the claimed effect refers to the increase in exercise performance, which in the present context refers to performing repeated exercise bouts with higher intensity, faster or with a higher power output.

The Panel considers that an increase in performance during intense and repeated anaerobic exercise bouts is a beneficial physiological effect.

1.8. Increase in endurance capacity (ID 1537, 1538)

The claimed effects are "increasing work capacity", and "enhancing training volume and intensity". The Panel assumes that the target population is adults performing endurance exercise.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to an increase in endurance capacity. Endurance capacity refers to the exercise time to self-reported fatigue when exercising at a constant workload or speed, generally at intensity <80 % maximum O_2 consumption.

The Panel considers that an increase in endurance capacity is a beneficial physiological effect.

1.9. Contribution to normal protein metabolism (ID 406)

The claimed effect is "formation and activation of protein". The Panel assumes that the target population is the general population.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to protein metabolism.

The Panel considers that the contribution to normal protein metabolism is a beneficial physiological effect.

2. Scientific substantiation of the claimed effect

2.1. Growth or maintenance of muscle mass (ID 858, 1536, 1540, 4038, 4712)

The references provided in relation to these claims included textbooks, narrative reviews or monographs which did not provide any original data for the scientific substantiation of the claims and human intervention studies on the effects of food constituents other than the specific combination of food constituents which is the subject of some claims (ID 1536, 1540, 4712). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

No human studies which investigated the effects of the food(s)/food constituent(s)/combination of food constituents on the growth or maintenance of muscle mass were provided in relation to any of the claims evaluated in this section.

Two references addressed the effects of the food(s)/food constituent(s) on muscle contractility, on the generation of free radicals and on lipid peroxidation in skeletal muscle *in vitro* using muscle biopsies and electrical stimulation. The Panel considers that evidence provided in *in vitro* studies is not sufficient to predict the occurrence of an effect of the consumption of the food(s)/food constituent(s) on the growth or maintenance of muscle mass *in vivo* in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s)/combination of food constituents, which are the subject of the claims evaluated in this section, and growth or maintenance of muscle mass.

2.2. Maintenance of normal joints (ID 659, 678, 696, 1513, 1627, 1855, 1981, 2126, 2514, 4501, 4672, 4718)

The references provided in relation to these claims included textbooks, narrative reviews and monographs which did not provide any original data for the scientific substantiation of the claims. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

Some human intervention studies, which investigated the effects of the food(s)/food constituent(s) on the treatment of osteoarthrosis or (osteo)arthritis of different origin (rheumatoid arthritis, psoriatic arthritis, arthritis of infectious origin), were submitted. The Panel considers that the evidence provided does not establish that patients with osteoarthrosis or (osteo)arthritis of different origin are representative of the general population with regard to the status of joint tissues, or that results obtained in studies on subjects with osteoarthrosis or (osteo)arthritis of different origin and related to the treatment of symptoms of these diseases (e.g. erosion of articular cartilage, reduced mobility of joints) can be extrapolated to the maintenance of normal joints in the general population. Thus, for claims supported only by references to human studies on patients with osteoarthrosis or (osteo)arthritis of different origin, the Panel considers that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) and the claimed effect in the general population.

No human studies which investigated the effects of the food(s)/food constituent(s) on the maintenance of normal joints were provided in relation to any of the claims evaluated in this section.

A number of *in vitro* studies were provided which addressed the effects of different food(s)/food constituent(s) on human chondrocytes/cartilage explants, chondrocyte cell lines and expression of cell surface molecules. Studies on the relationship between the intake of the food(s)/food constituent(s) and the claimed effect in animal models of experimentally-induced arthritis were also provided.

The Panel considers that evidence provided in *in vitro* studies is not sufficient to predict the occurrence of an effect of the consumption of the food(s)/food constituent(s) on the maintenance of normal joints *in vivo* in humans.

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 claims evaluated in this section, and maintenance of normal joints.

2.3. Maintenance of normal bone (ID 1860, 4501, 4672)

The references provided in relation to these claims were textbooks, narrative reviews and monographs which did not provide any original data for the scientific substantiation of the claims or reported on health outcomes (e.g. treatment of osteoarthritis) unrelated to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

No human studies which investigated the effects of the food(s)/food constituent(s) on the maintenance of normal bone were provided in relation to any of the claims evaluated in this section.

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 claims evaluated in this section and maintenance of normal bone.

2.4. Contribution to normal energy-yielding metabolism (ID 1381, 1613)

The references provided in relation to these claims were monographs and narrative reviews which did not provide any original data for the scientific substantiation of the claims or addressed health outcomes (e.g. daily activity in a murine model of chronic fatigue syndrome, treatment of fibromyalgia) unrelated to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

No human studies which investigated the effects of the food(s)/food constituent(s) on contribution to normal energy-yielding metabolism were provided in relation to any of the claims evaluated in this section.

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 claims evaluated in this section, and contribution to normal energy-yielding metabolism.

2.5. Increase in endurance performance (ID 472, 543, 1403, 1538, 1539, 3127)

The references provided in relation to these claims were monographs and narrative reviews which did not provide any original data for the scientific substantiation of the claims or addressed health outcomes (e.g. antioxidant activity, immune parameters, blood flow) unrelated to the claimed effect, studies which assessed the effects of food constituents other than the food constituent(s) or the specific combinations which are the subject of the claims on measures of endurance performance, and/or investigated health outcomes (e.g. rate of exogenous carbohydrate oxidation, muscle strength) other than endurance performance. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

No human studies which investigated the effects of the food(s)/food constituent(s)/combination of food constituents on measures of performance during endurance exercise were provided in relation to any of the claims evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s)/combination of food constituents which are the subject of the claims evaluated in this section and increase in endurance performance.

2.6. Increase in endurance performance during the subsequent exercise bout after strenuous exercise (ID 462, 1437, 1438)

The references provided in relation to these claims included narrative reviews or studies which addressed the effects of food(s)/food constituent(s) other than the food constituent(s) or the specific combination of food constituents which are the subject of the claims, and/or investigated health outcomes (e.g. gastric emptying rate, blood glucose concentration, serum insulin concentration) unrelated to the claimed effect. The references also included one study on the specific combination of the food constituents which is the subject of the claim on health outcomes (e.g. muscle glycogen stores) other than endurance performance. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

No human studies which investigated the effects of the food(s)/food constituent(s)/combination of food constituents on an increase in endurance performance during the subsequent exercise bout after strenuous exercise were provided in relation to any of the claims evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s)/combination of food constituents which are the subject of the claims evaluated in this section and increase in endurance performance during the subsequent exercise bout after strenuous exercise.

2.7. Increase in performance during intense and repeated anaerobic exercise bouts (ID 1543)

The references provided for the scientific substantiation of this claim included a number of human intervention studies which investigated the effect of food constituents other than the specific combination of food constituents which is the subject of the claim, and/or assessed health outcomes (e.g. muscle strength, endurance capacity) unrelated to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Among the references provided was a human intervention study in which participants were randomised to receive the specific combination of food constituents which is the subject of the claim or a “placebo” matched with the intervention, except for one constituent (Kreider et al., 1998). The Panel notes that the placebo used in this study does not allow conclusions to be drawn on an effect of the specific combination of food constituents which is the subject of the claim. The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claim.

No human studies which investigated the effects of the specific combination of food constituents on an increase in performance during intense and repeated anaerobic exercise bouts were provided in relation to the claim evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the combination of food constituents which is the subject of the claim evaluated in this section and increase in performance during intense and repeated anaerobic exercise bouts.

2.8. Increase in endurance capacity (ID 1537, 1538)

The references provided for the scientific substantiation of this claim included a number of human intervention studies which investigated the effect of food constituent(s) other than the specific

combination of food constituents which is the subject of the claims. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

No human studies which investigated the effects of the specific combination of food constituents on an increase in endurance capacity were provided in relation to any of the claims evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the combination of food constituents which is the subject of the claims evaluated in this section and increase in endurance capacity.

2.9. Contribution to normal protein metabolism (ID 406)

The reference provided in relation to this claim was a pharmacy leaflet which did not provide any original data for the scientific substantiation of the claim. The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claim.

No human studies which investigated the effects of the food on contribution to normal protein metabolism were provided in relation to the claim evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food which is the subject of the claim evaluated in this section and contribution to normal protein metabolism.

CONCLUSIONS

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) and the claimed effects evaluated in this opinion.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1193, EFSA-Q-2008-1249, EFSA-Q-2008-1259, EFSA-Q-2008-1330, EFSA-Q-2008-1446, EFSA-Q-2008-1465, EFSA-Q-2008-1483, EFSA-Q-2008-1645, EFSA-Q-2008-2118, EFSA-Q-2008-2140, EFSA-Q-2008-2174, EFSA-Q-2008-2175, EFSA-Q-2008-2250, EFSA-Q-2008-2273, EFSA-Q-2008-2274, EFSA-Q-2008-2275, EFSA-Q-2008-2276, EFSA-Q-2008-2277, EFSA-Q-2008-2280, EFSA-Q-2008-2349, EFSA-Q-2008-2363, EFSA-Q-2008-2588, EFSA-Q-2008-2593, EFSA-Q-2008-2714, EFSA-Q-2008-2859, EFSA-Q-2008-3247, EFSA-Q-2008-3859, EFSA-Q-2008-4750, EFSA-Q-2010-00454, EFSA-Q-2010-00625, EFSA-Q-2010-00665, EFSA-Q-2010-00671). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

REFERENCES

Kreider RB, Ferreira M, Wilson M, Grindstaff P, Plisk S, Reinardy J, Cantler E and Almada AL, 1998. Effects of creatine supplementation on body composition, strength, and sprint performance. Medicine and Science in Sports and Exercise, 30, 73-82.

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) that are not supported by pertinent human data, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
406	Gemüse / Rote Beete / Kalium Clarification provided beetroot as vegatable: potassium content	Aktivierung / Aufbau von Eiweiß / Kalium Clarification provided Formation and activation of protein	[In german :] Kalium ist an der Aktivierung einiger Enzyme und dem Aufbau von körpereigenem Eiweiß beteiligt. Clarification provided potassium is involved in activation processes of several enzymes as well as in formation of protein produced naturally in the body
	Conditions of use - Es werden nur die Nährstoffe beworben, die lt. Nährwertkennzeichnungs-verordnung (Anlage 1) mindestens 15 Prozent der empfohlenen Tagesdosis in 100 g oder 100 ml enthalten.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
462	Carbohydrate, protein and lipid combination Clarification provided A combination food for sports people containing amounts of fats, protein and carbohydrate (see CoU) that replaces deletion of these nutrients after exercise; claims made for constituent parts, rather than branded product.	Recovery Glycogen restoration through ingested carbohydrate Muscle tissue building from the amino acids obtained from protein Muscle lipid reloading by consuming the right amount of dietary fat	Helps your body rapidly rebuild so that you can perform at your peak during your next workout. Rebuild muscle glycogen. Repair muscle protein. Restore muscle lipid.
	Conditions of use - Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC. Metabolisable carbohydrates: 60 - 70% of total energy. High quality protein: 12 - 15% of total energy. Lipid: = 30% of total energy.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
472	Glucose and fructose.	Endurance Enhanced carbohydrate delivery to muscle. Clarification provided Endurance Enhanced carbohydrate delivery to	The ratio of 2:1 of glucose and fructose sources help deliver more energy to muscles. Delivers even longer lasting energy. Faster energy delivery

		muscle. Endurance during sport and exercise. Enhanced utilization of ingested carbohydrate [exogenous carbohydrate oxidation] during endurance exercise. Increased ingested fluid availability during endurance exercise. [as measured by rate of deuterium oxide accumulation in plasma] Co-ingestion of glucose and fructose sources: Increases ingested carbohydrate utilisation/provides more useable energy/is burned for energy at higher rates during endurance exercise compared to glucose sources alone. Increases ingested carbohydrate utilisation during endurance exercise by 20-55% compared to glucose sources alone. Delivers 20-55% more energy to muscles than glucose alone. Improves endurance performance [by 8%] compared to glucose sources alone. Delivers 8% longer lasting energy than glucose alone.	compared with glucose. Delivers more sustained energy to muscles. Enahnced carbohydrate delivery, availability and utilisation.
	Conditions of use - Gesunde normalgewichtige Erwachsene, 50 (bis zu 100) Gramm (g), alle 60 Min.; nach 5-10 Min. im Blut nachweisbar. Anmerkung Höchstmenge: Während körperlicher Leistung; an Energieverbrauch angepasst; Dextrose kann und sollte nicht als Mahlzeitersatz gesehen werden. Dextrose ist ein Helfer in bestimmten Situationen. - Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC. Carbohydrates: = 65% of total energy (for foods). Carbohydrates: = 75% of total energy (for beverages). Carbohydrate ratio of glucose to fructose of 2:1. - Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC. Carbohydrates: ≥ 65% of total energy (for foods) and ≥ 75% (for beverages). Carbohydrate ratio of glucose to fructose of 2:1.		

	Comments from Member States Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC. Product must contain glucose and fructose sources (e.g. glucose to include free glucose, dextrose or maltodextrins; sources of fructose to include free fructose or sucrose). Pattern of use: product consumption to ensure glucose and fructose sources are co-ingested at rates of ≥ 60 and ≥ 30 grams, respectively, per hour during endurance exercise.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
543	Caffeine and carbohydrate. Clarification provided Caffeine and carbohydrate in sport nutrition products: Product consumption to ensure a caffeine intake of ≥ 100 mg or ≥ 0.9 mg/kg body mass co-ingested with a metabolisable carbohydrate (e.g. glucose, glucose polymers, sucrose) intake of ≥ 30 g or ≥0.4 g/kg body mass per hour during endurance exercise.	Endurance performance and increases carbohydrate availability.	Helps increase carbohydrate availability during endurance exercise. Combination of caffeine and carbohydrate improves endurance performance.
	Conditions of use - Aus Teeblättern, mindestens 37,5 mg Koffein pro empfohlener Getränkemenge. - Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC. Carbohydrate intake of up to ~ 1 g/min and caffeine intake of 1-5 mg/kg body mass. Beverages must comply with the labelling requirements laid down by Directive 2002/67/EC.		
	Comments from Member States Claim to be only used for Foods for sportpeople under the Directive 2009/39/EC.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
659	Collagen.	Joints. Clarification provided Joints; joints health and function, joints mobility/flexibility.	Collagen can/could contribute to the maintenance of the healthy function of joints.
	Conditions of use - Minimum 20 microgram/day (II-type collagen).		
	Comments from Member States EFSA accepted similar relationship, under HR_ID 1513 without comment.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
678	Glucosamine.	Soigne l'ostéoarthrose.	Bon pour les articulations. A utiliser pour maintenir les articulations souples. Efficace dans les problèmes d'inflammation et de mobilité

			des articulations. Soulage les douleurs inflammatoires.
	Conditions of use - Exosquelette de crustacés 1500mg/jour. - Cartillage de requin 1200mg/jour.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
696	Evening Primrose Oil (EPO), Oenothera spp. and Fish Oil (FO) providing long chain omega 6 and omega 3 fatty acids [gamma-linolenic acid (GLA) and eicosapentaenoic acid (EPA)].	Joint Health.	Helps maintain joint mobility.
	Conditions of use - Ref 7 - 240 mg eicosapentaenoic acid from Fish Oil and 450 mg gamma-linolenic acid from Evening Primrose Oil per day. (Note: This is 6 g of a mixture of 80% evening primrose oil and 20% fish oil by weight).		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
858	Bioaktive Oligosaccharide, wie z. B. glykosylierte Phenylethanoide. Clarification provided Bioactive oligosaccharide, e.g. glcosylated phenylethanoides.	Glykosylierte Phenylethanoide beugten in vitro Ermüdungserscheinungen von Skelettmuskelzellen vor. Clarification provided Glcosylated phenylethanoides guard against symptoms of fatigue of skeleton muscle cells.	[In german:] Bioaktive Oligosaccharide zur natürlichen / aktiven Unterstützung / Optimierung der Muskelkraft. Clarification provided Bioactive oligosaccharides optimise mucular strength.
	Conditions of use - None provided		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1381	Brewer`s Yeast.	Energy metabolism.	1. Activates metabolism and energy conversion process in the body, promotes effective assimilation of nutrients. 2. Vitamins and micronutrients are highly essential for normal body functioning.
	Conditions of use - 2- 4g.		

	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1403	Mineralwasser/Hydrogencarbonat (Bicarbonat) Clarification provided Mineral water/Hydrogencarbonate (Bicarbonate) (from 1,3 g/l HCO3 upwards)	Muskeln/Leistungs-steigerung Clarification provided Muscles/increase in performance	[In german :] kann die Muskelermüdung beim Ausdauersport verzögern Clarification provided can delay tiring of muscles in endurance sports
	Conditions of use - ab 600 mg/l Hydrogen-carbonat (siehe EG-Mineralwasser-Richtlinie)		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1437	Amylopectin	Carbohydrate metabolism	Amylopectin facilitates the replenishment of glycogen stores in skeletal muscle.
	Conditions of use - A serving must contain approximately 75 grams.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1438	Amylopectin and L-carnitine	Carbohydrate and lipid metabolism	Amylopectin plus L-carnitine facilitate the replenishment of glycogen stores in skeletal muscle, and the switching from carbohydrate oxidation to fat oxidation.
	Conditions of use - A serving must contain approximately 75 grams of amylopectin and 1 gram of L-carnitine.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1513	Collagen hydrolysate.	Joint health.	Contributes to the functioning of cartilage building cells. Supports the (natural) regeneration of joint cartilage. Stimulates the build-up of joint cartilage. Contributes to improved joint functioning and joint mobility. Contributes to joint comfort. Provides the building blocks (peptides) for the biosynthesis of cartilage. Provides strength, flexibility and support to skin connective tissues, ligaments, tendons,

			bones and other parts of the body.
	Conditions of use - 10 g täglich (Typ I Collagen mit durchschn. Molekulargewicht bis zu 3.500 Dalton). - 10 g per day (Type I collagen with an average Molecular Weight of up to 3.500 Dalton). - 10 Gramm (g)/Tag, mindestens 3 Monate. - 1500 mg Biocell Kollagen Typ II. - Längerfristige tägliche Zufuhr von mindestens ca. 5 g Gelatine. - 10 g/Tag. 10g täglich (Typ I Collagen mit durchschn.Molekulargewicht bis zu 3.500 Dalton) - 10 g pro Tag - 10 g/day - Minimum 20 microgram/day (II-type collagen). - 10g per day (Type I collagen with an average Molecular Weight of up to 3.500 Dalton). 10gr/day with a recommended continuous use of at least 3 months - 10 gr/day with a recommended continuous use of at least 3 months. - 10 gr./Tag mit einer empfohlenen Dauer von mindestens 3 Monaten. - 5 to 10 g daily. - Täglich mindestens ca. 5 g Gelatine—(Gesamte Bevölkerung). - Producer's recommendation: daily dose of at least 8 mg. RDD was not specified. Administration: Regularly 1 cube a day in the morning before meal for at least 2 to 3 months, repeat twice a year.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1536	EAS Phosphagen Elite	Increasing Strength	EAS Phosphagen Elite is clinically shown to boost muscular strength EAS Phosphagen Elite is clinically shown to increase strength by up to 15% EAS Phosphagen Elite is designed to boost overall muscular strength Boost muscular strength
	Conditions of use - The product must contain at least 5 gram creatine monohydrate, 1 gram taurine and 33 grams dextrose and 1.6 grams beta-alanine per serving. Claim to be used for foods for active individuals.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1537	EAS Phosphagen Elite	Increasing Work Capacity	EAS Phosphagen Elite is clinically shown to increase anaerobic threshold

			EAS Phosphagen Elite is clinically shown to increase physical working capacity at fatigue threshold
	Conditions of use - The product must contain at least 5 gram creatine monohydrate, 1gram taurine and 33 grams dextrose and 1.6 grams beta-alanine per serving. Claim to be used for foods for active individuals		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1538	EAS Phosphagen Elite	Enhancing Training Volume & Intensity	EAS Phosphagen Elite is designed to provide a higher quality workout, and the addition of beta alanine appears to enhance average training volume more so than creatine alone EAS Phosphagen Elite is clinically shown to result in greater training volume threshold
	Conditions of use - The product must contain at least 5 gram creatine monohydrate, 1 gram taurine and 33 grams dextrose and 1.6 grams beta-alanine per serving. Claim to be used for foods for active individuals		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1539	EAS Phosphagen Elite	Increasing Exercise Thresholds	Amp up your workout with EAS Phosphagen Elite, clinically shown to improve ventilatory and lactate thresholds for greater cardiorespiratory endurance in intense workouts (training) EAS Phosphagen Elite is clinically shown to improve ventilatory and lactate thresholds
	Conditions of use - The product must contain at least 5 gram creatine monohydrate, 1gram taurine and 33 grams dextrose and 1.6 grams beta-alanine per serving. Claim to be used for foods for active individuals		

ID	Food or Food constituent	Health Relationship	Proposed wording
1540	EAS Phosphagen HP	Increasing Strength	EAS Phosphagen HP is clinically shown to increase strength EAS Phosphagen HP is clinically shown to boost muscular strength EAS Phosphagen HP is designed to boost overall muscular strength
	Conditions of use - The product must contain at least 5 gram creatine monohydrate, 1 gram taurine and 33 grams dextrose per serving. Claim to be used for foods for active individuals		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1543	EAS Phosphagen HP	Enhancing Anaerobic Working Capacity	EAS Phosphagen HP can help improve total anaerobic work performed EAS Phosphagen HP is clinically tested to help improve anaerobic work capacity EAS Phosphagen HP can help improve total anaerobic work performed
	Conditions of use - the product must contain at least 5 gram creatine monohydrate, 1gram taurine and 33 grams dextrose per serving - Claim to be used for foods for active individuals		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1613	Malic acid	Muscles/energy	Malic acid is needed for proper functioning of the energy cycle
	Conditions of use - 600mg/daily minimum is suggested. Safety during pregnancy/lactation has not been established.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1627	Omega-3 fatty acids (Hi-EPA) with Glucosamine.	Joint health.	Omega-3 fatty acids (Hi-EPA) with Glucosamine help to maintain joint health.
	Conditions of use - 200-500mg EPA, 50-250mg DHA, 1-1.5g Glucosamine per day. -		

ID	Food or Food constituent	Health Relationship	Proposed wording
1855	Shark cartilage + greenshell mussel. Clarification provided Shark cartilage + greenshell mussel. Daily dose (2-6 capsules) contains 220-660 mg of greenshell mussel powder and 200-600 mg of shark cartilage powder and 200-600 mg och shark cartilage extract (contains 240-720 mg glycosaminoglycans, of which 190-570 mg is chondroitin sulphate).	Joints.	Supports joint functioning. For joint health. Supports joint well-being
	Conditions of use - Food supplement with 220-260 mg of greenshell mussel powder and 200-600 mg of shark cartilage (contains 240-720 mg glycosamineglycans, of which 190-570 mg is chondroitin sulphate) in the daily dose.		
	Comments from Member States Addtion to conditions of use. New succestion to the claims: Contains chondroprotective agents; Enhances joint fluid production.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1860	Soy + magnesium + calcium + zinc + manganese + copper + vitamin B6 + vitamin D + vitamin K	Bone	Strong bones. The best for your bones. Good ageing. The soy flavones and mineral substances, calcium, magnesium, zinc, manganese and copper, together with vitamins B6, D and K protect the bones. Name or symbol included in the claim: Osteobalans®
	Conditions of use - Food supplement with 40 mg of soy flavones, 100 mg of magnesium, 200 mg of calcium, 15 mg of zinc, 2.5 mg of manganese, 2.0 mg of copper, 2.2 mg of vitamin B6, 5 µg of vitamin D and 70 µg of vitamin K in the daily dose. The state of the microbe population in the gut affects the usefulness of the soy isoflavones in the body.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1981	Cartilage de requin.	Articulations.	Souplesse et mobilité des articulations - Bien-être des articulations.

	Conditions of use - Hydrolysat de cartilage de requin.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2126	Ribes nigrum (Common Name: Blackcurrant).	Muscles and joint health.	Contributes to the proper functioning of muscles and joints/for supple joints.
	Conditions of use - Blätter / Äquivalent von getrockneten Blättern als Aufguss (20-50 g/ l). - Liście / równowartość 20-50 g/litr suchych liści jako napar. - Leaf / The equivalent of dried leaf as an infusion (20-50 g/litre). - Traditional use of the leaf / 2-4 g of leaves as an infusion one cup several times daily / Equivalent quantity in extract. - Leaf / 250-500 ml daily of infusion (20-50 g/litre) / 10 ml daily of fluid extract (1:1) / equivalent preparations. - Traditional use of leaf / 2-4 g cut leaves to infusing : drink one mug several times per day or an equivalent extract to these 2-4 g of leaves.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2514	Ananas tige "criteria": 6 Clarification provided Ananas comosus (Pineapple) fruit	Anti-inflammatoire Clarification provided Shows anti-inflammatory properties	Soulage les douleurs inflammatoires Clarification provided Shows anti-inflammatory properties/Helps reduce inflammatory reaction in joints and muscles/Helps maintain the flexibility and mobility of the joints
	Conditions of use - Tige 200-2000mg bromelaine		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3127	Cordyceps sinensis	Adaptogen, supports energy level, Invigoration of the body,supports immunesystem	Helps to strengthen the body Supports immune system Invigorates the body Supports energetic alertness Supports the immunesystem by delivering antioxidants Increases performance and endurance of a heavy exercise or sportsactivity
	Conditions of use - 3 gram dried powder or equivalent extracts		

ID	Food or Food constituent	Health Relationship	Proposed wording
4038	Emblica officinalis FRUIT RIND	Strength & energy	Gives strength and energy. Helps build muscle.
	Conditions of use - Powder 3-0.2 g/day; aqueous extra 1.5-0.1 g/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**
4501	Vaccinium vitis idaea, herba	Bones and Joins Health	Supports the health of bones and joins
	Conditions of use - Capsules, 270 mg./day in combination with other herbs		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4672	Glucosamine sulphate	Health of bones and joints, as a structural component of the cartilage	Helpful for joints mobility, Helpful for structural and functional maintaining, Building of joints surface, ligaments, bones, blood vessel and skin, Contributes to preserve the structure and the elasticity grade of the cartilage.
	Conditions of use - 1000 - 1500 mg/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4712	Fructose, Glucose, Maltodextrine, Milk protein concentrate, 5.Soy protein concentrate, Creatine, Vitamin C, Magnezium Oxide, Zinc Oxide,Alimentary flavors	Muscular Development	energizer and proteic food supplement / recomended for fast increase of energy, strenght and muscular development / recovery musular energy after physical and mental effort
	Conditions of use - 1-2 servings of 105 g daily / Not for diabetics.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4718	Glucosamin 500 mg, chondroitin 440 mg, vit. PP 6 mg, Sodium selenit 4,8 mg.cps	Bones and Joints Health	Supports the normal synthesis of the conjunctive tissue of joints.
	Conditions of use - 3 capsules/day - 2838 mg. food combination /day, min. 90 days		