EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion Part III on the substantiation of health claims related to various food(s)/food constituent(s) not supported by pertinent human data (ID 644, 946, 1717, 1730, 1742, 1760, 1871, 1894, 1910, 1926, 1933, 2000, 2024, 2028, 2095, 2124, 2127, 2137, 2213, 2332, 2337, 2380, 2435, 2833, 2917, 3072, 3075, 3080, 3129, 3193, 3636, 4037, 4044, 4313) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

EFSA Publication; Tetens, Inge

Link to article, DOI:
10.2903/j.efsa.2011.2248

Publication date:
2011

Document Version
Publisher's PDF, also known as Version of record

European Food Safety Authority

EFSA Journal 2011;9(6):2248

SCIENTIFIC OPINION

Scientific Opinion Part III on the substantiation of health claims related to various food(s)/food constituent(s) not supported by pertinent human data (ID 644, 946, 1717, 1730, 1742, 1760, 1871, 1894, 1910, 1926, 1933, 2000, 2024, 2028, 2095, 2124, 2127, 2137, 2213, 2332, 2337, 2380, 2435, 2833, 2917, 3072, 3075, 3080, 3129, 3193, 3636, 4037, 4044, 4313) 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

[1] On request from the European Commission, Question No EFSA-Q-2008-1431, EFSA-Q-2008-1733, EFSA-Q-2008-2453, EFSA-Q-2008-2466, EFSA-Q-2008-2475, EFSA-Q-2008-2493, EFSA-Q-2008-2604, EFSA-Q-2008-2627, EFSA-Q-2008-2643, EFSA-Q-2008-2659, EFSA-Q-2008-2666, EFSA-Q-2008-2733, EFSA-Q-2008-2757, EFSA-Q-2008-2761, EFSA-Q-2008-2828, EFSA-Q-2008-2857, EFSA-Q-2008-2860, EFSA-Q-2008-2870, EFSA-Q-2008-2946, EFSA-Q-2008-3065, EFSA-Q-2008-3070, EFSA-Q-2008-3113, EFSA-Q-2008-3168, EFSA-Q-2008-3566, EFSA-Q-2008-3650, EFSA-Q-2008-3804, EFSA-Q-2008-3807, EFSA-Q-2008-3812, EFSA-Q-2008-3861, EFSA-Q-2008-3925, EFSA-Q-2008-4360, EFSA-Q-2008-4749, EFSA-Q-2008-4756, EFSA-Q-2010-00266, adopted on 08 April 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

[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.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion Part III on the substantiation of health claims related to various food(s)/food constituent(s) not supported by pertinent human data (ID 644, 946, 1717, 1730, 1742, 1760, 1871, 1894, 1910, 1926, 1933, 2000, 2024, 2028, 2095, 2124, 2127, 2137, 2213, 2332, 2337, 2380, 2435, 2833, 2917, 3072, 3075, 3080, 3129, 3193, 3636, 4037, 4044, 4313) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2248. [31 pp.]. doi:10.2903/j.efsa.2011.2248. Available online: www.efsa.europa.eu/efsajournal

from any of the references provided for the scientific substantiation of the claims evaluated in this opinion.

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

Gastro-intestinal discomfort, vision, cognitive function, upper respiratory tract, menstrual discomfort, menopausal discomfort, stress-induced headache, apoptosis, bacterial vaginosis, heavy metals, upper respiratory tract defence, 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. Reduction of gastro-intestinal discomfort (ID 644, 1717, 1742, 1760, 2000, 2028, 2124, 2213, 2337, 3072, 3075, 3080, 3193, 4313)

The claimed effects are "digestive system", "relief for gastric discomfort", "zinc carnosine", "relaxation", "digestive health", "liver health", "digestion", "healthy digestion", "improvement of the digestion", "santé gastro-intestinale", and "digestive process/promotes intestinal well-being/can bind pathogenic bacteria/increases the activity of digestive enzymes". The Panel assumes that the target population is the general population.

[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

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effects refer to the reduction of gastro-intestinal discomfort.

The Panel considers that reduction of gastro-intestinal discomfort is a beneficial physiological effect.

1.2. Maintenance of normal vision (ID 2833, 4044)

The claimed effect is "eyes". 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 maintenance of normal vision.

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

1.3. Contribution to normal cognitive function (ID 1894, 1926, 2024)

The claimed effects are "nervous system: phospholipids improve memory and cognitive functions", "enhancing memory and cognitive function", and "brain/mental/cognitive health". 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 contribution to normal cognitive function. Cognitive function includes memory, attention (concentration), learning, intelligence and problem solving, which are well defined constructs and can be measured by validated psychometric cognitive tests.

The Panel considers that contribution to normal cognitive function is a beneficial physiological effect.

1.4. Relief in case of irritation in the upper respiratory tract (ID 1730, 2127, 2137, 2332, 2380, 2435)

The claimed effects are "respiratory health" and "respiratory system health". 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 relief in case of irritation in the upper respiratory tract, which could be assessed if adequate validated questionnaires were available.

The Panel considers that relief in case of irritation in the upper respiratory tract is a beneficial physiological effect.

1.5. Reduction of menstrual discomfort (ID 3636)

The claimed effect is "contributes to physical well-being". The Panel assumes that the target population is women with premenstrual syndrome.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to a reduction in menstrual discomfort, which can be assessed as changes in the severity of symptoms related to the premenstrual syndrome using validated questionnaires.

The Panel considers that a reduction of menstrual discomfort is a beneficial physiological effect.

1.6. Reduction of menopausal discomfort (ID 1933, 2095, 3129, 3636)

The claimed effects are "menopause", "phytoestrogenic properties", and "contributes to physical well-being". The Panel assumes that the target population is post-menopausal women.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effects refer to the reduction of menopausal discomfort, which can be assessed as changes in the severity of symptoms related to menopause using validated questionnaires.

The Panel considers that reduction of menopausal discomfort is a beneficial physiological effect.

1.7. Relief from stress-induced headache (ID 4037)

The claimed effect is "mental function and head". 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 the relief from stress-induced headache.

The Panel considers that relief from stress-induced headache is a beneficial physiological effect.

1.8. Apoptosis of damaged cells (ID 2917)

The claimed effect is "induction of apoptosis of transformed and damaged cells". 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 apoptosis of damaged cells.

The Panel considers that apoptosis of damaged cells is a beneficial physiological effect.

1.9. Defence against vaginal pathogens by increasing the proportion of lactobacilli and/or decreasing the proportion of potentially pathogenic bacteria and/or yeasts (ID 946)

The claimed effect is "urogenital tract/natural vaginal defence". The Panel assumes that the target population is the general female population.

From the clarifications provided by Member States, the Panel assumes that the claimed effect refers to defence against vaginal pathogens by increasing the number of lactobacilli and/or decreasing potentially pathogenic bacteria and/or yeasts.

Unlike any other anatomical site of the body, most vaginal vaults are dominated by one or more species of *Lactobacillus*. In over 70 % of women, vaginal microbiota is dominated by lactobacilli (> 50 %) (Ling et al., 2010; Ravel et al., 2011; Yamamoto et al., 2009). This microbiota is different from the more complex gut microbiota, where lactobacilli represent less than 3 % of the bacterial population (Franks et al., 1998; Lay et al., 2005; Sghir et al., 2000). The diagnosis of bacterial vaginosis (BV) is currently based on Nugent score (microscopic examination of Gram stained smear or vaginal discharge for bacteria and 'clue' cells). Nugent scores are classified into normal (0-3, lactobacilli are present, but not *Gardnerella/Bacteroides* or curved Gram-negative bacilli), intermediate (4-6, colonisation by *Bacteroides*/*Gardenella* and curved Gram-variable rods (*Mobiluncus*)), and BV (7-10, BV with domination of *Gardnerella/Bacteroides* or curved Gram-negative bacilli and absence of that lactobacilli).

The Panel considers that defence against vaginal pathogens by increasing the proportion of lactobacilli and/or decreasing the proportion of potentially pathogenic bacteria and/or yeasts is a beneficial physiological effect.

1.10. Elimination of heavy metals (ID 1871)

The claimed effect is "alginate binds heavy metals, stimulates mucin production and protects the colon, N-acetylcysteine detoxifies and removes heavy metals, piperine increases the bioavailability of n-acetylcysteine". The Panel assumes that the target population is the general population.

In the context of the proposed wordings and of the references provided, the Panel assumes that the claimed effect refers to the elimination of heavy metals.

The Panel considers that elimination of heavy metals is a beneficial physiological effect.

1.11. Maintenance of the upper respiratory tract defence against pathogens by maintaining immune defences (ID 1910)

The claimed effect is "immune system". 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 the maintenance of the upper respiratory tract defence against pathogens by maintaining immune defences.

The Panel considers that maintenance of the upper respiratory tract defence against pathogens by maintaining immune defences is a beneficial physiological effect.

2. Scientific substantiation of the claimed effect

2.1. Reduction of gastro-intestinal discomfort (ID 644, 1717, 1742, 1760, 2000, 2028, 2124, 2213, 2337, 3072, 3075, 3080, 3193, 4313)

The references provided in relation to these claims were textbooks or narrative reviews which did not provide any original data which could be used for the scientific substantiation of the claim, or reported on animal or *in vitro* studies which addressed the effects of the food(s)/food constituent(s) on, e.g., spontaneous contractions of the jejunum, adhesion properties of *Helicobacter pylori*, pharmacologically or stress-induced gastric ulcers, necrotising enterocolitis, intestinal inflammation. One human intervention study which addressed the effects of the food(s)/food constituent(s) on the treatment of *Helicobacter pylori* infection was also provided. 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 measures of gastro-intestinal discomfort 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 reduction of gastro-intestinal discomfort.

2.2. Maintenance of normal vision (ID 2833, 4044)

The references provided in relation to these claims included narrative reviews, animal and *in vitro* studies on the food(s)/food constituent(s) which reported on health outcomes (e.g. systemic inflammation, antioxidant status, haematopoiesis, cell mutations in response to exposure to heavy metals) 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 maintenance of normal vision 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 vision.

2.3. Contribution to normal cognitive function (ID 1894, 1926, 2024)

The references provided in relation to these claims included narrative reviews on the relationship between oxidative stress and age-related neuronal deficits or on the effect of different food(s)/food constituent(s) on memory, which did not provide any original data which could be used for the scientific substantiation of the claim, and on health outcomes unrelated to the claimed effect (e.g. anxiety). References regarding the composition of some food(s)/food constituent(s) were also provided. 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 measures of cognitive function were provided in relation to any of the claims evaluated in this section.

One *in vitro* study which assessed the effects of a food constituent on amyloid beta-peptide in neuronal cell cultures was 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 contribution to normal cognitive function *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 contribution to normal cognitive function.

2.4. Relief of irritation in the upper respiratory tract (ID 1730, 2127, 2137, 2332, 2380, 2435)

Most of the references provided in relation to these claims were textbooks, narrative reviews and monographs which did not provide any original data which could be used for the scientific substantiation, or assessed the effects of food(s)/food constituent(s) other than those for which the specific claims are proposed, and/or health outcomes (e.g. treatment of infectious diseases, treatment of influenza) 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 measures of relief of irritation in the upper respiratory tract 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 relief of irritation in the upper respiratory tract.

2.5. Reduction of menstrual discomfort (ID 3636)

The references provided in relation to this claim were *in vitro* and animal studies which assessed the effects of food(s) other than the one which is the subject of the claim and/or health outcomes (e.g. antioxidant activity, apoptosis in cancer cells, antimicrobial activity) unrelated to the claimed effect. 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 food on reduction of menstrual discomfort 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 reduction of menstrual discomfort.

2.6. Reduction of menopausal discomfort (ID 1933, 2095, 3129, 3636)

The references provided in relation to these claims were reviews, human, animal and *in vitro* studies which assessed the effects of food(s)/food constituent(s) other than those which are the subject of the claim and/or health outcomes (e.g. antioxidant activity, apoptosis in cancer cells, antimicrobial activity) 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 reduction of menopausal discomfort were provided in relation to any of the claims evaluated in this section.

One *in vitro* study which investigated the oestrogenic effect of the food, which is the subject of the claim, was 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 reduction of menopausal discomfort *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 reduction of menopausal discomfort.

2.7. Relief from stress-induced headache (ID 4037)

The references provided in relation to this claim were textbooks and monographs which did not provide any original data which could be used for the scientific substantiation of the claim and studies on health outcomes (e.g. memory, regulation of body temperature, sleeping time, muscle activity) unrelated to the claimed effect. 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 food on relief from stress-induced headache were provided in relation to the claim evaluated in this section.

Studies which assessed the effects of the food on pain in animal models were also provided. The Panel considers that evidence provided in animal studies is not sufficient to predict the occurrence of an effect of the consumption of the food on pain relief *in vivo* in humans.

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 relief from stress-induced headache.

2.8. Apoptosis of damaged cells (ID 2917)

The reference provided in relation to this claim was one *in vitro* study which investigated health outcomes (i.e. induction of the expression of breast cancer susceptibility genes and prostate cancer cell types) unrelated to the claimed effect. 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 constituent on measures of apoptosis of damaged cells 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 constituent which is the subject of the claim evaluated in this section and apoptosis of damaged cells.

2.9. Defence against vaginal pathogens by increasing the proportion of lactobacilli and/or decreasing the proportion of potentially pathogenic bacteria and/or yeasts (ID 946)

The references provided in relation to this claim were a narrative review which did not provide any original data which could be used for the scientific substantiation of the claim, and a study which assessed the effects of food(s)/food constituent(s) other than the food constituent for which the specific claim is proposed. 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 effect of the food constituent on the proportion of lactobacilli and/or potentially pathogenic bacteria and/or yeasts in the vagina 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 constituent which is the subject of the claim evaluated in this section and defence against vaginal pathogens by increasing the proportion of lactobacilli and/or decreasing the proportion of potentially pathogenic bacteria and/or yeasts.

2.10. Elimination of heavy metals (ID 1871)

The references provided in relation to this claim were studies which assessed the effects of food(s)/food constituent(s) other than the specific combination of food constituents which is the subject of the claim. 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 elimination of heavy metals 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 specific combination of food constituents which is the subject of the claim evaluated in this section and elimination of heavy metals.

2.11. Maintenance of the upper respiratory tract defence against pathogens by maintaining immune defences (ID 1910)

The references provided in relation to this claim included narrative reviews and animal studies which addressed health outcomes (e.g. tumour regression) unrelated to the claimed effect, and a non-scientific reference (web page of a food producer) which did not provide any original data for the

scientific substantiation of the claim. 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 food constituent on maintenance of the upper respiratory tract defence against pathogens by maintaining immune defences 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 constituent which is the subject of the claim evaluated in this section and maintenance of the upper respiratory tract defence against pathogens by maintaining immune defences.

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-2008-1431, EFSA-Q-2008-1733, EFSA-Q-2008-2453, EFSA-Q-2008-2466, EFSA-Q-2008-2475, EFSA-Q-2008-2493, EFSA-Q-2008-2604, EFSA-Q-2008-2627, EFSA-Q-2008-2643, EFSA-Q-2008-2659, EFSA-Q-2008-2666, EFSA-Q-2008-2733, EFSA-Q-2008-2757, EFSA-Q-2008-2761, EFSA-Q-2008-2828, EFSA-Q-2008-2857, EFSA-Q-2008-2860, EFSA-Q-2008-2870, EFSA-Q-2008-2946, EFSA-Q-2008-3065, EFSA-Q-2008-3070, EFSA-Q-2008-3113, EFSA-Q-2008-3168, EFSA-Q-2008-3566, EFSA-Q-2008-3650, EFSA-Q-2008-3804, EFSA-Q-2008-3807, EFSA-Q-2008-3812, EFSA-Q-2008-3861, EFSA-Q-2008-3925, EFSA-Q-2008-4360, EFSA-Q-2008-4749, EFSA-Q-2008-4756, EFSA-Q-2010-00266). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

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

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[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
644	Milk fat globule membrane/Milk phospholipids.	Digestive system.	Supports intestinal comfort. Supports the functioning of the digestive system.
	Conditions of use - 100mg phospholipids per serving.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
946	Lactobacillus acidophilus LA14	Urogenital tract /Natural vaginal defence Clarification provided Urogenital tract /Natural vaginal defence Contributes to a healthy colonization of lactobacilli in the vagina Helps to redress the healthy balanced vaginal microflora during and after the treatment of urogenital disorders	Helps to restore and maintain normal vaginal microflora; Helps during the treatment of urogenital disorders;
	Conditions of use - mind.1x10E9 KBE/Tag - at least 1x109 cfu/day		
	Comments from Member States GE proposal identical to first Dutch proposal		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1717	Chlorophyllin [Sodium copper chlorophyllin].	Relief for Gastric Discomfort.	"Provides antioxidant protection." "For daily detoxification support." "Research indicates that chlorophyllin may modulate the activity of detoxification enzymes and provide antioxidant protection against free radicals."
	Conditions of use - The recommended daily dosage: 50 – 150 mg/day.		

ID	Food or Food constituent	Health Relationship	Proposed wording
1730	Glycerol.	Respiratory health.	Soothing for mouth and throat. Reliefs in case of tickle in the throat and pharynx. Soothing and pleasant effect on throat, pharynx and vocal cords.
	Conditions of use - none provided		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1742	Milk fat globule membrane/Milk phospholipids.	Digestive system.	Supports intestinal comfort. Supports the functioning of the digestive system.
	Conditions of use - 100mg phospholipids per serving.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1760	Zinc carnosine.	Zinc carnosine.	Gastric comfort. Supports a healthy gastric environment. Zinc-carnosine supports the natural defenses and healthy ecology of the gastric lining.
	Conditions of use - The recommended daily dosage: 150 mg zinc-carnosine (including 32 mg zinc).		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1871	Name of Food product: Product-specific claim: sodium alginate, n-acetyl cysteine and piperine 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: No	Health benefits of food: Alginate binds heavy metals, stimulates mucin production and protects the colon. N-acetylcysteine detoxifies and removes heavy metals. Piperine increases the bioavailability of n-acetylcysteine. Do benefits relate to a disease risk factor: No Target group: Adults aged 18 years and over with some exceptions If exceptions describe: Pregnant, lactating	Exact wording of claim as it appears on product: Supports body detoxification Examples of any alternative wording that may be used in relation to claim: Rids toxins from the body/Aids colonic health/Protects the colon/Cleanses the body/Helps maintain a healthy colon/Promotes healthy conditions in the colon/Detoxes the body Is claim a picture: No

		women and children Reasons for excluding these groups: Alginate may decrease the absorption of calcium if taken concomitantly therefore it should be avoided by pregnant, lactating women and children and those with calcium deficiency or brittle bones. When taking N-acetyl cysteine it is recommended that two to three times as much vitamin C be taken at the same time. Failure to do so may result in more harm than good from taking this product because of the prolonged presence of the oxidized form of L-Cysteine.	
	Conditions of use - Number of nutrients/other substances that are essential to claimed effect: 3. Names of nutrient/other substances and Quantity in Average daily serving: 5g sodium alginate, 600 mg n-acetyl cysteine, 15 mg piperine. Weight of average daily food serving: 150 mililitre(s). Daily amount to be consumed to produce claimed effect: 450 mililitre(s). Number of food portions this equates to in everyday food portions: 1. Are there factors that could interfere with bioavailability: Yes. Please give reason: Alginate forms a gel in the stomach and it may trap a portion of N-acetyl-cysteine. Piperine increases the bioavailability of the untrapped portion of N-acetyl cysteine thus increaing its efficacy. Length of time after consumption for claimed effect to become apparent: up to 6 weeks. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Don't Know. Where applicable outline nutritional composition (g per 100g) of food: Total Fat: .01, Saturated Fat: .00, Trans Fat: .00, Sugar: .31, Salt: .00, Sodium: .01. Other conditions for use: This beverage must be consumed as part of a varied, balanced and healthy lifestyle. Three beverages are to be consumed daily in order to gain benefit. This product should be avoided by pregnant, lactating women and children and those with calcium deficiency or brittle bones.		
	No clarification provided by Member States **Comments provided by Member States** Further clarification to support the use of this claim was not submitted to the Food Safety Authority of Ireland. The FBO involved did submit further information on other claims and remarked in relation to the comment from EFSA that this claim is 'too vague', that they felt that the information they already provided is quite specific.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1894	Laitance de poisson. Clarification provided Lipids of fish gonads	Système nerveux, Mémoire, source de protéines-lipides dont des	Contribue à stimuler l'activité intellectuelle et à renforcer la mémoire.

	(phospholipids: phosphatidylserine, phosphatidylethanolamine and phosphatidylcholine).	phospholipides. Clarification provided Nervous system: phospholipids improve memory and cognitive functions.	A utiliser en cas d'efforts intellectuels. Favorise les facultés de concentration. Clarification provided May improve memory/may improve cognitive performance/ phospholipids play a role in healthy brain functions/supports memory and concentration/increase concentration and make the memory more effective.
	Conditions of use - 6x250mg/jour.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1910	WGP beta-glucan;(WGP® (1,3)-b-D-glucan);(from Saccharomy-ces cerevisiae).	Immune system. Clarification provided Immune system; WGP beta -glucan stimulates the white blood cells (macrophages and ganulocytes) thus improve the function of the immune system.	WGP beta-glucan contributes to the normal function of the immune system. WGP beta-glucan naturally contributes to adequate immune responses. The daily dietary supplementation with WGP beta-glucan promotes the normal function of the immune system. WPG beta-glucan enhances the production and activity of the macrophages and neutrophiles. Thus, it plays an important role in the adequate function of the immune system. WGP beta-glucan contributes to maitain the normal function of upper respiratoy tract.
	Conditions of use - 250-500 mg per day for adults; 125 mg per day for children.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1926	Homotaurine.	Enhancing memory and cognitive function.	Homotaurine has been shown to help maintain cognitive function.
	Conditions of use - 50 to 300 mg/diem in a food supplement formulation.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1933	Mung bean (Vigna Radiata)	Menopause Clarification provided Necessary to help women cope with the signs associated with the menopause, such as	Phytoestrogens are commonly used by women who cannot / do not want to use HRT during menopause. PB is a source of phytoestrogens. PB is a source of oestrogenic support during menopause and beyond. Oestrogenic support during menopause years and

		disturbed sleep, lethargy and irritability Necessary for a calm and comfortable menopause. Helps women coping with the teltale signsassociated with menopause, such as hot flushes, sweating, restlessness and irritablity.	beyond which helps maintain wellbeing and quality of life.
	Conditions of use - Suitable for healthy women during menopause years and beyond. First 4-6 weeks: 2 capsules twice daily, thereafter as required to maintain wellbeing. Women on medication should seek the advice of their GP prior to including Product in their diet (full information pack available for GPs from suppliers). (For additional details, please refer to Background Information).		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2000	Aspalathus linearis (Common Name : Rooibos/Red bush).	Relaxation. Clarification provided Spasmolytic - helps maintain intestinal comfort by reducing abdominal spasm and diarrhoea.	Contributes to optimal relaxation / helps to support the relaxation.
	Conditions of use - liście/ zwykle konsumowane jako tradycyjny artykuł żywnościowy w normalnej diecie. - Monoprodukt oder Zutat einer Mischung, zur Zubereitung eines Heißaufgusses. - Leaf / Usual consumption as traditional foodstuff in a normal diet.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2024	Cherries (Prunus cerasus, P. domestica), including Montmorency, Balaton or other sour/tart cherry varieties.	Brain/mental/cognitive health. Clarification provided Anxiolytic and antioxidant effects: Decrease in anxiety-related behaviors. Increases visuo-spatial task performance (in rats).	[Tart/sour] cherries help support healthy brain / mental function.
	Conditions of use - Variable, depending on formulation e.g. concentrate for dilution in water (typically 30 ml per day) or freeze-dried extract (typically, 1-2 capsules daily)		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2028	Citrus limon (Common	Digestive health.	Helps to support the digestion

	Name: Lemon).	Clarification provided Reduces gastrointestinal spasms and stimulates salivary, biliary and pancreatic secretions .	contributes to the normal function of intestinal tract helps support the digestive juice flow.
	Conditions of use - Skórka/ Zwykle konsumowana jako tradycyjny artykuł żywnościowy w normalnej diecie. - Peel / Usual consumption as tradtional foodstuf in a normal diet. - Schale / Üblicher Verzehr als traditionelles Lebensmittel im Rahmen einer ausgewogenen Ernährung.		
	Comments from Member States DE received new literature from applicant (available via FIS-VL: https://fisvl.bund.de/Members/irc/fisvl/healthclaims/library?l=/datenbank/anlagen_datenbank_hingewiesen_wi/nachgereichte_literatur/haupteintrag_2028/1246959776dosier/_DE_1.0_&a=d).		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2095	Mung bean (Vigna Radiata)	Menopause Clarification provided Necessary to help women cope with the signs associated with the menopause, such as disturbed sleep, lethargy and irritability Necessary for a calm and comfortable menopause. Helps women coping with the teltale signsassociated with menopause, such as hot flushes, sweating, restlessness and irritablity.	Phytoestrogens are commonly used by women who cannot / do not want to use HRT during menopause. PB is a source of phytoestrogens. PB is a source of oestrogenic support during menopause and beyond. Oestrogenic support during menopause years and beyond which helps maintain wellbeing and quality of life.
	Conditions of use - Suitable for healthy women during menopause years and beyond. First 4-6 weeks: 2 capsules twice daily, thereafter as required to maintain wellbeing. Women on medication should seek the advice of their GP prior to including Product in their diet (full information pack available for GPs from suppliers). (For additional details, please refer to Background Information). Product should not be included in women's diet if they are pregnant, or planning a pregnancy, taking contraceptives or HRT. Product should not be consumed by women with low blood pressure, oestrogen or over-active thyroid related disorders or using blood thinners/anticoagulants. Product may cause initial discomfort, wind and bloating in women with low dietary intake or intolerance of legumes/pulses.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2124	Raphanus sativus var niger (Common Name : Radish, Black radish, Japanese	Liver health. Clarification provided	Contributes to the elimination function of the gastrointestinal tract / contributes to bile flow fonction /

	radish, Daikon).	Liver health/ Liver health/ Contribute to have a good function of the upper digestive tract,to a good gall bladder function. Promotes / contribute to a normal biliary flow for the digestive well-being/comfort. Help to drain the liver and gall bladder.	supports healthy liver activity / contributes to healthy digestion/digestive well-beingl/liver well-being.
	Conditions of use - Wurzel / Äquivalent von 45-100 ml ausgepresstem Saft. - korzeń/ równowartość 45- 100 ml wyciśniętego soku z korzenia. - Root / The equivalenty of 45-100 ml pressed root juice. - Racine 50-100ml jus/jour.		
	Comments from Member States Several entries with the same or similar wording have NO comments of EFSA (0) (see for examples entries n°: 2186, 2227,2258,2260,2658,2694,2858,3391,3436,3721,3733,3947,3952,,,) Therefore, these entries 2124, 2329 and 2752 do not have to have the EFSA comment n°3.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2127	Rubus fructicosus L. (Common name: Blackberry).	Respiratory health.	Soothing for mouth and throat / Reliefs in case of irritation of throat and pharynx / Soothing and pleasant effect on throat, pharynx and vocal cords.
	Conditions of use - Folia (Leaves) 4 to 5 g dried drug equivalent per day - Folia–(Blätter)—usual consumption as a traditional foodstuff in a normal diet (cough drops)—4 bis 5 g der getrockneten Pflanzenteile (Droge) pro Tag.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2137	Sambucus nigra (Common Name : Elderberry)	Respiratory health Clarification provided Respiratory health. Used to promote respiratory comfort. Soothing for mouth and throat/ Relieves in case of tickle in the throat and pharynx / Soothing and pleasant effect on throat, pharynx and vocal cords.	helps to soothe common cold/pleasant for cough and croakiness

	Conditions of use - owoc, kwiaty/ zwykle konsumowane jako tradycyjny artykuł żywnościowy w normalnej diecie/ równowartość 5g kwiatów lub owoców na dzień - Fructus–(Frucht)—usual consumption as a traditional foodstuff in a normal diet (cough drops). - Flos–(Blüten)—usual consumption as a traditional foodstuff in a normal diet (cough drops). 10 bis 15 g der getrockneten Pflanzenteile (Droge) pro Tag. - 39 mg/kg KG, usual consumption as traditional foodstuff in a normal diet. - Fruit, flowers / Usual consumption as traditional foodstuff in a normal diet / The equivalent of 5 gram flowers or berries per day. - Fleur 10-15g/jour en infusion - Fructus (Fruit) - Flos (Flowers) 10 to 15 g dried drug equivalent per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2213	Ananas comosus - common name: Bromelain, Pineapple.	Digestion. Clarification provided Reduces gastrointestinal discomfort.	"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 / 80-320mg of bromelain two to three times daily for 8 to 10 days / Equivalent quantity in extract. - Extract of fruit: 200 - 400 mg / Used as part of a multibotanical combination. - Tige 6x280mg/jour. - Fruit / 160-960 mg of bromelain daily for 8 to 10 days / Equivalent quantity in extract.		
	Comments from Member States Claims 2122, 4106, 2109, 2014, 3948 have the same relationship and comment 0.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2332	Ribes nigrum L. (Common name: Blackcurrant).	Respiratory health.	Soothing for mouth and throat / Reliefs in case of tickle in the throat and pharynx / Soothing and pleasant effect on throat, pharynx and vocal cords.
	Conditions of use - Fructus (Fruit)		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2337	Rubus idaeus - common name: Blackberry	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 leaf / 1,5g of leaves as an infusion / Equivalent quantity in extract		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2380	Horseradish root (Armoracia rusticana)	Respiratory system health Clarification provided Respiratory system health Active ingredients of horseradish support healthy functioning of upper respiratory system, free air-flow, and are prosperous to soothe irritation of their mucous membranes. Horseradish root has antimicrobial properties.	Active ingredients of horseradish can support the respiratory system health.
	Conditions of use - 20 g/ day fresh horseradish root or 120mg / day horseradish root extract - Racine. 6x125mg/jour		
	Comments from Member States Exemple of wording: Helps to maintain the integrity of the respiratory tract thanks its antimicrobial effects		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2435	Emblica officinalis (Indian Gooseberry)	Respiratory health	Softens the mucous membrane of throat
	Conditions of use - Fruit extract (dry): 10- 100 mg / Used as part of a multibotanical combination		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2833	Wheat sprouts	Eyes	For eye health.
	Conditions of use - Food supplement with 600-1200mg of wheat sprout powder in the daily dose.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2917	Indole-3-carbinol	Induction of apoptosis of transformed and damanged cells Clarification provided Support of selective	Indole-3-carbinol supports the regular fenotype of cells and positively affects the induction of apoptosis of damaged cells

		apoptose(programmed cell death) of oncogenous cells	
	Conditions of use - 150 - 450mg daily		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3072	Beta vulgaris (red beet juice, lactic acid fermented)	Healthy digestion Clarification provided Beta vulgaris helps maintain normal bowel gas and comfort	Supports a healthy digestion.
	Conditions of use - At least 1 glass (= 150 ml) lactic acid fermented pure beet juice per day		
	Comments from Member States Additionally the example of wording is modified as follows: Helps maintain normal bowel gas and comfort		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3075	Beta carota (carrot juice, lactic acid fermented)	Healthy digestion Clarification provided Beta vulgaris helps maintain normal bowel gas and comfort	Supports a healthy digestion.
	Conditions of use - At least 1 glass (= 150 ml) lactic acid fermented carrot juice per day		
	Comments from Member States Additionally the example of wording is modified as follows: Helps maintain normal bowel gas and comfort		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3080	–Papayafruchtfleisch (CARICOL®)– ballaststoffreiche Fruchtzubereitung, hergestellt aus dem Fruchtfleisch baumgereifter Papayafrüchte nach einem international patentierten Verfahren (PCT/IB2003/005476).— CARICOL® ist eine international geschützte Marke (820.278) —CG 06—— Clarification provided	–Verbesserung der Verdauung CT 15 Clarification provided Improvement of the digestion.	Zur natürlichen Unterstützung und Regulierung der Verdauung, insbesondere bei der Neigung zu Blähungen, Sodbrennen, hartem oder ungeformtem Stuhl. Verbessert die Verdauung. Clarification provided Naturally supports and regulates the digestive system, especially relating to excessive flatulence or gas, or a tendency towards loose stool, constipation or heart burn. Improves the digestion.

	CARICOL® a fruit preparation, rich in dietary fiber prepared from the mature flesh tree ripened papayas according to an international patented procedure. (PCT/IB2003/005476). CARICOL® is an international registered trademark (820.278)		
	Conditions of use - Herstellung gemäß patentiertem Verfahren.—Tagesdosis–20-60ml–nach den Mahlzeiten.–		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3129	Lignans	Phyto-estrogenic properties Clarification provided Phyto-estrogenic properties: Contain phytonutrients that act as phytoestrogens. Maintains a calm and comfortable menopause (e.g. helps coping with hotflushes, night sweats)	Phytonutrients that show similar attributes to phytoestrogens in soya.
	Conditions of use - 2 mg/serving		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3193	Graines de brocoli et extraits de graines de brocoli	Santé gastro-intestinale	Le sulforaphane aide à maintenir la santé gastro-intestinale. Il apporte un effet bénéfique sur la santé gastro-intestinale.
	Conditions of use - Graines et extraits de graines de brocoli / équivalent de 100 à 500 mg de sulforaphane par jour		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3636	VACCINIUM VITIS-IDAEA L.	Contributes to physical well-being Clarification provided Relaxation	Helps during the premenstrual cycle.Contributes to relieve the menopause symptoms
	Conditions of use - 2-5 g fruits daily; decoction: 1 g leaves in 100 ml water, 2-3 tablespoons 2-3 times daily; 5-20 drops fresh leaves macerated in glycerine and alcohol, for min. 3 months		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**

4037	Emblica officinalis FRUIT RIND	Mental function & Head Clarification provided Its anodyne effect helps keep the head free from pain.	Supports mental function. Helps maintain freedom from pain in the head. Improves the body's resistance to stress. Helps the body to deal with stress
	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**
4044	Emblica officinalis FRUIT RIND	Eyes Clarification provided Helps protect the eyes from oxidative stress.	Supports eye function
	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**
4313	Brewer's yeast (Saccharomyces cerevisae)	Digestive process/promotes intestinal well-being/can bind pathogenic bacteria/increases the activity of digestive enzymes	Contribute to a normal intestinal fonction through promotion of beneficial microflora/helps to manage diarrhea episodes/has an anti-diarrheal effect through anti-microbial activity on pathogenic intestinal bacteria.
	Conditions of use - 250-500 mg/day		

GLOSSARY AND ABBREVIATIONS

BV Bacterial vaginosis