

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to various foods/food constituents and “immune function/immune system” (ID 573, 586, 1374, 1566, 1628, 1778, 1793, 1817, 1829, 1939, 2155, 2485, 2486, 2859, 3521, 3774, 3896), “contribution to body defences against external agents” (ID 3635), stimulation of immunological responses (ID 1479, 2064, 2075, 3139), reduction of inflammation (ID 546, 547, 641, 2505, 2862), increase in renal water elimination (ID 2505), treatment of diseases (ID 500), and increasing numbers of gastro-intestinal microorganisms (ID 762, 764, 884) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

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 foods/food constituents and “immune function/immune system”, “contribution to body defences against external agents”, stimulation of immunological responses, reduction of inflammation, increase in renal water elimination, treatment of diseases, and increasing numbers of gastro-intestinal microorganisms. The scientific substantiation is based on the information provided

¹ On request from the European Commission, Question No EFSA-Q-2008-1287, EFSA-Q-2008-1333, EFSA-Q-2008-1334, EFSA-Q-2008-1360, EFSA-Q-2008-1373, EFSA-Q-2008-1428, EFSA-Q-2008-1549, EFSA-Q-2008-1551, EFSA-Q-2008-1671, EFSA-Q-2008-2111, EFSA-Q-2008-2216, EFSA-Q-2008-2303, EFSA-Q-2008-2364, EFSA-Q-2008-2511, EFSA-Q-2008-2526, EFSA-Q-2008-2550, EFSA-Q-2008-2562, EFSA-Q-2008-2672, EFSA-Q-2008-2797, EFSA-Q-2008-2808, EFSA-Q-2008-2888, EFSA-Q-2008-3218, EFSA-Q-2008-3219, EFSA-Q-2008-3238, EFSA-Q-2008-3592, EFSA-Q-2008-3595, EFSA-Q-2008-3871, EFSA-Q-2008-4248, EFSA-Q-2008-4359, EFSA-Q-2008-4493, EFSA-Q-2008-4612, adopted on 28 January 2011.

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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.

“Immune function/immune system”

The claimed effects are “immunity”, “enhances natural resistance”, “immune health”, “maintenance of immune system”, “invigoration the body”, “immune support” and “Pleurotus ostreatus and immune system”. The target population is assumed to be the general population.

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

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

“Contribution to body defences against external agents”

The claimed effect is “contributes to body defences against external agents”. The target population is assumed to be the general population.

The claimed effect is not sufficiently defined and no further details were given in the proposed wording, the references or the clarifications provided by Member States.

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

Stimulation of immunological responses

The claimed effects are “immune health” and “support of immunity”. The target population is assumed to be the general population.

From the clarification provided by Member States, the Panel assumes that the claimed effects refer to the stimulation of various immunological responses, such as Th1 and Th2 balance, endothelial adhesion molecule regulation, increasing cytokine production, increasing numbers of macrophages, boosting natural killer cell activity, increasing concentrations of some immunocytes (immunocompetent cells), or stimulating components of cellular and humoral immunity.

The Panel considers that the evidence provided does not establish that the stimulation of these immunological responses is a beneficial physiological effect *per se*.

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

Reduction of inflammation

The claimed effects are “regulation of metabolic function”, “molecule precursors regulating cell functions (prostaglandins, leucotrienes)”, “supportive measure for healthy inflammatory responses”, “kidneys health” and “regulation of inflammatory responses in the body”. The target population is assumed to be the general population.

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

The Panel considers that no evidence has been provided to indicate the context in which the claimed effect could be considered to be a beneficial physiological effect.

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

Increase in renal water elimination

The claimed effect is “kidneys health”. The target population is assumed to be the general population.

In the context of the proposed wording, the Panel assumes that the claimed effect refers to an increase in renal water elimination (i.e. diuresis).

The Panel considers that the evidence provided does not establish that an increase in renal water elimination, which could lead to a negative fluid balance, is a beneficial physiological effect for the general healthy population.

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

Treatment of diseases

The claimed effects are “a high LNA to LA ratio has positive effects on eicosanoids and thus protects against inflammatory and thrombotic reactions”. The target population is assumed to be the general population.

From the clarifications provided by Member States and the references provided, the Panel assumes that the claimed effects refer to the treatment of diseases (e.g. rheumatoid arthritis and asthma).

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

Increasing numbers of gastro-intestinal microorganisms

The claimed effect is “helps maintain a healthy immune response in the elderly”, “immune support and immune health”, and “natural resistance/defence”. The target population is assumed to be the general population.

From the clarifications provided by Member States, the Panel assumes that the claimed effect refers to an increase in numbers of bacteria which are considered to be “beneficial”.

The numbers/proportions of bacterial groups which would constitute a “balanced or beneficial” gut/intestinal flora have not been established. Increasing the number of any groups of microorganisms, including bifidobacteria, is not in itself considered to be a beneficial physiological effect.

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

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

KEY WORDS

Immune, immunological responses, inflammation, renal water, gastro-intestinal microorganisms, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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EFSA DISCLAIMER

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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 1924/2006⁴ 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 out⁵. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

The approach used in the evaluation of Article 13(1) health claims is explained in the briefing document for stakeholders published by EFSA⁶.

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. “Immune function/immune system” (ID 573, 586, 1374, 1566, 1628, 1778, 1793, 1817, 1829, 1939, 2155, 2485, 2486, 2859, 3521, 3774, 3896)

The claimed effects are “immunity”, “enhances natural resistance”, “immune health”, “maintenance of immune system”, “invigoration the body”, “immune support” and “Pleurotus ostreatus and immune system”. The Panel assumes that the target population is the general population.

The claimed effects are not sufficiently defined and no further details were given in the proposed wording, the references or the clarifications provided by Member States. Given the multiple roles of

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

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

⁶ See footnote 5

the immune system, the specific aspect of immune function that is the subject of the health claim needs to be specified, but it has not been indicated in the information provided.

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

1.2. “Contribution to body defences against external agents” (ID 3635)

The claimed effect is “contributes to body defences against external agents”. The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were given in the proposed wording, the references or the clarifications provided by Member States.

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

1.3. Stimulation of immunological responses (ID 1479, 2064, 2075, 3139)

The claimed effects are “immune health” and “support of immunity”. The Panel assumes that the target population is the general population.

From the clarifications provided by Member States, the Panel assumes that the claimed effects refer to the stimulation of various immunological responses, such as Th1 and Th2 balance, endothelial adhesion molecule regulation, increasing cytokine production, increasing numbers of macrophages, boosting natural killer cell activity, increasing concentrations of some immunocytes (immunocompetent cells), or stimulating components of cellular and humoral immunity.

The Panel considers that the evidence provided does not establish that stimulation of these immunological responses is a beneficial physiological effect *per se*.

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

1.4. Reduction of inflammation (ID 546, 547, 641, 2505, 2862)

The claimed effects are “regulation of metabolic function”, “molecule precursors regulating cell functions (prostaglandins, leucotrienes)”, “supportive measure for healthy inflammatory responses”, “kidneys health” and “regulation of inflammatory responses in the body”. The Panel assumes that the target population is the general population.

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

Inflammation is a non-specific physiological response to tissue damage which is mediated by the immune system. Adequate inflammatory responses are of primary importance for the defence against injury of any origin. Changes in markers of inflammation such as various interleukins do not indicate a beneficial physiological effect *per se* but should be linked to a beneficial physiological or clinical outcome. The Panel considers that no evidence has been provided to indicate the context in which the claimed effect could be considered to be a beneficial physiological effect.

For ID 2862 the suppression of pro-inflammatory cytokine production (e.g. TNF- α) was mentioned in the clarifications provided, and additional inflammatory markers (e.g. prostaglandin E₂,

inhibitor-kappa-B-kinase, IL-8, NFkappaB) were addressed in the *in vitro* studies provided for the scientific substantiation of the claim. The Panel considers that no evidence has been provided to indicate the context in which the changes in these markers could indicate a beneficial physiological effect 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 health claims, and a beneficial physiological effect related to the reduction of inflammation.

1.5. Increase in renal water elimination (ID 2505)

The claimed effect is “kidneys health”. The Panel assumes that the target population is the general population.

In the context of the proposed wording, the Panel assumes that the claimed effect refers to an increase in renal water elimination (i.e. diuresis).

Substances which force diuresis also decrease the extracellular fluid volume by increasing renal sodium and water excretion.

Under normal conditions, fluid balance is tightly regulated over a 24-h period (Subudhi et al., 2005). Water deficits and excesses trigger compensatory changes in either water gains or losses until water balance is re-established (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010). A fall in intravascular volume or extracellular fluid volume will lead through a tightly regulated feedback system to increased renal tubular reabsorption of sodium and water (Shirreffs and Maughan, 2005).

Losses in body water, which are not adequately compensated, will result in dehydration.

The Panel considers that the evidence provided does not establish that an increase in renal water elimination, which could lead to a negative fluid balance, is a beneficial physiological effect for the general healthy population.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s), which are the subject of the health claim, and a beneficial physiological effect related to an increase in renal water elimination.

1.6. Treatment of diseases (ID 500)

The claimed effect is “a high LNA to LA ratio has positive effects on eicosanoids and thus protects against inflammatory and thrombotic reactions”. The Panel assumes that the target population is the general population.

From the clarifications provided by Member States and the references provided, the Panel assumes that the claimed effect refers to the treatment of disease (e.g. rheumatoid arthritis and asthma).

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

1.7. Increasing numbers of gastro-intestinal microorganisms (ID 762, 764, 884)

The claimed effects are “helps maintain a healthy immune response in the elderly”, “immune support and immune health”, and “natural resistance/defence”. The Panel assumes that the target population is the general population.

The claimed effects are not sufficiently defined and no further details were provided in the proposed wording. The specific aspect of immune function that is the subject of the health claim has not been indicated in the information provided.

From the clarifications provided by Member States, the Panel assumes that the claimed effects refer to an increase in numbers of bacteria which are considered to be “beneficial”.

The numbers/proportions of bacterial groups which would constitute a “balanced or beneficial” gut/intestinal flora have not been established. Increasing the number of any groups of microorganisms, including bifidobacteria, is not in itself considered to be a beneficial physiological effect.

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

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

CONCLUSIONS

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

“Immune function/immune system”

- The claimed effects are “immunity”, “enhances natural resistance”, “immune health”, “maintenance of immune system”, “invigoration the body”, “immune support” and “Pleurotus ostreatus and immune system”. The target population is assumed to be the general population.
- The claimed effects are general and non-specific, and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

“Contribution to body defences against external agents”

- The claimed effects are “contributes to body defences against external agents”. The target population is assumed to be the general population.
- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

Stimulation of immunological responses

- The claimed effects are “immune health” and “support of immunity”. The target population is assumed to be the general population. From the clarifications provided by Member States, the Panel assumes that the claimed effects refer to the stimulation of various immunological responses. The evidence provided does not establish that the stimulation of immunological responses is a beneficial physiological effect *per se*.

- A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s), which are the subject of the health claims, and a beneficial physiological effect related to stimulation of immunological responses.

Reduction of inflammation

- The claimed effects are “regulation of metabolic function”, “molecule precursors regulating cell functions (prostaglandins, leucotrienes)”, “supportive measure for healthy inflammatory responses”, “kidneys health” and “regulation of inflammatory responses in the body”. The target population is assumed to be the general population. In the context of the proposed wordings and the clarifications provided by Member States, the Panel assumes that the claimed effects refer to the reduction of inflammation. No evidence has been provided to indicate the context in which the claimed effect could be considered as a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s), which are the subject of the health claims, and a beneficial physiological effect related to the reduction of inflammation.

Increase in renal water elimination

- The claimed effect is “kidney health”. The target population is assumed to be the general population. The evidence provided does not establish that an increase in renal water elimination, which could lead to a negative fluid balance, is a beneficial physiological effect for the general healthy population.
- A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s), which are the subject of the health claim, and a beneficial physiological effect related to an increase in renal water elimination.

Treatment of diseases

- The claimed effect is “a high LNA to LA ratio has positive effects on eicosanoids and thus protects against inflammatory and thrombotic reactions”. The target population is assumed to be the general population. From the clarifications provided by Member States and the references provided, it is assumed that the claimed effect refers to the treatment of disease (e.g. rheumatoid arthritis and asthma).
- The claimed effect is related to the treatment of diseases and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

Increasing numbers of gastro-intestinal microorganisms

- The claimed effects are “helps maintain a healthy immune response in the elderly”, “immune support and immune health”, and “natural resistance/defence”. The target population is assumed to be the general population. The evidence provided does not establish that increasing numbers of gastro-intestinal microorganisms is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s), which are the subject of the health claims, and a beneficial physiological effect related to increasing numbers of gastro-intestinal microorganisms.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1287, EFSA-Q-2008-1333, EFSA-Q-2008-1334, EFSA-Q-2008-1360, EFSA-Q-2008-1373, EFSA-Q-2008-1428, EFSA-Q-2008-1549, EFSA-Q-2008-1551, EFSA-Q-2008-1671, EFSA-Q-2008-2111, EFSA-Q-2008-2216, EFSA-Q-2008-2303, EFSA-Q-2008-2364, EFSA-Q-2008-2511, EFSA-Q-2008-2526, EFSA-Q-2008-2550, EFSA-Q-2008-2562, EFSA-Q-2008-2672, EFSA-Q-2008-2797, EFSA-Q-2008-2808, EFSA-Q-2008-2888, EFSA-Q-2008-3218, EFSA-Q-2008-3219, EFSA-Q-2008-3238, EFSA-Q-2008-3592, EFSA-Q-2008-3595, EFSA-Q-2008-3871, EFSA-Q-2008-4248, EFSA-Q-2008-4359, EFSA-Q-2008-4493, EFSA-Q-2008-4612). 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

- EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010. Scientific Opinion on Dietary Reference Values for water. *EFSA Journal*, 8(3):1459, 48 pp.
- Shirreffs SM and Maughan RJ, 2005. Water-Electrolyte Balance. In: *Encyclopedia of Human Nutrition*. Eds Caballero B, Allen L, Prentice A. Elsevier, Oxford, 100-105.
- Subudhi AW, Askew EW and Luetkemeier MJ, 2005. Dehydration. In: *Encyclopedia of Human Nutrition*. Eds Caballero B, Allen L, Prentice A. Elsevier, Oxford, 518-525.

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 foods⁷ (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 FOOD⁸

Foods are commonly involved in many different functions⁹ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

⁷ OJ L12, 18/01/2007

⁸ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

⁹ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to various food(s)/food constituent(s) claiming effects on the immune system, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
500	<p>Essential fatty acid</p> <p>Alpha-linolenic acid (LNA - omega 3)</p> <p><u>Clarification provided</u></p> <p>Essential fatty acid</p> <p>Alpha-linolenic acid (LNA - omega 3)</p>	<p>A high LNA to LA ratio has positive effects on eicosanoids and thus protects against inflammatory and thrombotic reactions</p> <p><u>Clarification provided</u></p> <p>A balanced LA (n-6) over LNA (n-3) ratio has positive effects on eicosanoids and thus protects against inflammatory and thrombotic reactions.</p> <p>Western diets are deficient in omega-3 fatty acids, and have excessive amounts of omega-6 fatty acids compared with the diet on which human beings evolved and their genetic patterns were established. Excessive amounts of omega-6 polyunsaturated fatty acids (PUFA) and a very high omega-6/omega-3 ratio, as is found in today's Western diets, promote the pathogenesis of many diseases, including cardiovascular disease, cancer, and inflammatory and autoimmune diseases, whereas increased levels of omega-3 PUFA (a low omega-6/omega-3 ratio) exert suppressive effects.</p> <p>A ratio of 2–3/1 suppressed inflammation in patients with rheumatoid arthritis, and a ratio of 5/1 had a beneficial effect on patients with asthma, whereas a ratio of 10/1 had adverse consequences. These studies indicate that the optimal ratio</p>	<p>LNA contributes to the good balance in essential fatty acids in the diet and as such helps to maintain a strong body defense (system)</p>

		<p>may vary with the disease under consideration. (Reference: Simopoulos AP. The importance of the ratio of omega-6/omega-3 essential fatty acids. Biomedicine & Pharmacotherapy 2002; 56 (8):365-379)</p>	
<p>Conditions of use</p> <ul style="list-style-type: none"> - Amount of consumption: 2g/Tag. Other condition: min 10% fat (product basis), min 70% UFA (fat basis), max 2% TFA (fat basis); min 0,3g Alpha-linolenic Omega3 per 100g/ml and 100kcal (product basis), based on 15% of 2,0g GDA for Omega3 (ALA) - >1.5g per day–(BNF CVD 2005 p.217) 			
<p>Comments from Member States</p> <p>BE proposal</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
546	Echium oil.	<p>Regulation of metabolic function.</p> <p><u>Clarification provided</u></p> <p>Raises levels of anti-inflammatory compounds in the body at a dose of 5g/day.</p>	<p>Echium oil contains omega-3 fatty acid, stearidonic acid, which is efficiently metabolized in the body to anti-inflammatory n-3 LC PUFA's, i.e. EPA and DPA.</p> <p>Echium oil contains omega-6 fatty acid, γ-linoleic acid, which is efficiently metabolized in the body.</p>
<p>Conditions of use</p> <ul style="list-style-type: none"> - Oil extracted from Seeds of Echium Plantagineum. 			
ID	Food or Food constituent	Health Relationship	Proposed wording
547	Echium oil.	<p>Molecule precursors regulating cell functions (prostaglandins, leucotrienes).</p> <p><u>Clarification provided</u></p> <p>Inhibits the cellular production of leucotrienes.</p>	<p>Precursor of prostaglandins which are associated with many of the body's metabolic functions (immune system, reduction of inflammation).</p>
<p>Conditions of use</p> <ul style="list-style-type: none"> - Oil extracted from Seeds of Echium Plantagineum. 			
ID	Food or Food constituent	Health Relationship	Proposed wording
573	Blackcurrant seed oil (carbon dioxide extracted) + vitamin E.	<p>Immunity</p> <p><u>Clarification provided</u></p> <p>Blackcurrant seed oil is rich in stearidonic acid and gamma-linolenic acid that support the healthy immune response of the body.</p>	<p>Blackcurrant seed oil regulates the immune response.</p> <p>Blackcurrant seed oil maintains and supports the body's normal defence system.</p>

		Supplementation of blackcurrant seed oil increases the level of dihomo-gamma-linolenic acid and reduces the production of prostaglandin E2, which are important in maintaining the normal immune function of the body.	
Conditions of use			
- Food supplement with 100-2000 mg of blackcurrant seed oil (standardised, carbon dioxide extracted) and 5-10 mg of vitamin E in the daily dose.			
ID	Food or Food constituent	Health Relationship	Proposed wording
586	Sea buckthorn berry oil (cold-pressed)	Immunity	Strengthens immunity
Conditions of use			
- Food supplement with 2 g of cold-pressed sea buckthorn berry oil (pulp oil) in the daily dose.			
Comments from Member States			
No further clarification received			
ID	Food or Food constituent	Health Relationship	Proposed wording
641	Gamma-linolenic acid + eicosapentaenoic acid (GLA+EPA) <u>Clarification provided</u> 260-520 mg GLA+ 106-212 mg EPA/day	Supportive measure for healthy inflammatory responses <u>Clarification provided</u> GLA relies on EPA to improve immune system functioning while preserving a healthy circulation.	/ partners in maintaining a healthy immune system
Conditions of use			
- 360-540 mg GLA/day (current knowledge: GLA/EPA ratio lower or equal to 6/1)			
ID	Food or Food constituent	Health Relationship	Proposed wording
762	Galacto-oligosaccharides	Helps maintain a healthy immune response in the elderly <u>Clarification provided</u> Regular consumption of B-GOS galacto-oligosaccharides significantly increases the numbers of immunity-boosting Bifidobacteria in the gut, helping to improve the natural defences in Elderly consumers.	Helps support a healthy immune system in an ageing population
Conditions of use			

	- contains at least 2.66 g of galacto-oligosaccharides		
ID	Food or Food component	Health Relationship	Proposed wording
764	Galacto-oligosaccharides	<p>Immune support and immune health</p> <p><u>Clarification provided</u></p> <p>Immune support and immune health</p> <p>Clarification:</p> <p>B-GOS galacto-oligosaccharides significantly increases the number of Bifidobacteria in the gut which can improve the immune-response in healthy consumers</p>	<p>Energises your immunity boosting bacteria</p> <p>Helps boost your body's self defence</p>
Conditions of use			
- contains at least 2.66 g of galacto-oligosaccharides			
ID	Food or Food constituent	Health Relationship	Proposed wording
884	Lactobacillus acidophilus NCFM ATCC SD5221.	<p>Natural resistance/defence.</p> <p><u>Clarification provided</u></p> <p>Contributes to/supports the body's natural resistance/defence by supporting a well-balanced gut flora through an increased number of beneficial bacteria.</p>	<p>Probiotic - helps to strengthen your body's natural defences; helps to strengthen the natural defenses; helps to strengthen the natural defences of your body; contributes to enhance your body's resistance.</p>
Conditions of use			
<ul style="list-style-type: none"> - Other condition: Mind. 10E9 KBE täglich. - 109 CFU/day, 109 αριθμός αποικιών/ημέρα. - At least 10[9] cfu/day. 			
ID	Food or Food constituent	Health Relationship	Proposed wording
1374	<p>Name of Food product: fermented dairy products.</p> <p>Description of food in terms of food legislation categories: food not covered by specific food legislation.</p> <p>Was food on Irish market before 1st July 2007: Yes.</p>	<p>Health benefits of food: Enhances natural resistance.</p> <p>Do benefits relate to a disease risk factor: No.</p> <p>Target group: All adults aged 18 years and over.</p> <p><u>Clarification provided</u></p> <p>Health benefits of food: Enhances natural resistance.</p> <p>Strengthen your immunity.</p> <p>Quantity in average serving is</p>	<p>Exact wording of claim as it appears on product: Enhances natural resistance.</p> <p>Strengthen your immunity.</p> <p>Is claim a picture: No.</p>

		<p>109 CFU per day.</p> <p>Do benefits relate to a disease risk factor: No.</p> <p>Target group: All adults aged 18 years and over.</p>	
<p>Conditions of use</p> <ul style="list-style-type: none"> - Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance. <p>Number of nutrients/other substances that are essential to claimed effect: 1.</p> <p>Names of nutrient and Quantity in Average daily serving: LGG is present in 1,000,000,000 CFUs.</p> <p>Weight of average daily food serving: 100 gram(s).</p> <p>Daily amount to be consumed to produce claimed effect: 100 gram(s).</p> <p>Number of food portions this equates to in everyday food portions: 1.</p> <p>Are there factors that could interfere with bioavailability: No.</p> <p>Length of time after consumption for claimed effect to become apparent: It is apparent after a period of regular use.</p> <p>Number of days: 21.</p> <p>Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No.</p> <p>Other conditions for use: The product should be consumed in the context of a healthy diet and lifestyle.</p>			
<p>Comments from Member States</p> <p>Clarification/ further information/alternative wording which was provided by the FBO has been included. Further references to support this claim were provided by the FBO - these are included in a separate document (identified by claim number - additional information).</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
1479	Bromelain.	<p>Immune health.</p> <p><u>Clarification provided</u></p> <p>Immune health.</p> <p>Clarification: Contributes to the normal functioning of the immune system to helps to maintain the body's natural defense mechanisms. Supports healthy immune responsiveness by helping to maintain the balance of stimulatory and inhibitory immune mechanisms (e.g. Th1 and Th2 balance; endothelial adhesion molecules regulation).</p>	<p>Contributes to the normal functioning of the immune system.</p> <p>Helps maintain the body's natural defences.</p>
<p>Conditions of use</p>			

	<ul style="list-style-type: none"> - Amount of consumption: 200 Milligramm (mg) mg/Tag. Other condition: tägl. Dosierung: \geq 200 mg (5 F.I.P/mg). - Daily dosage: \geq 200 mg (with activity 5 F 5 F.I.P/mg). - Food supplement with 400 mg of curcuma, 400 mg of boswellia extract, 200 mg of pineapple pulp powder and 200 mg of quercetin in the daily dose. - Personen, bei denen eine raschere und/oder bessere Wundheilung gewünscht wird. 150 mg Bromelain. - Besonders für Personen mit schlechter Wundheilung oder altersbedingter, verminderter Gewebsregeneration - Papain 150 mg – Bromelain 100 mg. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
1566	Glucosinolates.	Immune health.	Foods containing glucosinolates help strengthen our body's defences.
		<u>Clarification provided</u> Glucosinolates (as precursor) contribute to proper functioning of the cells/support a proper functioning immune system.	
Conditions of use <ul style="list-style-type: none"> - Other condition: Der Gehalt an dem sekund. Pflanzenstoff in Gemüse im Verhältnis zum tägl. Bedarf und dem Schwellenwert für die Wirkung: bis zu 20 mg. - Phytoconstituent's content in vegetables expressed in comparison with the daily needs and threshold for activity: Up to 20 mg. 			
ID	Food or Food constituent	Health Relationship	Proposed wording
1628	Papain	Immune health	Supports normal immune function /supports body own defence mechanisms
		<u>Clarification provided</u> Immune health. Supports normal immune function (supports body own defense mechanisms). Helps to maintain the balance of immune cells (macrophages) and immune mediators (cytokines). Supports healthy reactivity of immune system to immune complexes.	
Conditions of use <ul style="list-style-type: none"> - Amount of consumption: 200 mg/Tag. Other condition: $>$ 200 mg (Aktiviät 1,5 FIP/mg) - $>$ 200 mg (with activity 1,5 FIP/mg) - 0,25 mg Papain– 			
ID	Food or Food constituent	Health Relationship	Proposed wording

1778	Lecithin	Immune health	Strengthens the immune system of the body
	Conditions of use		
	- 1,2- 3,6 g		
No clarification provided by Member States			
ID	Food or Food constituent	Health Relationship	Proposed wording
1793	Beta-glucan + olive leaf extract	Immunity	Supports the body's own defence mechanism / immunity Maintains natural defence mechanism / immunity Helps strengthen natural immunity
	Conditions of use		
	- Food supplement with beta-glucan content of 125-250 mg and olive leaf extract content of 150-300 mg in the daily dose.		
Comments from Member States			
No further clarification received			
ID	Food or Food constituent	Health Relationship	Proposed wording
1817	Herbal yeast plasmolytate (saccharomyces cerevisiae)	Immunity <u>Clarification provided</u> Immunity Clarification: Herbal yeast plasmolytate strengthens the body's defence system and improves the body's resistance	Strengthens the body's defence system. Increases immunity
	Conditions of use		
	- Herbal yeast preparation with 2.7-4.5 g of herbal yeast plasmolytate (saccharomyces cerevisiae) in the daily dose. - 5ml to be taken three times daily		
ID	Food or Food constituent	Health Relationship	Proposed wording
1829	Mycelium, biologically activated (contains ACHH, active hemicellulose compound)	Immunity	For immune protection. Makes the body's immune system more effective.
	Conditions of use		
	- Food supplement with 400mg of freeze-dried microencapsulated and biologically activated mycelium preparation that contains ACHH (active hemicellulose compound).		
Comments from Member States			
No further clarification received			

ID	Food or Food constituent	Health Relationship	Proposed wording
1939	Cryptoxanthin from orange juice.	Maintenance of immune system. <u>Clarification provided</u> Antioxidant properties.	(Cryptoxanthin from) orange juice participate to strengthen immune system. <u>Clarification provided</u> (Cryptoxanthin from) orange juice ensure antioxidant action / ensure protective effect on the organism.
	Conditions of use - One glass per day.		
ID	Food or Food constituent	Health Relationship	Proposed wording
2064	Griffola fondosa (Common Name : Maitake)	Immune health <u>Clarification provided</u> Has immunostimulant properties thanks to polysaccharide (glucan). Also immunomodulatory; increases cytokine production and increases macrophage and killer T-cell activity.	Contributes to the natural defences /support of natural resistance
	Conditions of use - grzyb/ 0.5 do 1 mg na kilogram masy ciała (35-70 mg) na dzień - Mushroom / 0.5 to 1 mg per kg of body weight (35-70 mg) per day - Thalle entier. 6x200mg/jour		
ID	Food or Food constituent	Health Relationship	Proposed wording
2075	Lentilus edodes (Common Name : Shiitake)	Immune health <u>Clarification provided</u> Immune health/ Helps support the body's immune system/Boosts the immune system/Increases level of some immunocytes (immunocompetent cells) Stimulates components of cellular and humoral immunity/	Contributes to natural immunological defences
	Conditions of use - Other condition: getrockneter Pilz/ Äquivalent von 6-16 g LEM (Extrakt des Myzels von Lentinan edodes) - Thalle. 6x140mg/jour - wysuszone grzyby/ równowartość 6-16 g całościowego wyciągu z kultury grzybnii shiitake (LEM)		

	- Dried extract of the shii-ta-ke mushroom titrated in beta glucan polysaccharides : 16 mg per day including lentinan 6 mg and 10 mg other polysaccharides as KS2, AC2P polysaccharides		
ID	Food or Food constituent	Health Relationship	Proposed wording
2155	Vaccinium macrocarpon (Common Name : Cranberry)	Immune health	- Contributes to the natural defences of the body - support of the body's defence - supports the immune system
	Conditions of use		
	- owoce/ zwykle konsumowane jako tradycyjny artykuł żywnościowy w normalnej diecie/ równowartość minimum 15ml soku z żurawin lub 800 mg owocu żurawiny na dzień - Fruit. The equivalent of minimum 15 ml of cranberry juice or 800 mg of cranberry solids per day		
Comments from Member States No clarification from producers			
ID	Food or Food constituent	Health Relationship	Proposed wording
2485	Ribes nigrum (Blackcurrant).	Invigoration the body.	1. Builds up resistance against stress and unfavourable environmental conditions. 2. A generally restorative tea which is rich in vitamins, minerals, antioxidants and essential herbal oils and helps the body overcome stress and exertion, prevents setting in of changes associated with age, improves the immunity.
	Conditions of use		
	- Leaf: 140 - 250 mg, Fruit: 80 - 90 mg / Used as part of a multibotanical combination.		
No clarification provided by Member States			
ID	Food or Food constituent	Health Relationship	Proposed wording
2486	Rubus caesicus.	Invigoration the body.	1. A generally restorative tea which is rich in vitamins, minerals, antioxidants and essential herbal oils and helps the body overcome stress and exertion, prevents setting in of changes associated with age, improves the immunity.
	Conditions of use		
	- Herb: 140 - 150 mg / Used as part of a multibotanical combination.		
No clarification provided by Member States			
ID	Food or Food constituent	Health Relationship	Proposed wording
2505	Zea mays (Maize)	Kidneys health	For the urogenital system health

			— kidney activity improving, lightly diuretic, disinfecting and anti-inflammatory effect
Conditions of use			
- Extract: 10mg / Used as part of a multibotanical combination			
ID	Food or Food constituent	Health Relationship	Proposed wording
2859	Mangosteen (<i>Garcinia mangostana</i> L) fruits and extracts derived from the fruits	Immune support <u>Clarification provided</u> Its digestive, carminative & stomachic effects help keep the digestive tract healthy.	Mangosteen whole fruit juice/concentrate [contains xanthones which] may help to support the immune system
Conditions of use			
- Typical adult dosage: 30-100 ml daily of whole fruit juice.			
ID	Food or Food constituent	Health Relationship	Proposed wording
2862	Mangosteen (<i>Garcinia mangostana</i> L) fruits and extracts derived from the fruits	Regulation of inflammatory responses in the body <u>Clarification provided</u> Antioxidant (free radical scavenging) activity and suppression of pro-inflammatory cytokines production (e.g. TNF- α)	Mangosteen whole fruit juice/concentrate [contains xanthones which] may help regulate anti-inflammatory responses [in the body]
Conditions of use			
- Typical adult dosage: 30-100 ml daily of whole fruit juice.			
ID	Food or Food constituent	Health Relationship	Proposed wording
3139	AHCC - Active Hexose Correlated Compound	support of immunity <u>Clarification provided</u> AHCC supplementation boosts NK activity - natural killer cells (or NK cells) are a type of cytotoxic lymphocyte that constitute a major component of the innate immune system. AHCC supplementation boosts NK cells (natural killer cells) and thus increase immunity response	activates immune system, exert potential effects on the immune system - stimulating immunity
Conditions of use			
- 320 mg of AHCC per day			
ID	Food or Food constituent	Health Relationship	Proposed wording
3521	Pleurotus ostreatus (oyster mushroom)	Pleurotus ostreatus and Immune system	Contributes to natural immunological defences

	<p>Conditions of use</p> <ul style="list-style-type: none"> - The equivalent of 2 grams dried Pleurotus ostreatus per day 		
	<p>Comments from Member States</p> <p>Only the example of wording is modified as follows: Contributes to the natural defences/support of natural resistance</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
3635	VACCINIUM VITIS-IDAEA L.	Contributes to body defences against external agents	Increases the physiological resistance of the organism in case of severe ambient conditions.
	<p>Conditions of use</p> <ul style="list-style-type: none"> - 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 		
	<p>No clarification provided by Member States</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
3774	Lentinula edodes (Common Name : Shitake)	Immune health	Contributes to natural immunological defences
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Dried mushroom / The equivalent of 6-16 g LEM (Lentinan edodes mycelium extract) 		
	<p>No clarification provided by Member States</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
3896	Vaccinium macrocarpon (Common Name : Cranberry)	Immune health	<ul style="list-style-type: none"> - contributes to the natural defences of the body - support of the body's defence - supports the immune system
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Fruit / Usual consumption as traditional foodstuff in a normal diet / The equivalent of minimum 15 ml of cranberry juice or 800 mg of cranberry solids per day 		
	<p>No clarification provided by Member States</p>		

GLOSSARY AND ABBREVIATIONS

IL	Interleukin
LA	Linoleic acid
LNA	Alpha-linolenic acid
NFkappaB	Nuclear factor-kappa B
Th	T helper
TNF	Tumor necrosis factor