

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to vitamin B12 and contribution to normal neurological and psychological functions (ID 95, 97, 98, 100, 102, 109), contribution to normal homocysteine metabolism (ID 96, 103, 106), maintenance of normal bone (ID 104), maintenance of normal teeth (ID 104), maintenance of normal hair (ID 104), maintenance of normal skin (ID 104), maintenance of normal nails (ID 104), reduction of tiredness and fatigue (ID 108), and cell division (ID 212) 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 vitamin B12 and contribution to normal neurological and psychological functions, contribution to normal homocysteine metabolism, maintenance of normal bone, maintenance of normal teeth, maintenance of normal hair, maintenance of normal skin, maintenance of normal nails, reduction of tiredness and fatigue, and cell division. 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.

¹ On request from the European Commission, Question No EFSA-Q-2008-883, EFSA-Q-2008-890, EFSA-Q-2008-891, EFSA-Q-2008-893, adopted on 30 April 2010. Question No EFSA-Q-2008-882, EFSA-Q-2008-884, EFSA-Q-2008-885, EFSA-Q-2008-887, EFSA-Q-2008-889, EFSA-Q-2008-895, EFSA-Q-2008-896, EFSA-Q-2008-999, adopted on 09 July 2010.

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The food constituent that is the subject of the health claims is vitamin B12, which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that vitamin B12 is sufficiently characterised.

Contribution to normal neurological and psychological functions

The claimed effects are “neurological system: structure and function”, “cognitive function in ageing”, “nerve system and cognitive function”, “the role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)”. The target population is assumed to be the general population. The Panel considers that contribution to normal neurological and psychological functions, which encompass cognitive and affective domains, is a beneficial physiological effect.

Vitamin B12 has a central role in the normal functions of the brain and nervous system. It is well established from clinical studies that vitamin B12 deficiency produces adverse neurological and psychological effects.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B12 and contribution to normal neurological and psychological functions.

Contribution to normal homocysteine metabolism

The claimed effects are “homocysteine metabolism”, “homocysteine levels”, and “heart health”. The target population is assumed to be the general population. The Panel considers that contribution to normal homocysteine metabolism is a beneficial physiological effect.

Deficiencies of folate, vitamin B6 and vitamin B12 lead to impaired remethylation of homocysteine causing mild, moderate, or severe elevations in plasma homocysteine.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B12 and contribution to normal homocysteine metabolism.

Maintenance of normal bone

The claimed effect is “bone/teeth/hair/skin and nail health”. The target population is assumed to be the general population. The Panel considers that maintenance of normal bone is a beneficial physiological effect.

The Panel considers that no conclusions on a causal relationship between the dietary intake of vitamin B12 and the claimed effect can be drawn from the observational study provided.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal bone.

Maintenance of normal teeth

The claimed effect is “bone/teeth/hair/skin and nail health”. The target population is assumed to be the general population. The Panel considers that maintenance of normal teeth is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal teeth.

Maintenance of normal hair

The claimed effect is “bone/teeth/hair/skin and nail health”. The target population is assumed to be the general population. The Panel considers that maintenance of normal hair is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal hair.

Maintenance of normal skin

The claimed effect is “bone/teeth/hair/skin and nail health”. The target population is assumed to be the general population. The Panel considers that maintenance of normal skin is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal skin.

Maintenance of normal nails

The claimed effect is “bone/teeth/hair/skin and nail health”. The target population is assumed to be the general population. The Panel considers that maintenance of normal nails is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal nails.

Reduction of tiredness and fatigue

The claimed effect is “vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status”. The target population is assumed to be the general population. The Panel considers that reduction of tiredness and fatigue is a beneficial physiological effect.

Haematological effects of vitamin B12 deficiency include amongst others a gradual onset of the common symptoms of anaemia, such as diminished energy and exercise tolerance, fatigue, shortness of breath and palpitations.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B12 and reduction of tiredness and fatigue.

Cell division

The claimed effect is “supports folic acid metabolism, in succession: DNA synthesis”. The target population is assumed to be the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect is related to cell division.

A claim on vitamin B12 and normal cell division has already been assessed with a favourable outcome.

Conditions and possible restrictions of use

The Panel considers that in order to bear the claims a food should be at least a source of vitamin B12 as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

KEY WORDS

Vitamin B12, neurological, psychological, homocysteine, bone, teeth, hair, skin, nails, fatigue, cell division, 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

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is vitamin B12, which is a specific group of cobalt-containing corrinoids with biological activity in humans. Recommended biochemical nomenclature restricts the term vitamin B12 for the particular form of cobalamin known as cyanocobalamin and all cobalamins exhibiting qualitatively the biological activity of cyanocobalamin. Cobalamins do not occur in plants but are synthesised by certain bacteria, fungi and algae, which constitute the ultimate source of all cobalamin found in nature (Green, 2005). Vitamin B12 is a well recognised nutrient and is measurable in foods by established methods.

Vitamin B12 occurs naturally in foods and is authorised for addition to foods and for use in food supplements (Annex I of the Regulation (EC) No 1925/2006⁶ and Annex I of Directive 2002/46/EC⁷). This evaluation applies to vitamin B12 naturally present in foods and those forms authorised for addition to foods (Annex II of the Regulation (EC) No 1925/2006 and Annex II of Directive 2002/46/EC).

The Panel considers that the food constituent, vitamin B12, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Contribution to normal neurological and psychological functions (ID 95, 97, 98, 100, 102, 109)

The claimed effects are “neurological system: structure and function”, “cognitive function in ageing”, “nerve system and cognitive function”, “the role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions

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 Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38.

⁷ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57.

which determine aspects like concentration, learning, memory and reasoning)”. The Panel assumes that the target population is the general population.

The Panel notes that the claimed effects relate to neurological and psychological functions.

The Panel considers that contribution to normal neurological and psychological functions, which encompass cognitive and affective domains, is a beneficial physiological effect.

2.2. Contribution to normal homocysteine metabolism (ID 96, 103, 106)

The claimed effects are “homocysteine metabolism”, “homocysteine levels”, and “heart health”. The Panel assumes that the target population is the general population.

In the context of the proposed wording for ID 106, the Panel assumes that the claimed effect is related to normal homocysteine metabolism.

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

2.3. Maintenance of normal bone (ID 104)

The claimed effect is “bone/teeth/hair/skin and nail health”. The Panel assumes that the target population is the general population.

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

2.4. Maintenance of normal teeth (ID 104)

The claimed effect is “bone/teeth/hair/skin and nail health”. The Panel assumes that the target population is the general population.

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

2.5. Maintenance of normal hair (ID 104)

The claimed effect is “bone/teeth/hair/skin and nail health”. The Panel assumes that the target population is the general population.

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

2.6. Maintenance of normal skin (ID 104)

The claimed effect is “bone/teeth/hair/skin and nails health”. The Panel assumes that the target population is the general population.

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

2.7. Maintenance of normal nails (ID 104)

The claimed effect is “bone/teeth/hair/skin and nail health”. The Panel assumes that the target population is the general population.

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

2.8. Reduction of tiredness and fatigue (ID 108)

The claimed effect is “vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status”. The Panel assumes that the target population is the general population.

The Panel considers that reduction of tiredness and fatigue is a beneficial physiological effect.

2.9. Cell division (ID 212)

The claimed effect is “supports folic acid metabolism, in succession: DNA synthesis”. 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 is related to cell division.

A claim on vitamin B12 and normal cell division has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009).

3. Scientific substantiation of the claimed effect

The two forms of vitamin B12 that function as coenzymes for metabolic reactions are methylcobalamin and 5'-deoxyadenosylcobalamin.

3.1. Contribution to normal neurological and psychological functions (ID 95, 97, 98, 100, 102, 109)

Vitamin B12 has a central role in the normal functions of the brain and nervous system. It is well established from clinical studies that vitamin B12 deficiency produces adverse neurological effects owing to demyelination in the spinal cord, brain, and optic and peripheral nerves (Allen et al., 1996; Gibney et al., 2002; Wynn and Wynn, 1998). Serious vitamin B12 deficiency leads to an irreversible polyneuropathy. Clinical signs include e.g. abnormal proprioception, taste, smell and vision, irritability, memory loss, dementia, ataxia (Allen et al., 1996; Gibney et al., 2002; Wynn and Wynn, 1998).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B12 and contribution to normal neurological and psychological functions.

3.2. Contribution to normal homocysteine metabolism (ID 96, 103, 106)

Methylcobalamin, a coenzyme form of vitamin B12, is involved in the remethylation of homocysteine to methionine by the methionine synthase which requires both folate and vitamin B12 as cofactors (Stabler, 2006).

Under conditions of maximal metabolic efficiency, plasma concentration of homocysteine ranges from 4 to 10 µmol/L. Metabolic blocks in homocysteine metabolism lead to accumulation of intracellular homocysteine with subsequent export into the blood. Depending on the magnitude of the metabolic impairment, plasma homocysteine can rise to varying degrees. Deficiencies of folate, vitamin B6 and vitamin B12 lead to impaired remethylation of homocysteine causing mild, moderate, or severe elevations in plasma homocysteine, depending on the severity of the deficiency, as well as coexistence of genetic or other factors that interfere with homocysteine metabolism (Miller, 2005).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B12 and contribution to normal homocysteine metabolism.

3.3. Maintenance of normal bone (ID 104)

A total of nine references were provided, including three textbooks, two opinions from authoritative bodies, one review and three human studies.

One textbook mentioned that cobalamin deficiency had been described in association with reduced bone-derived alkaline phosphatase and osteocalcin in the plasma (Green, 2005). Two studies solely dealt with the putative role of homocysteine as a potential risk factor for the development of osteoporosis (McLean et al., 2004; Van Meurs et al., 2004), without referring to vitamin B12. Dhonukshe-Rutten et al. (2005) reported that high plasma concentrations of homocysteine and low serum concentrations of vitamin B12 and especially the combination of these two parameters were related to high fracture risk, low broadband ultrasound attenuation, and increased bone turnover markers, as studied in 1,267 subjects of the Longitudinal Aging Study Amsterdam. The Panel notes that no conclusions on a causal relationship between the dietary intake of vitamin B12 and the claimed effect can be drawn from this study because residual confounding by other dietary and lifestyle factors inherent in the observational study design cannot be excluded.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal bone.

3.4. Maintenance of normal teeth (ID 104)

A total of nine references were provided, including three textbooks, two opinions from authoritative bodies, one review and three human studies, which were unrelated to the claimed effect. The Panel considers that no conclusions could be drawn for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal teeth.

3.5. Maintenance of normal hair (ID 104)

A total of nine references were provided, including three textbooks, two opinions from authoritative bodies, one review and three human studies, which were unrelated to the claimed effect. The Panel considers that no conclusions could be drawn for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal hair.

3.6. Maintenance of normal skin (ID 104)

A total of nine references were provided, including three textbooks, two opinions from authoritative bodies, one review and three human studies, which were unrelated to the claimed effect. The only reference referring to skin mentioned that cobalamin deficiency may also be associated with skin hyper-pigmentation (Green, 2005). The Panel considers that no conclusions can be drawn for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal skin.

3.7. Maintenance of normal nails (ID 104)

A total of nine references were provided, including three textbooks, two opinions from authoritative bodies, one review and three human studies, which were unrelated to the claimed effect. The Panel considers that no conclusions can be drawn for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal nails.

3.8. Reduction of tiredness and fatigue (ID 108)

The haematological effects of vitamin B12 deficiency are indistinguishable from those of folate deficiency. These include pallor of the skin associated with a gradual onset of the common symptoms of anaemia, such as diminished energy and exercise tolerance, fatigue, shortness of breath and palpitations (IoM, 2000).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B12 and reduction of tiredness and fatigue.

4. Panel's comments on the proposed wording

4.1. Contribution to normal neurological and psychological functions (ID 95, 97, 98, 100, 102, 109)

The Panel considers that the following wording reflects the scientific evidence: "Vitamin B12 contributes to normal neurological and psychological functions".

4.2. Contribution to normal homocysteine metabolism (ID 96, 103, 106)

The Panel considers that the following wording reflects the scientific evidence: "Vitamin B12 contributes to normal homocysteine metabolism".

4.3. Reduction of tiredness and fatigue (ID 108)

The Panel considers that the following wording reflects the scientific evidence: "Vitamin B12 can contribute to the reduction of tiredness and fatigue".

5. Conditions and possible restrictions of use

The Panel considers that in order to bear the claims a food should be at least a source of vitamin B12 as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population. For vitamin B12 no adverse effects have been reported after high dose supplementation and no Tolerable Upper Intake Levels (ULs) have been set (SCF, 2000).

CONCLUSIONS

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

- The food constituent, vitamin B12, which is the subject of the health claims is sufficiently characterised.

Contribution to normal neurological and psychological functions (ID 95, 97, 98, 100, 102, 109)

- The claimed effects are “neurological system: structure and function”, “cognitive function in ageing”, “nerve system and cognitive function”, “the role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)”. The target population is assumed to be the general population. Contribution to normal neurological and psychological functions, which encompass cognitive and affective domains, is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of vitamin B12 and contribution to normal neurological and psychological functions.
- The following wording reflects the scientific evidence: “Vitamin B12 contributes to normal neurological and psychological functions”.

Contribution to normal homocysteine metabolism (ID 96, 103, 106)

- The claimed effects are “homocysteine metabolism”, “homocysteine levels”, and “heart health”. The target population is assumed to be the general population. Contribution to normal homocysteine metabolism is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of vitamin B12 and contribution to normal homocysteine metabolism.
- The following wording reflects the scientific evidence: “Vitamin B12 contributes to normal homocysteine metabolism.”

Maintenance of normal bone (ID 104)

- The claimed effect is “bone/teeth/hair/skin and nail health”. The target population is assumed to be the general population. Maintenance of normal bone is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal bone.

Maintenance of normal teeth (ID 104)

- The claimed effect is “bone/teeth/hair/skin and nail health”. The target population is assumed to be the general population. Maintenance of normal teeth is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal teeth.

Maintenance of normal hair (ID 104)

- The claimed effect is “bone/teeth/hair/skin and nail health”. The target population is assumed to be the general population. Maintenance of normal hair is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal hair.

Maintenance of normal skin (ID 104)

- The claimed effect is “bone/teeth/hair/skin and nail health”. The target population is assumed to be the general population. Maintenance of normal skin is a beneficial physiological effect.

- A cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal skin.

Maintenance of normal nails (ID 104)

- The claimed effect is “bone/teeth/hair/skin and nail health”. The target population is assumed to be the general population. Maintenance of normal nails is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of vitamin B12 and maintenance of normal nails.

Reduction of tiredness and fatigue (ID 108)

- The claimed effect is “vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status”. The target population is assumed to be the general population. Reduction of tiredness and fatigue is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of vitamin B12 and reduction of tiredness and fatigue.
- The following wording reflects the scientific evidence: “Vitamin B12 can contribute to the reduction of tiredness and fatigue.”

Cell division (ID 212)

- The claimed effect is “supports folic acid metabolism, in succession: DNA synthesis”. The target population is assumed to be the general population.
- A claim on vitamin B12 and normal cell division has already been assessed with a favourable outcome.

Conditions and possible restrictions of use

- In order to bear the claims a food should be at least a source of vitamin B12 as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-882, EFSA-Q-2008-883, EFSA-Q-2008-884, EFSA-Q-2008-885, EFSA-Q-2008-887, EFSA-Q-2008-889, EFSA-Q-2008-890, EFSA-Q-2008-891, EFSA-Q-2008-893, EFSA-Q-2008-895, EFSA-Q-2008-896, EFSA-Q-2008-999). 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 foods⁸ (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 FOOD⁹

Foods are commonly involved in many different functions¹⁰ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

⁸ OJ L12, 18/01/2007

⁹ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

¹⁰ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

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

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

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

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

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

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

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

WORDING OF HEALTH CLAIMS

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

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

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a

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

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

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

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

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

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

TERMS OF REFERENCE

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

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

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

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

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

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

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

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/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 vitamin B12, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
95	Vitamin B12	Neurological system: structure and function	Contributes to the maintenance of a healthy nervous system; Aids in normal mental function.
	Conditions of use - Must at least be a source of vitamin/s as per annex to regulation 1924/2006 - Applicable to both children and adults		
ID	Food or Food constituent	Health Relationship	Proposed wording
96	Vitamin B12 (cyanocobalamin)	Homocysteine metabolism	vitamin B12 (cyanocobalamin) helps maintain normal blood homocysteine levels.
	Conditions of use - Zufuhrempfehlung (RDA): 2 µg / d Tolerable Upper Intake Level: 1 mg / d - MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG - MUST AT LEAST BE ASOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 - Only for products with at least 100 % RDA		
ID	Food or Food constituent	Health Relationship	Proposed wording
97	Vitamin B12	Neurological system: structure and function	Is needed to keep the nervous system healthy; Is needed for normal mental function
	Conditions of use - Minimum 15% RDA (0.15 mg) daily - Daily amount to be consumed to produce claimed effect: 1 - 1.40 mg - Target group: All adults aged 18 years and over - Target group: general population including children and adults		
ID	Food or Food constituent	Health Relationship	Proposed wording
98	Vitamin B12	Cognitive function in ageing	Helps maintain cognitive performance as you get older; Helps maintain perception as you get older; Support cognitive performance as you get older;

			Support cognitive performance.
Conditions of use - At least 15% of the RDA (RDA is 1µg) - Food supplement with 75µg of vitamin B12 in the daily dose - All adults aged 18 years and over			
ID	Food or Food constituent	Health Relationship	Proposed wording
100	Vitamin B12	Neurological system: structure and function	Supports the structure and function of the neurological system.
Conditions of use - Minimum 15% RDA (0.15 µg)			
ID	Food or Food constituent	Health Relationship	Proposed wording
102	Vitamin B12	Nerve system and cognitive function	Helps maintain the nerve system and cognitive performance.
Conditions of use - 15% of RDA			
ID	Food or Food constituent	Health Relationship	Proposed wording
103	Vitamin B12	Homocysteine levels	Vitamin B12 helps maintain a normal blood homocysteine level.
Conditions of use - Source of / 15% of RDA per 100 g - Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance - Number of nutrients/other substances that are essential to claimed effect: 1 - Names of nutrient/other substances and Quantity in Average daily serving: 15 microgram(s) vitamin B12 - Daily amount to be consumed to produce claimed effect: .15 microgram(s) - Length of time after consumption for claimed effect to become apparent: Regular consumption			
ID	Food or Food constituent	Health Relationship	Proposed wording
104	Vitamin B12	Bone/Teeth/Hair /Skin and Nail health	Necessary for healthy teeth, bones, hair, skin and nails.
Conditions of use - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.			
ID	Food or Food constituent	Health Relationship	Proposed wording
106	Vitamin B12	Heart Health	Supplementation of Vitamin B12 can lower blood levels of amino acid homocysteine which may help maintain a healthy heart and circulation.

<p>Conditions of use</p> <ul style="list-style-type: none"> - Food supplement with 75µg of vitamin B12 in the daily dose - Only for products with at least 100 % RDA - Minimum 100% RDA dla kwasu foliowego (200 µg), witaminy B6 (2 mg) oraz witaminy B12 (1µg). - Minimum 15% RDA (0,15 µg) 			
ID	Food or Food constituent	Health Relationship	Proposed wording
108	Vitamin B12	<p>Vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status</p> <p><u>Clarification provided</u></p> <p>Improve work endurance in situations of inadequate micronutrient status</p>	<p>Supplementation with B-vitamins, iron, magnesium as well as vitamin C can reduce fatigue and tiredness in situations of inadequate micro-nutrient status.</p>
<p>Conditions of use</p> <ul style="list-style-type: none"> - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006. 			
ID	Food or Food constituent	Health Relationship	Proposed wording
109	Vitamin B12	<p>The role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)</p>	<p>Water-soluble vitamins, calcium, magnesium and zinc are essential for mental function and performance. In situations of inadequate micronutrient status, supplementation with water-soluble vitamins, minerals and zinc can sustain mental performance;</p> <p>Helps maintain activity, memory, perception of the environment, particularly in the elderly;</p> <p>Promotes mental concentration;</p> <p>Stimulates mental capacities;</p> <p>Improves the psychoemotional state.</p>
<p>Conditions of use</p> <p>Only for products with at least 100 % RDA of vitamins.</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
212	Vitamin B12	<p>DNA-Synthese</p> <p><u>Clarification provided</u></p> <p>supports folic acid metabolism, in succession:</p>	<p>An allen Wachstumsvorgängen beteiligt.</p> <p><u>Clarification provided</u></p> <p>Significantly involved in all</p>

		DNA synthesis	growth processes
	Conditions of use - none provided		