SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to vitamin B12 and red blood cell formation (ID 92, 101), cell division (ID 93), energy-yielding metabolism (ID 99, 190) and function of the immune system (ID 107) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

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

European Food Safety Authority (EFSA), Parma, Italy

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 the following claimed effects: red blood cell formation, cell division, energy-yielding metabolism and function of the immune system. 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 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.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B12 and normal red blood cell formation, normal cell division, normal energy-yielding metabolism and normal function of the immune system.

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, vitamins, cell division, red blood cells, energy metabolism, immune system, health claims.

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2 Panel members: Jean-Louis Bresson, Albert Flynn, Marina Heinonen, Karin Hulshof, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Hildegard Przyrembel, Seppo Salminen, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Henk van den Berg, Hendrik van Loveren and Hans Verhagen.
Correspondence: nda@efsa.europa.eu

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[3] submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims. The information provided in the consolidated list for the health claims subject to 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 it is authorised for addition to foods and for use in food supplements (Annex I of the Regulation (EC) No 1925/2006[4] and Annex I of Directive 2002/46/EC[5]). 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. Red blood cell formation (ID 92, 101)

The claimed effects are “blood formation” and “blood function”. The Panel assumes that the target population is the general population.

The Panel considers that normal red blood cell formation is beneficial to human health.

2.2. Cell division (ID 93)

The claimed effect is “cell division”. The Panel assumes that the target population is the general population.

The Panel notes that cell division is a crucial process for tissue growth and development and for tissue maintenance through cell turnover.

[3] 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.
[4] 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.
[5] 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.

The Panel considers that normal cell division is beneficial to human health.

2.3. Energy-yielding metabolism (ID 99, 190)

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

The Panel considers that normal energy-yielding metabolism is beneficial to human health.

2.4. Function of the immune system (ID 107)

The claimed effect is "the role of vitamins and minerals in immunity". The Panel assumes that the target population is the general population.

The Panel considers that the normal function of the immune system is beneficial to human health.

3. Scientific substantiation of the claimed effect

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

3.1. Red blood cell formation (ID 92, 101)

Vitamin B12, in association with folate, is needed for the metabolism of methyl groups involved in the synthesis of nucleotides, so that vitamin B12 deficiency leads to impaired DNA synthesis that results in megaloblastic anaemia. The nuclei of the developing hematopoietic precursor cells in the bone marrow remain immature compared with the cytoplasm, which is maturing normally. The morphological result is a macrocytic red blood cell (high mean cell volume). Many cells die in the bone marrow, possibly by apoptosis (Stabler, 2006).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B12 and normal red blood cell formation.

3.2. Cell division (ID 93)

Vitamin B12 is required as coenzyme in the form of methylcobalamin for the transmethylation of homocysteine to methionine by 5-methyl-tetrahydrofolate. Methionine is an essential amino acid that is necessary for protein synthesis but is also a crucial methyl donor after activation to S-adenosylmethionine (SAM). SAM is a source of methyl groups for the synthesis of creatine phospholipids and neurotransmitters, and for DNA, RNA, and protein methylation (Green, 2005; Stabler, 2006).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B12 and normal cell division.

3.3. Energy-yielding metabolism (ID 99, 190)

Vitamin B12 is required as coenzyme in the form of deoxyadenosylcobalamin for the isomerisation of methylmalonyl coenzyme A (CoA) to succinyl-CoA, which is an intermediate in the citric acid cycle (Stabler, 2006).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B12 and normal energy-yielding metabolism.

3.4. Function of the immune system (ID 107)

Vitamin B12 interferes with immune function through its involvement in nucleic acid and protein biosynthesis in concert with vitamin B6 and folate. In human studies with vitamin B12-deficient patients an abnormally high CD4+/CD8+ ratio and suppressed NK cell activity were reported, which could be restored by administration of vitamin B12. Another finding was an impaired antibody response to pneumococcal polysaccharide vaccine, suggesting that the decreased availability of vitamin B12 to rapidly proliferating B lymphocytes may impair clonal expansion and synthesis of specific immunoglobulins (Wintergerst et al., 2007).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B12 and normal function of the immune system.

4. Panel's comments on the proposed wordings

4.1. Red blood cell formation (ID 92, 101)

The Panel considers that the following wording reflects the scientific evidence: "vitamin B12 contributes to normal red blood cell formation".

4.2. Cell division (ID 93)

The Panel considers that the following wording reflects the scientific evidence: "vitamin B12 contributes to normal cell division".

4.3. Energy-yielding metabolism (ID 99, 190)

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

4.4. Function of the immune system (ID 107)

The Panel considers that the following wording reflects the scientific evidence: "vitamin B12 contributes to a normal function of the immune system".

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. Tolerable Upper Intake Levels (UL) have not been established for vitamin B12 in children, adolescents and adults.

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.

Red blood cell formation (ID 92, 101)

- The claimed effects are "blood formation" and "blood function". The target population is assumed to be the general population. Normal red blood cell formation is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin B12 and normal red blood cell formation.
- The following wording reflects the scientific evidence: "vitamin B12 contributes to normal red blood cell formation".

Cell division (ID 93)

- The claimed effect is "cell division". The target population is assumed to be the general population. Normal cell division is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin B12 and normal cell division.
- The following wording reflects the scientific evidence: "vitamin B12 contributes to normal cell division".

Energy-yielding metabolism (ID 99, 190)

- The claimed effect is "energy metabolism". The target population is assumed to be the general population. Normal energy-yielding metabolism is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin B12 and normal energy-yielding metabolism.
- The following wording reflects the scientific evidence: "vitamin B12 contributes to normal energy metabolism".

Function of the immune system (ID 107)

- The claimed effect is "the role of vitamins and minerals in immunity". The target population is assumed to be the general population. Normal function of the immune system is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin B12 and normal function of the immune system.
- The following wording reflects the scientific evidence: "vitamin B12 contributes to a normal function of the immune system".

Conditions and possible restrictions of use

- In order to bear the claim 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-2008-879, EFSA-Q-2008-880, EFSA-Q-2008-886, EFSA-Q-2008-888, EFSA-Q-2008-894, EFSA-Q-2008-977). The scientific substantiation is based on the information provided by the Members States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

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

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[6] (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

a) the role of a nutrient or other substance in growth, development and the functions of the body; or

b) psychological and behavioural functions; or

c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[7]

Foods are commonly involved in many different functions[8] 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.

[6] OJ L12, 18/01/2007
[7] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[8] 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 DISCAIMER

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
92	Vitamin B12	Blood formation	- vitamin B12 (cyanocobalamin) is needed for blood formation
	Conditions of use - Must at least be a source of vitamins as per annex to Regulation 1924/2006 - Applicable to both children and adults - Quantity in Average daily serving: 0.15 microgram(s) Vitamin b12 - Daily amount to be consumed to produce claimed effect: 0.15 microgram(s) - Length of time after consumption for claimed effect to become apparent: Regular consumption - Milks, buttermilks and milk drinks with B12 vitamin content of 0.4µg/100g, 0.8µg/serving - Mind. 15% der RDA gem. NWK-RL 90/496/EWG - Tagesbedarf gemäß NwKVO –1 µg		
93	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Vitamin B12	Cell division (such as in the gastrointestinal tract)	- vitamin B12 (cyanocobalamin) contributes to cell division
	Conditions of use - Must meet minimum requirements for use of the claim "source of Vitamin B12 (Cyanocobalamin) " as per Annex to Regulation 1924/2006. - Applicable to both children and adults - Quantity in Average daily serving: 0.15 microgram(s) Vitamin B12 - Daily amount to be consumed to produce claimed effect: 0.15 microgram(s) - Length of time after consumption for claimed effect to become apparent: Regular consumption - Zufuhrempfehkung (RDA): 2 µg /d - Tolerable Upper Intake Level: 1 mg /d		
99	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Vitamin B12	Energy metabolism: propionate and amino acids	- vitamin B12 (cyanocobalamin) is needed/important for energy metabolism/the transformation of food into energy
	- Must at least be a source of vitamins as per annex to Regulation 1924/2006 - Tagesbedarf (B12): DGE: 3 µg, durchschnittlicher Gehalt der wichtigsten Fischarten:		

	3µg/100g		
101	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Vitamin B12	Blood function	- Vitamin B12 is important for normal blood function
	Conditions of use - Source of / 15% of RDA per 100 g - Daily amount to be consumed to produce claimed effect: 1.40 microgram(s) - Length of time after consumption for claimed effect to become apparent: Habitual intake		
107	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Vitamin B12	The role of vitamins and minerals in immunity	- Vitamin C, E, A, D, B6, B12, folic acid, Selenium, Zinc, Copper and Iron are important for the immune system/natural defenses
	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. - Minimum 15% RDA (0,15 µg) dziennie. - Witaminy na poziomie 100% RDA. Cynk 15%. RDA (2,25 mg). Żelazo 15% RDA (2,1 mg). Selen minimum 8,25 µg dziennie. Miedź minimum 135 µg dziennie.		
190	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Vitamin B12	Energy metabolism	- vitamin b12 is essential for energy metabolism -vitamin b12 is essential for the transformation of food into energy
	Conditions of use - Quantity in average daily serving: 0.15 micrograms - Daily amount to be consumed to produce claimed effect: 0.15 microgram(s) - Length of time after consumption for claimed effect to become apparent: Regular consumption		

GLOSSARY / ABBREVIATIONS

CoA	Coenzyme A
NK cell	Natural killer cell
SAM	S-adenosylmethionine
UL	Tolerable Upper Intake Levels