

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to vitamin B6 and protein and glycogen metabolism (ID 65, 70, 71), function of the nervous system (ID 66), red blood cell formation (ID 67, 72, 186), function of the immune system (ID 68), regulation of hormonal activity (ID 69) and mental performance (ID 185) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

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 B6 and the following claimed effects: protein and glycogen metabolism, function of the nervous system, red blood cell formation, function of the immune system, regulation of hormonal activity and mental performance. 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 B6, which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that vitamin B6 is sufficiently characterised.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B6 and normal protein and glycogen metabolism, normal function of the nervous system, normal red blood cell formation, normal function of the immune system and regulation of hormonal activity.

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¹ On request from the European Commission, Question No EFSA-Q-2008-852, EFSA-Q-2008-853, EFSA-Q-2008-854, EFSA-Q-2008-855, EFSA-Q-2008-856, EFSA-Q-2008-857, EFSA-Q-2008-858, EFSA-Q-2008-859, EFSA-Q-2008-972, EFSA-Q-2008-973 adopted on 02 July 2009.

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The evidence provided does not establish that inadequate intake of vitamin B6 leading to impaired function of the above health relationships occurs in the general EU population.

The Panel considers that, in order to bear the claims, a food should be at least a source of vitamin B6 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.

The Panel considers that the claim for vitamin B6 and mental performance encourages excess consumption of vitamin B6 and therefore does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

KEY WORDS

Vitamin B6, protein, glycogen, metabolism, iron, hormones, immune system, red blood cells, nervous system, 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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The European Food Safety Authority wishes to thank for the preparation of this opinion:

The members of the Working Group on Claims: Jean-Louis Bresson, Albert Flynn, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Sean (J.J.) Strain, Inge Tetens, Henk van den Berg, Hendrik van Loveren and Hans Verhagen.

The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain and Peter Willatts.



INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006³ 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 B6, which is a group of compounds comprising three free forms, pyridoxine, pyridoxal, pyridoxamine, and their 5'-phosphates derivatives (PNP, PLP and PMP). Vitamin B6 occurs naturally in foods, mainly as pyridoxal phosphate (animals), pyridoxine beta-glucoside (plants), and some pyridoxyl peptides (processed foods), with varied bioavailability as vitamin B6. Vitamin B6 is a well recognised nutrient and is measurable in foods by established methods.

Vitamin B6 it is authorised for addition to foods (Annex I of the Regulation (EC) No 1925/2006⁴ and Annex I of Directive 2002/46/EC⁵). This evaluation applies to vitamin B6 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 B6, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Protein and glycogen metabolism (ID 65, 70, 71)

The claimed effect is "protein, glucose, glycogen/stored carbohydrate, macronutrient metabolism". The Panel assumes that the target population is the general population.

The Panel considers that a normal protein and glycogen metabolism is beneficial to human health.

2.2. Function of the nervous system (ID 66)

The claimed effect is "nervous system function". The Panel assumes that the target population is the general population.

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

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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.



2.3. Red blood cell formation (ID 67, 72, 186)

The claimed effects are "transport and metabolism of iron", "blood health", "vitamin B6 helps the body effective use iron". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that the claimed effect relates to the formation of normal red blood cells.

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

2.4. Function of the immune system (ID 68)

The claimed effect is "immune system function". The Panel assumes that the target population is the general population.

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

2.5. Regulation of hormonal activity (ID 69)

The claimed effect is "essential co-factor in fatty acid metabolism that impacts upon hormonal health". The Panel assumes that the target population is the general population.

The Panel notes that the claimed effect has not been sufficiently defined in the evidence provided. The Panel assumes that the claimed effect relates to the regulation of hormonal activity.

The Panel considers that regulation of hormonal activity is beneficial to human health.

2.6. Mental performance (ID 185)

The claimed effect is "mental state and performance". The Panel assumes that the target population is the general population.

The Panel considers that normal mental performance is beneficial to human health.

3. Scientific substantiation of the claimed effect

Vitamin B6 functions as a coenzyme in a variety of enzymatic reactions in the metabolism of amino acids, one-carbon units, lipids, the pathways of gluconeogenesis, haem, and neurotransmitter biosynthesis (McCormick, 2006; Mackey, 2006).

3.1. Protein and glycogen metabolism (ID 65, 70, 71)

Nearly all amino acids require at least one pyridoxal phosphate (PLP)-dependent enzyme in their metabolism. PLP is a coenzyme for aminotransaminases that catalyse reversible conversions of amino acids to their corresponding alpha-keto acids with the simultaneous transfer of the amino group to yield PMP. Amino acids can also be modified by PLP-dependent decarboxylation, dehydration, and desulfuration reactions. PLP-dependent decarboxylation reactions are particularly important in the biosynthesis of neurotransmitters (Mackey et al., 2006; IoM, 2000).

Vitamin B6, as PLP, plays a dual role in the synthesis of glucose. Glycogen phosphorylase relies on PLP as a coenzyme in the enzymatic cleavage of glycogen that sequentially releases glucose-1-phosphate units. PLP-dependent transaminases convert gluconeogenic amino acids to alpha-keto acids to create substrates for the production of glucose (Mackey et al., 2006).



The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B6 and normal protein and glycogen metabolism. However, the evidence provided does not establish that inadequate intake of vitamin B6 leading to impaired protein and glycogen metabolism occurs in the general EU population.

3.2. Function of the nervous system (ID 66)

The references provided included 11 textbooks and two reports. One of the reports was on pantothenic acid and the other was an opinion on upper levels of vitamin B6.

Vitamin B6 is taken up into the brain via a transport carrier that has not been well described. In humans, vitamin B6 deficiency is rare. However, when identified, it has been associated with increased seizure activity, an effect which can be ameliorated by vitamin B6 (Fernstrom and Fernstrom, 2005).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B6 and normal function of the nervous system. However, the evidence provided does not establish that inadequate intake of vitamin B6 leading to an impaired function of the nervous system occurs in the general EU population.

3.3. Red blood cell formation (ID 67, 72, 186)

Vitamin B6 plays an important role in haem biosynthesis in the form of PLP. The first enzyme and committed step in haem biosynthesis, aminolevulinate synthase (ALAS), uses PLP as a coenzyme. ALAS catalyses the condensation of succinyl coenzyme A and glycine to form δ -aminolevulinate, which is the precursor for the porphyrin ring. Chronic vitamin B6 deficiency can cause microcytic, hypochromic anaemia in which the haemoglobin concentration of erythrocytes is reduced. Sideroblastic anaemia is an inherited form of ALAS deficiency which can often be successfully treated with pyridoxine supplementation (Mackey et al., 2006; IoM, 2000). Pyridoxal and pyridoxal phosphate also bind to haemoglobin increasing the oxygen-binding capacity, and preventing sickling in sickle-cell haemoglobin (EVM, 2002).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B6 and normal red blood cell formation. However, the evidence provided does not establish that inadequate intake of vitamin B6 leading to impaired red blood cell formation occurs in the general EU population.

3.4. Function of the immune system (ID 68)

The importance of adequate vitamin B6 status for proper immune function in animals, particularly cell-mediated and to a lesser degree humoral immunity, has been shown since the 1950s (Chandra and Sudhakaran, 1990). Vitamin B6 is required as a coenzyme in the metabolism of antibodies and cytokines. Lymphocytes isolated from vitamin B6-deficient persons display reduced proliferation, reduced interleukin-2 production in response to mitogens, and reduced antibody production in response to immunisation (Mackey et al., 2006; Wintergerst et al., 2007).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B6 and normal function of the immune system. However, the evidence provided does not establish that inadequate intake of vitamin B6 leading to an impaired function of the immune system occurs in the general EU population.



3.5. Regulation of hormonal activity (ID 69)

Vitamin B6 in the form of pyridoxal phosphate (PLP) has a role in controlling the action of hormones that act by binding to a nuclear receptor protein and modulating gene expression. Such hormones include androgens, oestrogens, progesterone, glucocorticoids, and thyroid hormone. PLP reacts with a lysine residue in the receptor protein and displaces the hormone-receptor complex from DNA binding, so terminating the hormone action (Bender, 2005).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin B6 and regulation of hormonal activity. However, the evidence provided does not establish that inadequate intake of vitamin B6 leading to impaired regulation of hormonal activity occurs in the general EU population.

3.6. Mental performance (ID 185)

A total of eight references were provided in the consolidated list to support this claim. These included three reviews, one textbook and four human studies where the effect of vitamin B6 on symptoms of depression, cognition, ageing, premenstrual syndrome and memory performance was assessed. The daily doses of vitamin B6 supplementation ranged from 40 - 600 mg.

The Panel notes that the evidence provided for substantiation of the claim relates to studies with vitamin B6 at intakes above the Tolerable Upper Intake Level (UL) (25 mg; SCF, 2000) and that the proposed conditions of use refer to intakes up to three times the UL. The Panel considers that this claim (the proposed wording of this claim) encourages excess consumption of vitamin B6 and therefore does not comply with the criteria laid down in Regulation (EC) No 1924/2006 (Article 3c).

4. Panel's comments on the proposed wordings

4.1. Protein and glycogen metabolism (ID 65, 70, 71)

The Panel considers that the following wording reflects the scientific evidence: "Vitamin B6 contributes to normal protein and glycogen metabolism".

4.2. Function of the nervous system (ID 66)

The Panel considers that the following wording reflects the scientific evidence: "Vitamin B6 contributes to the normal function of the nervous system".

4.3. Red blood cell formation (ID 67, 72, 186)

The Panel considers that the following wording reflects the scientific evidence: "Vitamin B6 contributes to normal red blood cell formation".

4.4. Function of the immune system (ID 68)

The Panel considers that the following wording reflects the scientific evidence: "Vitamin B6 contributes to normal function of the immune system".

4.5. Regulation of hormonal activity (ID 69)

The Panel considers that the following wording reflects the scientific evidence: "Vitamin B6 contributes to the regulation of hormonal activity".



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 B6 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 been established for vitamin B6 in children, adolescents and adults (SCF, 2000).

CONCLUSIONS

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

• The food constituent, vitamin B6, which is the subject of the health claims is sufficiently characterised.

Protein and glycogen metabolism (ID 65, 70, 71)

- The claimed effect is "protein, glucose, glycogen/stored carbohydrate, macronutrient metabolism". The target population is assumed to be the general population. Normal protein and glycogen metabolism is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin B6 and normal protein and glycogen metabolism.
- The evidence provided does not establish that inadequate intake of vitamin B6 leading to impaired protein and glycogen metabolism occurs in the general EU population.
- The following wording reflects the scientific evidence: "Vitamin B6 contributes to normal protein and glycogen metabolism".

Function of the nervous system (ID 66)

- The claimed effect is "nervous system function". The target population is assumed to be the general population, especially women. Normal function of the nervous system is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin B6 and normal function of the nervous system.
- The evidence provided does not establish that inadequate intake of vitamin B6 leading to an impaired function of the nervous system occurs in the general EU population.
- The following wording reflects the scientific evidence: "Vitamin B6 contributes to the normal function of the nervous system".

Red blood cell formation (ID 67, 72, 186)

- The claimed effects are "transport and metabolism of iron", "blood health", "vitamin B6 helps the body effective use iron". 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 B6 and normal red blood cell formation.
- The evidence provided does not establish that inadequate intake of vitamin B6 leading to impaired red blood cell formation occurs in the general EU population.
- The following wording reflects the scientific evidence: "Vitamin B6 contributes to normal red blood cell formation".



Function of the immune system (ID 68)

- The claimed effect is "immune system function". 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 B6 and normal function of the immune system.
- The evidence provided does not establish that inadequate intake of vitamin B6 leading to an impaired function of the immune system occurs in the general EU population.
- The following wording reflects the scientific evidence: "Vitamin B6 contributes to normal function of the immune system".

Regulation of hormonal activity (ID 69)

- The claimed effect is "essential co-factor in fatty acid metabolism that impacts upon hormonal health". The target population is assumed to be the general population. Regulation of hormonal activity is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin B6 and regulation of hormonal activity.
- The evidence provided does not establish that inadequate intake of vitamin B6 leading to impaired regulation of hormonal activity occurs in the general EU population.
- The following wording reflects the scientific evidence: "Vitamin B6 contributes to the regulation of hormonal activity".

Mental performance (ID 185)

- The claimed effect is "mental state and performance". The target population is assumed to be the general population. Normal mental performance is beneficial to human health.
- The claim should not be evaluated in the context of health claims made on foods.

Conditions and possible restrictions of use

• In order to bear the claim a food should be at least a source of vitamin B6 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-2008-852, EFSA-Q-2008-853, EFSA-Q-2008-854, EFSA-Q-2008-855, EFSA-Q-2008-856, EFSA-Q-2008-857, EFSA-Q-2008-858, EFSA-Q-2008-859, EFSA-Q-2008-972, EFSA-Q-2008-973). 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 foods⁶ (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 FOOD⁷

Foods are commonly involved in many different functions⁸ 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.

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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, doseresponse, 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 B6, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
65	Vitamin B6	Protein and glycogen/ stored carbohydrate metabolism	 - vitamin B6 (pyridoxine) is needed for muscle function; - vitamin B6 (pyridoxine) is needed to release energy from carbohydrates stored in muscle; - vitamin B6 (pyridoxine) is necessary for the body to use protein.

Conditions of use

- Must at least be a source of vitamins as per annex to Regulation 1924/2006
- Quantity in Average daily serving: 0.3 mg Vitamin B6 (Pyridoxine)
- Daily amount to be consumed to produce claimed effect: 0.3 milligram (s)
- At least 15% RDA as per annex to Nutrition Labelling Directive 90/496/EEC.
- Daily requirment as per annex to 90/496/EEC 2 mg

	Food or Food constituent	Health Relationship	Proposed wording
66	Vitamin B6	Nervous system function	- vitamin B6 (pyridoxine) is important for the function of the nervous system.

Conditions of use

- Must at least be a source of vitamins as per annex to Regulation 1924/2006
- Only for products with at least 100 % RDA
- Agency guidance for supplements is that products containing >10 mg of vitamin B6 should carry the label advisory statement "Long term intakes [of this amount of vitamin B6] may lead to mild tingling and numbness"
- Applicable to both children and adults
- Milk-based drinks with 0.66mg/100g = serving of vitamin B6, $66 \mu g/serving$ of folic acid and $0.33\mu g/serving$ of vitamin B12.
- Only for products which contain at least 15% RDA in 100 g or 100 ml as per annex to Nutrition Labelling Directive 90/496/EEC

	Food or Food constituent	Health Relationship	Proposed wording
67	Vitamin B6	Transport and metabolism of iron	- vitamin B6 (pyridoxine) helps the body handle iron

Conditions of use

- Must at least be a source of vitamin/s as per annex to regulation 1924/2006
- Agency guidance for supplements is that products containing >10 mg mg of Vitamin B6 (Pyridoxine) should carry the label advisory statement "Long term in takes of this amount of Vitamin B6 may lead to mild tingling and numbness"



- Applicable to both children and adults
- At least 15% RDA in 100 g or 100 ml or per portion according to 90/496/EEC
- Minimum 15% RDA
- 0.4 miligrams vitamin B6, Weight of average daily food serving: 100 gram(s), Daily amount to be consumed to produce claimed effect: 100 gram(s), Product should be consumed in the context of a healthy diet and lifestyle

	Food or Food constituent	Health Relationship	Proposed wording
68	Vitamin B6	Immune system function	- vitamin B6 (pyridoxine) is important for the immune system/natural defences

Conditions of use

- Must at least be a source of vitamin/s as per annex to regulation1924/2006
- Agency guidance for supplements is that products containing >10 mg mg of Vitamin B6 (Pyridoxine) should carry the label advisory statement "Long term in takes of this amount of Vitamin B6 may lead to mild tingling and numbness"
- Applicable to both children and adults
- Only for products which contain at least 15% RDA in 100 g or 100 ml as per annex to Nutrition Labelling Directive 90/496/EEC.
- 30 mg vitamin B6/day, regular consumption
- 2 mg per day

	Food or Food constituent	Health Relationship	Proposed wording
69	Vitamin B6	An essential co-factor in fatty acid metabolism that	- vitamin B6 contributes to the maintenance of hormonal health.
		impacts upon hormonal health	- vitamin B6 helps to maintain hormonal health.
			- vitamin B6 is an essential co-factor in fatty acid metabolism which impacts upon hormonal health.
			- vitamin B6 is an essential co-factor in fatty acid metabolism

Conditions of use

- 1600 μg Daily requirement (B6): 1,6-1,8 mg, average content of common fish: 0,4 mg/100 g
- 30 mg, to treat nausea and emesis during pregnancy 3 x daily 1 pill (if necessary 3 x daily 2 pills) with 10 mg vitamin B6 per pill
- The product must contain no less than 15% RDA; long term intakes of over 10mg of vitamin B6 per day may lead to mild tingling and numbness.

	Food or Food constituent	Health Relationship	Proposed wording
70	Vitamin B6	Protein metabolism	- vitamin B6 is necessary for the normal metabolism of protein.
			- vitamin B6 is involved in the metabolism of amino acids and



proteins.
- vitamin B6 helps release energy from food.

Conditions of use

- Must at least be a source of vitamin/s as per annex to regulation1924/2006
- At least 15% RDA in 100 g or 100 ml or per portion according to 90/496/EEC
- 0,02 mg/g protein (recommendation of DGE); men 1,8 mg, women 1,6 mg; Tolerable Upper Intake Level: 25 mg/d

	Food or Food constituent	Health Relationship	Proposed wording
71	Vitamin B6	Glucose and macronutrient metabolism	- vitamin B6 helps the body build proteins.

Conditions of use

- Source of 15% of RDA per 100g
- Agency guidance for supplements is that products containing >10mg of vitamin B6 should carry the label advisory statement "long term intakes of this amount of vitamin B6 may lead to mild tingling and numbness"
- Minimum 15% RDA

	Food or Food constituent	Health Relationship	Proposed wording
72	Vitamin B6	Blood health	- Important to make normal red blood cells.

Conditions of use

- Only for products which contain at least 15% RDA in 100 g or 100 ml as per annex to Nutrition Labelling Directive 90/496/EEC.
- Source of / 15% of RDA per 100 g
- Agency guidance for supplements is that products containing >10mg of vitamin B6 should carry the label advisory statement "long term intakes of this amount of vitamin B6 may lead to mild tingling and numbness"

	Food or Food constituent	Health Relationship	Proposed wording
185	Vitamin B6	Mental state and	- Positive impact on the mood
		performance	especially in women

Conditions of use

- Food supplement with 75 mg of vitamin B6 in the daily dose.
- <1-50mg daily—Erwachsene

	Food or Food constituent	Health Relationship	Proposed wording
186	Vitamin B6	Vitamin B6 helps the body effective use iron	- vitamin B6 helps the body handle iron.
			- vitamin B6 helps in the transport and metabolism of iron.

Conditions of use

- 0.3 mg vitamin B6 / serving
- Daily amount: .30 milligram(s), Regular consumption



GLOSSARY / ABBREVIATIONS

ALAS Aminolevulinate synthase

PLP Pyridoxal phosphate

PMP Pyridoxamine phosphate

PNP Pyridoxine phosphate

UL Tolerable Upper Intake Levels