SCIENTIFIC OPINION

Scientific Opinion on substantiation of health claims related to thiamine and energy-yielding metabolism (ID 21, 24, 28), cardiac function (ID 20), function of the nervous system (ID 22, 27), maintenance of bone (ID 25), maintenance of teeth (ID 25), maintenance of hair (ID 25), maintenance of nails (ID 25), maintenance of skin (ID 25) 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) No1924/2006. This opinion addresses the scientific substantiation of health claims in relation to thiamine and the following claimed effects: energy-yielding metabolism, cardiac function, function of the nervous system, maintenance of bone, maintenance of teeth, maintenance of hair, maintenance of nails, maintenance of skin. 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 thiamine, which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that thiamine is sufficiently characterised.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of thiamine and normal energy-yielding metabolism, normal cardiac function, and normal function of the nervous system. The evidence provided does not establish that inadequate intake of thiamine leading to impaired function of the above-mentioned health relationships occurs in the general EU population.

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1 On request from the European Commission, Question No EFSA-Q-2008-807, EFSA-Q-2008-808, EFSA-Q-2008-809, EFSA-Q-2008-811, EFSA-Q-2008-812, EFSA-Q-2008-814, EFSA-Q-2008-815, adopted on 02 July 2009.

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.
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For citation purposes: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on substantiation of health claims related to thiamine and energy-yielding metabolism (ID 21, 24, 28), cardiac function (ID 20), function of the nervous system (ID 22, 27), maintenance of bone (ID 25), maintenance of teeth (ID 25), maintenance of hair (ID 25), maintenance of nails (ID 25), maintenance of skin (ID 25) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from the European Commission. EFSA Journal 2009; 7(9):1222. [18 pp.]. doi:10.2903/j.efsa.2009.1222. Available online: www.efsa.europa.eu

On the basis of the data available, the Panel concludes that a cause and effect relationship has not been established between the dietary intake of thiamine and maintenance of bone, maintenance of teeth, maintenance of hair, maintenance of nails, and maintenance of skin.

The Panel considers that, in order to bear the claim, a food should be at least a source of thiamine 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

Thiamine, vitamin B1, nervous system, cardiac function, energy metabolism, bone, teeth, hair, skin, nails, health claims.

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ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the members of the Working Group on Claims for the preparation of this opinion: 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.

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 claim is thiamine (also named vitamin B1), which is a well recognised nutrient and is measurable in foods by established methods.

Thiamine occurs naturally in foods and is authorised for addition to foods (Annex I of the Regulation (EC) No 1925/2006[4] and Annex I of Directive 2002/46/EC[5]). This evaluation applies to thiamine 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, thiamine, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Energy-yielding metabolism (ID 21, 24, 28)

The claimed effects are related to "energy metabolism" and "macronutrient metabolism". The Panel assumes that the target population is the general population.

The Panel notes that in the context of the proposed wording, energy metabolism and macronutrient metabolism relates to energy-yielding metabolism of macronutrients.

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

2.2. Cardiac function (ID 20)

The claimed effect is "normal cardiac function". The Panel assumes that the target population is the general population.

The Panel considers that normal cardiac function is beneficial to human health.

2.3. Function of the nervous system (ID 22, 27)

The claimed effect is "neurological function/neurological systems". The Panel assumes that the target population is the general population.

[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 function of the nervous system is beneficial to human health.

2.4. Maintenance of bone (ID 25)

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 the maintenance of normal bone is beneficial to human health.

2.5. Maintenance of teeth (ID 25)

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 the maintenance of normal teeth is beneficial to human health.

2.6. Maintenance of hair (ID 25)

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 the maintenance of normal hair is beneficial to human health.

2.7. Maintenance of nails (ID 25)

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 the maintenance of normal nails is beneficial to human health.

2.8. Maintenance of skin (ID 25)

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 the maintenance of normal skin is beneficial to human health.

3. Scientific substantiation of the claimed effect

Thiamine (as thiamine diphosphate, a co-enzyme for several oxidative decarboxylation reactions and for transketolase) has a central role in energy-yielding metabolism, especially in the metabolism of carbohydrates and of branched-chain amino acids (Bender, 1999; EC, 2003). Thiamine (as thiamine triphosphate), has a function in nerve conduction (Bender, 1999; IoM, 1998). Thiamine deficiency can result in three distinct syndromes: Beriberi, a chronic peripheral neuritis, which may or may not be associated with heart failure and oedema, acute pernicious (fulminating) beriberi, in which heart failure and life-threatening metabolic acidosis predominate, with little or no evidence of peripheral neuritis, and central nervous system disturbances, Wernicke's encephalopathy with Korsakoff's psychosis (SCF, 1993).

3.1. Energy-yielding metabolism (ID 21, 24, 28)

Thiamine is the precursor for thiamine diphosphate, which is a co-enzyme for a number of reactions involved in carbohydrates and of branched-chain amino acids metabolism and central energy-yielding metabolic pathways, e.g. alpha-ketoacid decarboxylation and transketolation reactions.

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

3.2. Cardiac function (ID 20)

Thiamine has a role in energy metabolism in all cells including cells of the cardiac system (Bender, 1999; IoM, 1998).

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

3.3. Function of the nervous system (ID 22, 27)

Thiamine has a role in energy metabolism in all cells including cells of the nervous system. (Bender, 1999; IoM, 1998).

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

3.4. Maintenance of bone (ID 25)

A total of 6 textbooks or opinions of scientific bodies were provided in which the claimed effect was not stated. The Panel notes that the reference cited did not provide any scientific data that could be used to substantiate the claimed effect.

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

3.5. Maintenance of teeth (ID 25)

A total of 6 textbooks or opinions of scientific bodies were provided in which the claimed effect was not stated. The Panel notes that the reference cited did not provide any scientific data that could be used to substantiate the claimed effect.

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

3.6. Maintenance of hair (ID 25)

A total of 6 textbooks or opinions of scientific bodies were provided in which the claimed effect was not stated. The Panel notes that the reference cited did not provide any scientific data that could be used to substantiate the claimed effect.

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

3.7. Maintenance of nails (ID 25)

A total of 6 textbooks or opinions of scientific bodies were provided in which the claimed effect was not stated. The Panel notes that the reference cited did not provide any scientific data that could be used to substantiate the claimed effect.

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

3.8. Maintenance of skin (ID 25)

A total of 6 textbooks or opinions of scientific bodies were provided in which the claimed effect was not stated. The Panel notes that the reference cited did not provide any scientific data that could be used to substantiate the claimed effect.

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

4. Panel's comments on the proposed wording

4.1. Energy-yielding metabolism (ID 21, 24, 28)

The Panel considers that the following wording reflects the scientific evidence:

"Thiamine contributes to normal energy-yielding metabolism".

4.2. Cardiac function (ID 20)

The Panel considers that the following wording reflects the scientific evidence:

"Thiamine contributes to the normal function of the heart".

4.3. Function of the nervous system (ID 22, 27)

The Panel considers that the following wording reflects the scientific evidence:

"Thiamine contributes to the normal function of the nervous 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 thiamine as per Annex to Regulation 1924/2006. Tolerable Upper Intake Levels (UL) have not been established for thiamine in children, adolescents and adults. The target population is the general population.

CONCLUSIONS

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

- The food constituent, thiamine (vitamin B1), which is the subject of the health claims, is sufficiently characterised.

Energy-yielding metabolism (ID 21, 24, 28)

- The claimed effect is "energy metabolism, macronutrient 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 thiamine and normal energy-yielding metabolism.
- The evidence provided does not establish that inadequate intake of thiamine leading to impaired energy-yielding occurs in the general EU population.
- The following wording reflects the scientific evidence: "Thiamine contributes to normal energy metabolism".

Cardiac function (ID 20)

- The claimed effect is "cardiac function". The target population is assumed to be the general population. Normal cardiac function is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of thiamine and cardiac function.
- The evidence provided does not establish that inadequate intake of thiamine leading to impaired cardiac function occurs in the general EU population.
- The following wording reflects the scientific evidence: "Thiamine contributes to the normal function of the heart".

Function of the nervous system (ID 22, 27)

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

Maintenance of bone (ID 25)

- The claimed effect is "bone/teeth/hair/skin and nail health". The Panel assumes that the target population is the general population. Maintenance of normal bone is beneficial to human health.
- A cause and effect relationship has not been established between the dietary intake of thiamine and the maintenance of normal bone.

Maintenance of teeth (ID 25)

- The claimed effect is "bone/teeth/hair/skin and nail health". The Panel assumes that the target population is the general population. Maintenance of normal teeth is beneficial to human health.

- A cause and effect relationship has not been established between the dietary intake of thiamine and the maintenance of normal teeth.

Maintenance of hair (ID 25)

- The claimed effect is "bone/teeth/hair/skin and nail health". The Panel assumes that the target population is the general population. Maintenance of normal hair is beneficial to human health.
- A cause and effect relationship has not been established between the dietary intake of thiamine and the maintenance of normal hair.

Maintenance of nails (ID 25)

- The claimed effect is "bone/teeth/hair/skin and nail health". The Panel assumes that the target population is the general population. Maintenance of normal function of nails is beneficial to human health.
- A cause and effect relationship has not been established between the dietary intake of thiamine and the maintenance of normal nails.

Maintenance of skin (ID 25)

- The claimed effect is "bone/teeth/hair/skin and nail health". The Panel assumes that the target population is the general population. Maintenance of normal skin is beneficial to human health.
- A cause and effect relationship has not been established between the dietary intake of thiamine and the maintenance of normal skin.

Conditions and possible restrictions of use

- In order to bear the claims a food should be at least a source of thiamine as per Annex to Regulation 1924/2006.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-807, EFSA-Q-2008-808, EFSA-Q-2008-809, EFSA-Q-2008-811, EFSA-Q-2008-812, EFSA-Q-2008-814, EFSA-Q-2008-815). 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/EFSA/efsa_locale-1178620753812_article13.htm.

REFERENCES

Bender DA, 1999. Optimum nutrition: thiamine, biotin and pantothenate. Proceedings of the Nutrition Society, 58, 427-433.

SCF (Scientific Committee for Food), 1992. Nutrient and energy intakes for the European Community.

IoM (Institute of Medicine), 1998. Thiamin In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 4, pp 58-86.

APPENDICES

APPENDIX A:

BACKGROUND AND TERMS OF REFERENCES 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 FOOD[7]

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.

[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 constituent or food, a positive assessment of its safety, nor a decision on whether magnesium 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 wording of the claim and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to Thiamine, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food component	Health Relationship	Proposed wording
20	Vitamin B1	Cardiac function	- vitamin B1 (Thiamin) is needed to keep the heart working properly. - Thiamin is necessary for normal cardiac function. - Thiamin is needed for the normal function of the heart. - Thiamin is necessary for normal neurological and cardiac function.
	Conditions of use - The product must contain at least 15% of the RDA - MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 - MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG - Number of nutrients/other substances that are essential to claimed effect: 1, Names of nutrient/other substances and Quantity in Average daily serving: .21 miligram(s) vitamin B1/ Thiamin, Daily amount to be consumed to produce claimed effect: .21 miligram(s), Length of time after consumption for claimed effect to become apparent: Regular consumption - Oat bran and flakes with thiamine content of 0.5mg/100g, 0.25mg/dl = serving		
21	**Food or Food component**	**Health Relationship**	**Proposed wording**
	Vitamin B1 (Thiamin)	Energy and Carbohydrate metabolism	vitamin B1 (Thiamin) is needed to release the energy from foods; vitamin B1 (Thiamin) is needed to release the energy from carbohydrates.
	Conditions of use • MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG • MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 • Minimum 15% RDA per daily dosage as per 90/496/EC • Tagesbedarf gemäß NwKVO 1,4 mg pro Tag • 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: .21 miligram(s) Vitamin B1 (Thiamin), Daily amount to be consumed to produce claimed effect: .21 miligram(s), Length of time after consumption for claimed effect to become apparent: Regular consumption		

<table>
<tr><td></td><td colspan="3">

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: 8, Names of nutrient/other substances and Quantity in Average daily serving: 0.25mg Vitamin B1, 0.29mg Vitamin B2, 3.20mg Vitamin B3, 1.08mg Vitamin B5, 0.36mg Vitamin B6 2.70mg Zinc, 144.00mg Phosphorus, .03mg, Daily amount to be consumed to produce claimed effect: 500g, Length of time after consumption for claimed effect to become apparent: Depends on the individual's nutritional status
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: 6, Names of nutrient/other substances and Quantity in Average daily serving: 1.4mg Vitamin B1, 2.20mg Vitamin B2, 18mg Vitamin B3, 4mg Vitamin B5, 1.8mg Vitamin B6, 0.11mg Biotin, Daily amount to be consumed to produce claimed effect: 303 ml, Length of time after consumption for claimed effect to become apparent: Depends on the individual's nutritional status

</td></tr>
<tr><td rowspan="2">22</td><td>Food or Food component</td><td>Health Relationship</td><td>Proposed wording</td></tr>
<tr><td>Thiamine</td><td>Neurological function</td><td>vitamin B1(Thiamin) helps keeping the nervous system working properly.</td></tr>
<tr><td></td><td colspan="3">
Conditions of use

MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG
Es werden nur die Nährstoffe beworben, die lt. Nährwertkennzeichnungs-verordnung (Anlage 1) mindestens 15 Prozent der empfohlenen Tagesdosis in 100 g oder 100 ml enthalten.
MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006
Entsprechend der einzelnen B-Vitamine, ein–facher TB gemäß NwKVO
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: .21 miligram(s) Vitamin B1 (Thiamin), Daily amount to be consumed to produce claimed effect: .21 miligram(s), Length of time after consumption for claimed effect to become apparent: Regular consumption
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: 2, Names of nutrient/other substances and Quantity in Average daily serving: 0.25mg Vitamin B1, 0.18 micrgrams Vitamin B12, Daily amount to be consumed to produce claimed effect: 500g, Length of time after consumption for claimed effect to become apparent: Depend's on the individuals nutritional status

</td></tr>
<tr><td rowspan="2">24</td><td>Food or Food component</td><td>Health Relationship</td><td>Proposed wording</td></tr>
<tr><td>Vitamin B1</td><td>Macronutrient metabolism</td><td>- Vitamin B1 helps release nutrients from food.
- Vitamin B1 is involved in the metabolism of carbohydrates and protein.</td></tr>
<tr><td></td><td colspan="3">Conditions of use:</td></tr>
</table>

	• Source of 15% of RDA per 100g		
	Food or Food component	**Health Relationship**	**Proposed wording**
25	Vitamin B1	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.		
27	**Food or Food component**	**Health Relationship**	**Proposed wording**
	Thiamine	Neurological system	Thiamin is necessary for normal neurological and cardiac function
	Conditions of use • Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC		
28	**Food or Food component**	**Health Relationship**	**Proposed wording**
	Thiamin	Thiamin participates as a coenzyme in the carbohydrate metabolism	- Thiamin is of importance for the formation of energy from carbohydrate - Thiamin is of importance for carbohydrate metabolism - Thiamin/vitamin B1 supports the metabolism of carbohydrates
	Conditions of use • 0,7mg/day (equal to 50% of ADI (Acceptable Daily Intake) • The product must contain at least 15% of the RDA • applicable to both adults and children		