

## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to niacin and reduction of tiredness and fatigue (ID 47), contribution to normal energy-yielding metabolism (ID 51), contribution to normal psychological functions (ID 55), maintenance of normal blood flow (ID 211), and maintenance of normal skin and mucous membranes (ID 4700) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>**

**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>**

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 niacin and reduction of tiredness and fatigue, contribution to normal energy-yielding metabolism, contribution to normal psychological functions, maintenance of normal blood flow, and maintenance of normal skin and mucous membranes. 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 niacin. The Panel considers that niacin is sufficiently characterised.

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<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-834, EFSA-Q-2008-838, EFSA-Q-2008-842, EFSA-Q-2008-998, EFSA-Q-2010-00653, adopted on 09 July 2010.

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### **Reduction of tiredness and fatigue**

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

The clinical features of pellagra are dermatitis, diarrhoea and dementia. Symptoms also include depression, apathy, headache, fatigue and loss of memory.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of niacin and the reduction of tiredness and fatigue. However, the evidence provided does not establish that inadequate intake of niacin leading to tiredness and fatigue occurs in the general EU population.

### **Contribution to normal energy-yielding metabolism**

The claimed effect is “energy and vitality”. The target population is assumed to be the general population. In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect is related to energy-yielding metabolism.

A claim on niacin and normal energy-yielding metabolism has already been assessed with a favourable outcome.

### **Contribution to normal psychological functions**

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

A combined deficiency of niacin and tryptophan causes the classical symptoms of pellagra. The clinical features of pellagra are dermatitis, diarrhoea and dementia. Symptoms also include depression, apathy, headache, fatigue and loss of memory.

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

### **Maintenance of normal blood flow**

The claimed effect is “niacin enhances the blood flow because of its vascular dilatation effect”. The target population is assumed to be the general population. The Panel considers that maintenance of normal blood flow is a beneficial physiological effect.

The Panel notes that in the references provided the effect of nicotinic acid on vasodilatation at daily doses above the Tolerable Upper Intake Level (UL) was studied.

The Panel considers that the claim for niacin and maintenance of normal blood flow encourages excess consumption of niacin and therefore does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

### **Maintenance of normal skin and mucous membranes**

The claimed effect is “normal structure and function of skin and mucous membranes (such as the intestine)”. The target population is assumed to be the general population.

A claim on niacin and maintenance of normal skin and mucous membranes has already been assessed with a favourable outcome.

#### **Conditions and possible restrictions of use**

The Panel considers that in order to bear the claims a food should be at least a source of niacin 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**

Niacin, tiredness, fatigue, energy-yielding metabolism, psychological functions, blood flow, skin, mucous membranes, health claims.

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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<sup>4</sup> submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out<sup>5</sup>. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is niacin, which is a well recognised nutrient and is measurable in foods by established methods.

Preformed niacin occurs naturally in foods either as nicotinamide, as derived pyridine nucleotide coenzymes (nicotinamide adenine dinucleotide, NAD and nicotinamide adenine dinucleotide phosphate, NADP) or as nicotinic acid. Niacin can also be synthesised in the body from dietary tryptophan. Niacin is the common term for nicotinamide and nicotinic acid and is authorised for addition to foods (Annex I of the Regulation (EC) No 1925/2006<sup>6</sup> and Annex I of Directive 2002/46/EC<sup>7</sup>). This evaluation applies to niacin naturally present in foods and those forms authorised for addition to foods (Annex II of Regulation (EC) No 1925/2006 and Annex II of Directive 2002/46/EC).

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

### 2. Relevance of the claimed effect to human health

#### 2.1. Reduction of tiredness and fatigue (ID 47)

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

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

#### 2.2. Contribution to normal energy-yielding metabolism (ID 51)

The claimed effect is “energy and vitality”. The Panel assumes that the target population is the general population.

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<sup>4</sup> 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.

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

<sup>6</sup> 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.

<sup>7</sup> 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.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect is related to energy-yielding metabolism.

A claim on niacin and normal energy-yielding metabolism has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009).

### **2.3. Contribution to normal psychological functions (ID 55)**

The claimed effect is “the role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)”. The Panel assumes that the target population is the general population.

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

### **2.4. Maintenance of normal blood flow (ID 211)**

The claimed effect is “niacin enhances the blood flow because of its vascular dilatation effect”. The Panel assumes that the target population is the general population.

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

### **2.5. Maintenance of normal skin and mucous membranes (ID 4700)**

The claimed effect is “normal structure and function of skin and mucous membranes (such as the intestine)”. The Panel assumes that the target population is the general population.

A claim on niacin and maintenance of normal skin and mucous membranes has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009).

## **3. Scientific substantiation of the claimed effect**

### **3.1. Reduction of tiredness and fatigue (ID 47)**

A combined deficiency of niacin and tryptophan causes the classical symptoms of pellagra. The clinical features of pellagra are dermatitis, diarrhoea and dementia. Symptoms also include depression, apathy, headache, fatigue and loss of memory (Jacob, 2006; EVM, 2002; IoM, 2000).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of niacin and reduction of tiredness and fatigue. However, the evidence provided does not establish that inadequate intake of niacin leading to tiredness and fatigue occurs in the general EU population.

### **3.2. Contribution to normal psychological functions (ID 55)**

A combined deficiency of niacin and tryptophan causes the classical symptoms of pellagra. The clinical features of pellagra are dermatitis, diarrhoea and dementia. Symptoms also include depression, apathy, headache, fatigue and loss of memory (Jacob, 2006; EVM, 2002; IoM, 2000).

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

### **3.3. Maintenance of normal blood flow (ID 211)**

Five references were cited to substantiate the claim, two of which were textbooks where the claimed effect was not mentioned, and one of which was related to dietary reference values for vitamins and minerals from an authoritative body. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

In the remaining two textbooks the effect of nicotinic acid at daily doses of at least 30 mg on vasodilatation was mentioned. The Panel notes that this dose of nicotinic acid is above the Tolerable Upper Intake level (UL) (10 mg; SCF, 2002).

The Panel considers that this claim (the proposed wording of this claim) encourages excess consumption of niacin and therefore does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

## **4. Panel's comments on the proposed wording**

### **4.1. Reduction of tiredness and fatigue (ID 47)**

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

### **4.2. Contribution to normal psychological functions (ID 55)**

The Panel considers that the following wording reflects the scientific evidence: "Niacin contributes to normal psychological functions".

## **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 niacin 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 (ULs) have been established for free nicotinic acid and nicotinamide (SCF, 2002).

## **CONCLUSIONS**

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

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

### **Reduction of tiredness and fatigue (ID 47)**

- The claimed effect is "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status". The target population is assumed to be the general population. Reduction of tiredness and fatigue is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of niacin and the reduction of tiredness and fatigue.
- The evidence provided does not establish that inadequate intake of niacin leading to tiredness and fatigue occurs in the general EU population.
- The following wording reflects the scientific evidence: "Niacin can contribute to the reduction of tiredness and fatigue".

### **Contribution to normal energy-yielding metabolism (ID 47)**

- The claimed effect is “energy and vitality”. The target population is assumed to be the general population. In the context of the clarifications provided by Member States, it is assumed that the claimed effect is related to energy-yielding metabolism.
- A claim on niacin and normal energy-yielding metabolism has already been assessed with a favourable outcome.

### **Contribution to normal psychological functions (ID 55)**

- The claimed effect is “the role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)”. The target population is assumed to be the general population. Contribution to normal psychological functions, which encompass cognitive and affective domains, is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of niacin and contribution to normal psychological functions.
- The evidence provided does not establish that inadequate intake of niacin leading to impaired psychological functions occurs in the general EU population.
- The following wording reflects the scientific evidence: “Niacin contributes to normal psychological functions”.

### **Maintenance of normal blood flow (ID 211)**

- The claimed effect is “niacin enhances the blood flow because of its vascular dilatation effect”. The target population is assumed to be the general population. Maintenance of normal blood flow is a beneficial physiological effect.
- The claim for niacin and maintenance of normal blood flow encourages excess consumption of niacin and therefore does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

### **Maintenance of normal skin and mucous membranes (ID 4700)**

- The claimed effect is “normal structure and function of skin and mucous membranes (such as the intestine)”. The target population is assumed to be the general population.
- A claim on niacin and maintenance of normal skin and mucous membranes has already been assessed with a favourable outcome.

### **Conditions and possible restrictions of use**

- In order to bear the claims a food should be at least a source of niacin 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-2008-834, EFSA-Q-2008-838, EFSA-Q-2008-842, EFSA-Q-2008-998, EFSA-Q-2010-00653).

The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

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

## REFERENCES

- EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009. Scientific Opinion on the substantiation of health claims related to niacin and energy-yielding metabolism (ID 43, 49, 54), function of the nervous system (ID 44, 53), maintenance of the skin and mucous membranes (ID 45, 48, 50, 52), maintenance of normal LDL-cholesterol, HDL-cholesterol and triglyceride concentrations (ID 46), maintenance of bone (ID 50), maintenance of teeth (ID 50), maintenance of hair (ID 50, 2875) and maintenance of nails (ID 50, 2875) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from European Commission. *EFSA Journal*, 7(9):1224, 17 pp.
- EVM (Expert Group on Vitamins and Minerals, 2002. Review of Niacin. Revised Version.
- Jacob RA, 2006. Niacin. In: *Present Knowledge in Nutrition*. Eds Bowman BA and Russell RM. International Life Sciences Institute (ILSI), Washington, DC, 260-268.
- IoM (Institute of Medicine), 2000. *Dietary Reference Intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin and choline*. National Academy Press, Washington, DC.
- SCF (Scientific Committee on Food), 2002. *Opinion of the Scientific Committee on Food on the tolerable upper intake levels of nicotinic acid and nicotinamide (niacin)*.

## 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<sup>8</sup> (hereinafter "the Regulation") entered into force on 19<sup>th</sup> 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<sup>9</sup>

Foods are commonly involved in many different functions<sup>10</sup> 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.

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

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<sup>8</sup> OJ L12, 18/01/2007

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

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

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

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

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

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

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

#### **WORDING OF HEALTH CLAIMS**

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

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

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

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

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

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

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

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

## **TERMS OF REFERENCE**

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

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

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

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

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.

- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

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

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

## **APPENDIX B**

### **EFSA DISCLAIMER**

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

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

APPENDIX C

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

ID	Food or Food constituent	Health Relationship	Proposed wording
47	Niacin	Vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status <u>Clarification provided</u> Reduce fatigue and tiredness, particularly in situations of inadequate micronutrient status, due to role in macronutrient metabolism	Supplementation with B-vitamins, iron, magnesium as well as vitamin C can reduce fatigue and tiredness in situations of inadequate micronutrient status
		<b>Conditions of use</b> - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006.	
ID	Food or Food constituent	Health Relationship	Proposed wording
51	Vitamin B3	Energy and Vitality <u>Clarification provided</u> Energy and Vitality- (Necessary for the utilisation of energy from food)	Necessary to maintain energy and general vitality
		<b>Conditions of use</b> - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.	
ID	Food or Food constituent	Health Relationship	Proposed wording
55	Niacin	"The role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)"	Water-soluble vitamins, calcium, magnesium and zinc are essential for mental function and performance  In situations of inadequate micronutrient status, supplementation with water-soluble vitamins, minerals and zinc can sustain mental performance. Helps maintain activity, memory, perception of the environment, particularly in the elderly  - Promotes mental concentration - Stimulates mental capacities - Improves the psychoemotional state
		<b>Conditions of use</b> - Tagesbedarf gemäß NwKVO 18 mg pro Tag	

	- Only for products with at least 100 % RDA of vitamins. Agency guidance for supplements is that products containing >20 mg of nicotinic acid should carry the label advisory statement "[This amount of nicotinic acid] may cause skin flushes in sensitive individuals".		
ID	Food or Food constituent	Health Relationship	Proposed wording
211	Niacin	Es besitzt eine gefäßerweiternde Wirkung. Wird bei Durchblutungsstörungen der Netzhaut und des Auges eingesetzt. <u>Clarification provided</u> niacin enhances the blood flow because of its vascular dilatation effect	[In german : ] Wichtig für den Blutfluss der Gefäße <u>Clarification provided</u> Important for vascular blood flow
	<b>Conditions of use</b> - No conditions of use provided		
	<b>Comments from Member States:</b> med.: use within the scope of circulatory disorders of eye/retina		
ID	Food or Food constituent	Health Relationship	Proposed wording
4700	Vitamin B3 (Niacin)	Normal structure and function of skin and mucous membranes (such as the intestine)	Niacin (vit. B3) helps keep your skin and mucous membranes healthy.
	<b>Conditions of use</b> - Capsule, syrup/ / equivalent at maximum of 60 mg vit.B3/ day, or as per individual conditions of use, during two weeks		