SCIENTIFIC OPINION

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[1]

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

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to niacin and the following claimed effects: energy-yielding metabolism, function of the nervous system, maintenance of skin and mucous membranes, maintenance of normal LDL-cholesterol, HDL-cholesterol and triglyceride concentrations, maintenance of bone, maintenance of teeth, maintenance of hair, and maintenance of nails. 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, which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that niacin is sufficiently characterised.

1 On request from European Commission, Question No EFSA-Q-2008-830, EFSA-Q-2008-831, EFSA-Q-2008-832, EFSA-Q-2008-833, EFSA-Q-2008-835, EFSA-Q-2008-836, EFSA-Q-2008-837, EFSA-Q-2008-839, EFSA-Q-2008-840, EFSA-Q-2008-841, EFSA-Q-2008-3608, 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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The Panel concludes that a cause and effect relationship has been established between the dietary intake of niacin and normal energy-yielding metabolism, normal function of the nervous system, and maintenance of normal skin and mucous membranes.

The evidence provided does not establish that inadequate intake of niacin leading to impaired functions of the above-mentioned 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 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.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of niacin and maintenance of normal bone, maintenance of normal teeth, maintenance of normal hair, and maintenance of normal nails.

The Panel considers that the claim for niacin and maintenance of normal LDL-cholesterol, HDL-cholesterol and triglyceride concentrations encourages excess consumption of niacin and therefore does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

KEY WORDS

Niacin, energy-yielding metabolism, nervous system, skin, mucous membranes, LDL-cholesterol, HDL-cholesterol, triglycerides, bone, teeth, hair, nails, health claims.

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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 Cardiovascular Health/Oxidative Stress: Antti Aro, Marianne Geleijnse, Marina Heinonen, Ambroise Martin, Wilhelm Stahl and Henk van den Berg.

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[3] submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims. The information provided in the consolidated list for the health claims subject to this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

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

Preformed niacin occurs naturally in foods either as nicotinamide or as the 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[4] and Annex I of Directive 2002/46/EC[5]). 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 claim is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Energy-yielding metabolism (ID 43, 49, 54)

The claimed effects are related to "energy metabolism / nutrient utilisation" "macronutrient metabolism" and "NAD and NADP. These nucleotides are key components of oxidation-reduction reactions, ATP synthetic pathways and ADP-ribose transfer reactions". 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.

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

[3] European Parliament and Council (2006). 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. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

[4] European Parliament and of the Council (2006). 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. Official Journal of the European Union OJ L 404, 30.12.2006, p. 26-38.

[5] European Parliament and of the Council (2002). Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements Official Journal of the European Union OJ L 183, 12.7.2002, p. 51–57.

2.2. Function of the nervous system (ID 44, 53)

The claimed effects are "neurological functions" and "neurological systems". 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.

2.3. Maintenance of skin and mucous membranes (ID 45, 48, 50, 52)

The claimed effects are "normal structure and function of skin and mucous membranes (such as in the intestines)", "structure and function of skin", "bone/teeth/hair/skin and nail health" and "skin and mucous membranes". The Panel assumes that the target population is the general population.

The Panel considers that maintenance of normal skin and mucous membranes is beneficial to human health.

2.4. Maintenance of normal LDL-cholesterol, HDL-cholesterol and triglyceride concentrations (ID 46)

The claimed effect is "blood lipids". The Panel assumes that the target population is the general population.

From the wordings proposed the Panel assumes that the claim refers to the maintenance of normal blood triglycerides, LDL- and HDL-cholesterol concentrations.

The Panel considers that maintenance of normal LDL-cholesterol, normal HDL-cholesterol and triglycerides concentrations are beneficial to human health.

2.5. Maintenance of bone (ID 50)

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

The Panel considers that maintenance of normal bone is beneficial to human health.

2.6. Maintenance of teeth (ID 50)

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

The Panel considers that maintenance of normal teeth is beneficial to human health.

2.7. Maintenance of hair (ID 50, 2875)

The claimed effect is "bone/teeth/hair/skin and nail health" and "hairs and nails care". The Panel assumes that the target population is the general population.

The Panel considers that maintenance of normal hair is beneficial to human health.

2.8. Maintenance of nails (ID 50, 2875)

The claimed effect is "bone/teeth/hair/skin and nail health" and "hairs and nails care". The Panel assumes that the target population is the general population.

The Panel considers that maintenance of normal nails is beneficial to human health.

3. Scientific substantiation of the claimed effect

Niacin (as NAD and NADP) has a central role in the hydrogen/electron transfer redox reactions in cells. The most important functions of NAD are in the major catabolic pathways in relation to the oxidation of energy-producing fuels whereas the principal functions of NADP are in reductive biosyntheses, such as lipid biosynthesis (Jacob, 2006; EVM, 2002; IoM, 2000).

3.1. Energy-yielding metabolism (ID 43, 49, 54)

Niacin supports energy-yielding metabolism as it is the functional factor of two important coenzymes, nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP), which activate over 200 dehydrogenases essential to electron transport and other cellular respiratory reactions (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 normal energy-yielding metabolism. However, the evidence provided does not establish that inadequate intake of niacin leading to impaired energy-yielding metabolism occurs in the general EU population.

3.2. Function of the nervous system (ID 44, 53)

A combined deficiency of niacin and tryptophan causes the classical symptoms of pellagra. The clinical features of pellagra are dermatitis, diarrhoea and dementia. Neurological symptoms 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 normal function of the nervous system. However, the evidence provided does not establish that inadequate intake of niacin leading to impaired function of the nervous system occurs in the general EU population.

3.3. Maintenance of skin and mucous membranes (ID 45, 48, 50, 52)

A combined deficiency of niacin and tryptophan causes the classical symptoms of pellagra. The clinical features of pellagra are dermatitis, diarrhoea and dementia. The changes in the skin are among the most characteristic in humans. A pigmented rash develops symmetrically in areas of the skin exposed to sunlight. Changes in the digestive tract are associated with vomiting, constipation or diarrhoea, and a bright red tongue (Jacob, 2006; EVM, 2002; IoM, 2000; Bourgeois et al., 1999; SCF, 2002; SCF, 1993).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of niacin and maintenance of normal skin and mucous membranes. However, the evidence provided does not establish that intake of niacin inadequate for the maintenance of normal skin and mucous membranes occur in the general EU population.

3.4. Maintenance of normal LDL-cholesterol, HDL-cholesterol and triglyceride concentrations (ID 46)

Nicotinic acid in high doses (1-6 g/d) has been used for decades in the drug therapy of hyperlipidaemias.

A total of 17 references were cited for the substantiation of the claimed effect, including four review papers, one meta-analysis and twelve human studies. The effects of nicotinic acid at daily doses ranging from 100 mg to 6 g on the lipid profile were assessed in these studies.

The Panel notes that the evidence provided for the substantiation of the claim relates to studies with niacin at intakes above the Tolerable Upper Intake Level (UL) (10 mg; SCF, 2002) and that the proposed conditions of use refer to intakes up to 300 times the UL. 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 (Article 3c).

3.5. Maintenance of bone (ID 50)

A total of 14 references were cited for the substantiation of the claimed effect, including 10 textbooks and 3 opinions from authoritative bodies in which the claimed effect was not stated. One human study dealt with hair loss, which is unrelated to the claimed effect. The Panel notes that the references 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 niacin and maintenance of normal bone.

3.6. Maintenance of teeth (ID 50)

A total of 14 references were cited for the substantiation of the claimed effect, including 10 textbooks and 3 opinions from authoritative bodies in which the claimed effect was not stated. One human study dealt with hair loss, an outcome unrelated to the claimed effect. The Panel notes that the references 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 niacin and maintenance of normal teeth.

3.7. Maintenance of hair (ID 50, 2875)

A total of 21 references were cited for the substantiation of the claimed effect, including 10 textbooks and 4 opinions from authoritative bodies in which the claimed effect was not stated and a private-public medicinal database. Four references dealt with outcomes unrelated to the claimed effect such as regulation of vascular tone and the development of an experimental model for niacin deficiency. The Panel notes that these references did not provide any scientific data that could be used to substantiate the claimed effect. One reference cited was not accessible to the Panel after having made every reasonable effort to retrieve it (El-Fekih et al., 2005).

In a non-controlled human study with 41 volunteers presenting with hair loss, the effect of niacin in combination with other compounds on hair loss was examined using subjective evaluation (Raoudi and Robreau, 2006). The Panel notes the small size of the study, the lack of information on the overall nutritional status of the subjects and that no objective methods were used to determine the improvement in hair loss in this study.

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

3.8. Maintenance of nails (ID 50, 2875)

A total of 21 references were cited for the substantiation of the claimed effect, including 10 textbooks and 4 opinions from authoritative bodies in which the claimed effect was not stated and a private-

public medicinal database. Five references dealt with outcomes unrelated to the claimed effect such as hair loss, regulation of vascular tone and the development of an experimental model for niacin deficiency. The Panel notes that these references did not provide any scientific data that could be used to substantiate the claimed effect. One reference cited was not accessible to the Panel after having made every reasonable effort to retrieve it (El-Fekih et al., 2005).

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

4. Panel's comments on the proposed wording

4.1. Energy-yielding metabolism (ID 43, 49, 54)

The Panel considers that the following wording reflects the scientific evidence: "Niacin contributes to normal energy-yielding metabolism".

4.2. Function of the nervous system (ID 44, 53)

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

4.3. Maintenance of skin and mucous membranes (ID 45, 48, 50, 52)

The Panel considers that the following wording reflects the scientific evidence: "Niacin contributes to the maintenance of normal skin and mucous membranes".

5. Conditions and possible restrictions of use

The Panel considers that in order to bear the claim 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 (UL) have been established for free nicotinic acid as 10 mg/day for adults and for children and adolescents as 2 mg/day for 1-3 years, 3 mg/day for 4-6 years, 4 mg/day for 7-10 years, 6 mg/day for 11-14 years and 8 mg/day for 15-17 years. Tolerable Upper Intake Levels (UL) have been also established for nicotinamide as 900 mg/day for adults and for children and adolescents as 150 mg/day for 1-3 years, 220 mg/day for 4-6 years, 350 mg/day for 7-10 years, 500 mg/day for 11-14 years and 700 mg/day for 15-17 years (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 characterized.

Energy-yielding metabolism (ID 43, 49, 54)

- The claimed effects are "energy metabolism / nutrient utilization" "macronutrient metabolism" and "NAD and NADP. These nucleotides are key components of oxidation-reduction reactions, ATP synthetic pathways and ADP-ribose transfer reactions". 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 niacin and normal energy-yielding metabolism.
- The evidence provided does not establish that inadequate intake of niacin leading to impaired energy-yielding metabolism occurs in the general EU population.
- The following wording reflects the scientific evidence: "Niacin contributes to normal energy-yielding metabolism".

Function of the nervous system (ID 44, 53)

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

Maintenance of skin and mucous membranes (ID 45, 48, 50, 52)

- The claimed effects are "normal structure and function of skin and mucous membranes (such as in the intestines)", "structure and function of skin" and "skin and mucous membranes". The Panel assumes that the target population is the general population. Maintenance of normal skin and mucous membranes is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of niacin and maintenance of normal skin and mucous membranes.
- The evidence provided does not establish that intake of niacin inadequate for the maintenance of normal skin and mucous membranes occur in the general EU population.
- The following wording reflects the scientific evidence: "Niacin contributes to the maintenance of normal skin and mucous membranes".

Maintenance of normal LDL-cholesterol, HDL-cholesterol and triglyceride concentrations (ID 46)

- The claimed effect is "blood lipids". The target population is assumed to be the general population. Maintenance of normal LDL-cholesterol, normal HDL cholesterol and triglycerides concentration are beneficial to human health.
- The claim should not be evaluated in the context of health claims made on foods.

Maintenance of bone (ID 50)

- 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 niacin and maintenance of normal bone.

Maintenance of teeth (ID 50)

- 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 niacin and maintenance of normal teeth.

Maintenance of hair (ID 50, 2875)

- The claimed effects are "bone/teeth/hair/skin and nail health" and "hairs and nails care". 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 niacin and maintenance of normal hair.

Maintenance of nails (ID 50, 2875)

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

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

Conditions and possible restrictions of use

- In order to bear the claim 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 (EFSA-Q-2008-830, EFSA-Q-2008-831, EFSA-Q-2008-832, EFSA-Q-2008-833, EFSA-Q-2008-835, EFSA-Q-2008-836, EFSA-Q-2008-837, EFSA-Q-2008-839, EFSA-Q-2008-840, EFSA-Q-2008-841, EFSA-Q-2008-3608). The scientific substantiation is based on the information provided by the Members States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

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

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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

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

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

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

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

b) psychological and behavioural functions; or

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

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

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

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

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[7]

Foods are commonly involved in many different functions[8] of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

[6] OJ L12, 18/01/2007
[7] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[8] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

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

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

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

(a) the claimed effect of the food is beneficial for human health,

(b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

(c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

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

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

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

WORDING OF HEALTH CLAIMS

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

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

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

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

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

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

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

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

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

TERMS OF REFERENCE

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

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

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.

- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.

- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

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

- the claimed effect of the food in the identified function is beneficial.

- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.

- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.

- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

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

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

APPENDIX B

EFSA DISCAIMER

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

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

APPENDIX C

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

ID	Food or Food constituent	Health Relationship	Proposed wording
43	Niacin (Vitamin B3)	Energy metabolism / Nutrient utilisation	Niacin (vitamin B3) helps release the energy from foods.
	Conditions of use - Tagesbedarf gemäß NwKVO 18 mg pro Tag - Must at least be a source of vitamin/s as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >20mg Nicotinic acid should carry the label statement: '[This amount of Nicotinic acid] may cause skin flushes in sensitive individuals'. Applicable to both children and adults - Minimum 15% RDA per daily dosage as per 90/496/EC - Number of nutrients/other substances that are essential to claimed effect: 1. Names of nutrient/other substances and Quantity in Average daily serving: 2.70 miligram(s) vitamin B3. Daily amount to be consumed to produce claimed effect: 2.7 miligram(s). Length of time after consumption for claimed effect to become apparent: Regular consumption - Mindestens 15 % RDA je 100 G oder 100 ml oder je portion gemäß 90/496/EWG - Mind. 15% der RDA, gem. NWK-RL 90/496/EWG		
	Food or Food component	**Health Relationship**	**Proposed wording**
44	Nacin	Neurological functions	Niacin (vitamin B3) helps keep the nervous system functioning Niacin (vitamin B3) is needed for normal mental function.
	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. Agency guidance for supplements is that products containing >20mg Nicotinic acid should carry the label statement: '[This amount of Nicotinic acid] may cause skin flushes in sensitive individuals'. Applicable to both children and adults - Names of nutrient/other substances and Quantity in Average daily serving: 2.70 miligram(s) niacin (vitamin B3). Daily amount to be consumed to produce claimed effect: 2.7 miligram(s). Length of time after consumption for claimed effect to become apparent: Regular consumption. - Tagesbedarf gemäß NwKVO 18 mg pro Tag		
	Food or Food component	**Health Relationship**	**Proposed wording**
45	Niacin	Normal structure and function of skin and mucous membranes (such as the intestines)	Niacin helps keep your skin and mucous membranes healthy.
	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 >20mg Nicotinic acid should carry the		

<table>
<tr><td rowspan="4"></td><td colspan="3">label statement: '[This amount of Nicotinic acid] may cause skin flushes in sensitive individuals. Applicable to both children and adults.
- Names of nutrient/other substances and Quantity in Average daily serving: 2.70 miligram(s) Niacin (Vitamin B3). Daily amount to be consumed to produce claimed effect: 2.7 miligram(s). Length of time after consumption for claimed effect to become apparent: Regular consumption.</td></tr>
<tr><td>Food or Food component</td><td>Health Relationship</td><td>Proposed wording</td></tr>
<tr><td>Niacin (nicotinic acid)</td><td>Blood lipids</td><td>Niacin (nicotinic acid) may help to control blood lipid profiles/cholesterol/ triglycerides</td></tr>
<tr><td colspan="3">Conditions of use
- Adults: Typical starting dose = 10-100 mg three times daily, which can be increased to 1000 mg three times daily, or to tolerance. There is no evidence that low doses (<50 mg daily) have a significant effect on controlling blood lipid levels. Sustained-release formulations of niacin exhibit a significantly lower rate of adverse reactions (notably cutaneous flushing) at equivalent dosages compared with immediate-release forms. Label warning should include: “Product should be taken with food and used under the supervision of a qualified healthcare provider. Some individuals may experience minor adverse reactions such as cutaneous flushing or gastrointestinal upset on starting supplementation with niacin at such doses, but tolerance in most is acquired after 1-2 weeks of supplementation.” 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. Agency guidance for supplements is that products containing >20 mg nicotinic acid should carry the label advisory statement "this amount of nicotinic acid may cause skin flushes in sensitive individuals".
- Food supplement with 75mg of NE niacin in the daily dose.</td></tr>
<tr><td rowspan="3">46</td><td colspan="3"></td></tr>
<tr><td>Food or Food component</td><td>Health Relationship</td><td>Proposed wording</td></tr>
<tr><td>Niacin</td><td>Structure and function of skin</td><td>Niacin/vitamin B3 supports the structure and function of skin</td></tr>
<tr><td colspan="3">Conditions of use
- 17mg-Äquivalent / Tag—Erwachsene .
- The product must contain at least 15% of the RDA. 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". Product must contain at least 15% of the RDA per daily dosage as per 90/496/EC applicable to both adults and children.
- The DRA for B3 is 16 mg (M) and 14 mg (F).
- 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.</td></tr>
<tr><td rowspan="3">48</td><td colspan="3"></td></tr>
<tr><td>Food or Food component</td><td>Health Relationship</td><td>Proposed wording</td></tr>
<tr><td>Niacin</td><td>Macronutrient metabolism</td><td>Niacin helps release nutrients from food</td></tr>
<tr><td colspan="3">Conditions of use
- Source of 15% of RDA. Agency guidance for supplements is that products containing >20mg nicotinic acid should carry the label advisory statement "this amount of nicotinic acid may cause skin flushes in sensitive individuals".</td></tr>
<tr><td>49</td><td colspan="3"></td></tr>
</table>

	Food or Food component	Health Relationship	Proposed wording
50	Vitamin B3	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. Agency guidance for supplements is that products containing >20mg of nicotinic acid carry the label statement "may cause skin flushes in sensitive individuals." - 18 mg/day of vitamin B3		
	Food or Food component	**Health Relationship**	**Proposed wording**
52	Niacin (vitamin B3)	Skin and mucous membranes	Niacin is necessary for the normal structure and function of skin and mucous membranes (such as in the intestines).
	Conditions of use - Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC. 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".		
	Food or Food component	**Health Relationship**	**Proposed wording**
53	Niacin (vitamin B3)	Neurological systems	Niacin is necessary for normal neurological function.
	Conditions of use - Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC. 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".		
	Food or Food component	**Health Relationship**	**Proposed wording**
54	Niacin	NAD and NADP. These nucleotides are key components of oxidation-reduction reactions, ATP synthetic pathways and ADP-ribose transfer reactions.	Niacin is a component in the formation of energy Niacin takes part in the energy metabolism
	Conditions of use - 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. - 9.5mg/day (equal to 50% of ADI (Acceptable Daily Intake). Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006. (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").		

	Food or Food component	Health Relationship	Proposed wording
2875	Vitamin B3	Hairs and nails care	Activate the scalp microcirculation
	Conditions of use - 18 mg per day		

GLOSSARY AND ABBREVIATIONS

NAD	Nicotinamide adenine dinucleotide
NADP	Nicotinamide adenine dinucleotide phosphate
ATP	Adenosine triphosphate
ADP	Adenosine diphosphate
LDL	Low-density lipoprotein
HDL	High-density lipoprotein
UL	Tolerable Upper Intake Levels