SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to biotin and maintenance of normal skin and mucous membranes (ID 121), maintenance of normal hair (ID 121), maintenance of normal bone (ID 121), maintenance of normal teeth (ID 121), maintenance of normal nails (ID 121, 2877), reduction of tiredness and fatigue (ID 119), contribution to normal psychological functions (ID 120) and contribution to normal macronutrient metabolism (ID 4661) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

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 biotin and maintenance of normal skin and mucous membranes, maintenance of normal hair, maintenance of normal bone, maintenance of normal teeth, maintenance of normal nails, reduction of tiredness and fatigue, contribution to normal psychological functions and contribution to normal macronutrient metabolism. 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 biotin. The Panel considers that biotin is sufficiently characterised.

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[1] On request from the European Commission, Question No EFSA-Q-2008-908, EFSA-Q-2008-3610, adopted on 11 February 2010 and Question No EFSA-Q-2008-906, EFSA-Q-2008-907, EFSA-Q-2010-00614, adopted on 09 July 2010.

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[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on claims : Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain, and Peter Willatts.

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Maintenance of normal skin and mucous membranes

The claimed effect is "bone/teeth/hair/skin and nail health". The target population is assumed to be the general population.

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

Maintenance of normal hair

The claimed effect is "bone/teeth/hair/skin and nail health". The target population is assumed to be the general population.

A claim on biotin and the maintenance of normal hair has already been assessed with a favourable outcome.

Maintenance of normal bone

The claimed effect is "bone/teeth/hair/skin and nail health". The target population is assumed to be the general population. The Panel considers that maintenance of normal bone is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the dietary intake of biotin and the maintenance of normal bone.

Maintenance of normal teeth

The claimed effect is "bone/teeth/hair/skin and nail health". The target population is assumed to be the general population. The Panel considers that maintenance of normal teeth is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the dietary intake of biotin and the maintenance of normal teeth.

Maintenance of normal nails

The claimed effect is "bone/teeth/hair/skin and nail health" and "resistance and strength of nails". The target population is assumed to be the general population. The Panel considers that maintenance of normal nails is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that all but one study were not blinded and did not control for factors other than biotin that might have influenced the outcome, that in three of the five studies no objective methods to determine changes in nail quality were used, that the evidence provided in the remaining study did not establish that the endpoints used in this study are appropriate measures of nail quality and that in all studies the doses studied were considerably higher than the ones proposed in the conditions of use.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the dietary intake of biotin and the maintenance of normal nails.

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.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the dietary intake of biotin and the reduction of tiredness and fatigue.

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.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of biotin and contribution to normal psychological functions.

Contribution to normal macronutrient metabolism

The claimed effect is "role in protein and amino acid metabolism". The target population is assumed to be the general population.

A claim on biotin and normal macronutrient metabolism 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 biotin 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

Biotin, skin, mucous membranes, hair, bone, teeth, nail, tiredness, fatigue, psychological functions, macronutrient metabolism, 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[4] 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[5]. 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 biotin, which is a well recognised nutrient and is measurable in foods by established methods. Biotin occurs naturally in foods as free biotin and in protein bound forms; there are eight stereoisomers, but D(+)-biotin is the only naturally occurring isomer that plays a role in human metabolism, and currently the only form authorised for addition to foods (Annex II of the Regulation (EC) No 1925/2006[6] and Annex II of Directive 2002/46/EC[7]). This evaluation applies to biotin 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, biotin, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effects to human health

2.1. Maintenance of normal skin and mucous membranes (ID 121)

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

A claim on biotin 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).

2.2. Maintenance of normal hair (ID 121)

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

[4] 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.
[5] 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
[6] 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.
[7] 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.

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

2.3. Maintenance of normal bone (ID 121)

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 a beneficial physiological effect.

2.4. Maintenance of normal teeth (ID 121)

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 a beneficial physiological effect.

2.5. Maintenance of normal nails (ID 121, 2877)

The claimed effects are "bone/teeth/hair/skin and nail health" and "resistance and strength of nails". The Panel assumes that the target population is the general population.

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

2.6. Reduction of tiredness and fatigue (ID 119)

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.

2.7. Contribution to normal psychological functions (ID 120)

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.

2.8. Contribution to normal macronutrient metabolism (ID 4661)

The claimed effect is "role in protein and amino acid metabolism". The Panel assumes that the target population is the general population.

Protein and amino acid metabolism is part of normal macronutrient metabolism.

The Panel considers that the claimed effect is related to macronutrient metabolism.

A claim on biotin and normal macronutrient metabolism 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

It is well established that biotin is a cofactor for the acetyl-CoA, propionyl-CoA, ß-methylcrotonyl-CoA and pyruvate carboxylase enzymes, which are important in the synthesis of fatty acids, the catabolism of some branched-chain amino acids and for the gluconeogenic pathway.

Pyruvate carboxylase catalyses the carboxylation of pyruvate to form oxaloacetate which, in turn, serves as an intermediate in gluconeogenesis as well as in the citric acid cycle.

Methylcrotonyl-CoA carboxylase is required for the degradation of leucine, a branched-chain amino acid.

Acetyl-CoA carboxylase catalyses the carboxylation of acetyl-CoA to malonyl-CoA which, in turn, serves as a substrate for fatty acid elongation.

Propionyl-CoA carboxylase carboxylates propionyl-CoA to form D-methylmalonyl-CoA which is epimerised to the L-isomer and then transformed to succinyl-CoA, which then enters the citric acid cycle. The metabolic pathway from propionyl-CoA to succinyl-CoA is also part of the oxidation of fatty acids with an odd number of carbon atoms where the final cleavage forms acetyl-CoA and propionyl-CoA. This pathway is also involved in the catabolism of the branched-chain amino acids isoleucine and valine as well as the amino acids methionine and threonine (IoM, 1998; Stryer, 1988).

Biotin may also have a role in the regulation of gene expression arising from its interaction with nuclear histone proteins (EVM, 2003).

Biotin deficiency only appears after weeks to several years of raw egg-white feeding or biotin-free parenteral nutrition. Thinning of hair and progression to loss of all hair, including eyebrows and lashes, has been reported. A scaly (seborrhoeic), red (eczematous) skin rash was present in the majority; in several, the rash was distributed around the eyes, nose, mouth, and perineal orifices. Depression, lethargy, hallucinations, and paraesthesia of the extremities were prominent neurological symptoms in the majority of adults. The most striking neurological findings in infants were hypotonia, lethargy, and developmental delay (Mock, 2005).

3.1. Maintenance of normal bone (ID 121)

A total of 21 references were cited to substantiate the claim. 13 were textbooks or opinions from scientific bodies in which the claimed effect was not stated. Seven references dealt with outcomes unrelated to the claimed effect, such as the effect of biotin on skin, hair and nails. One reference was related to biotin deficiency in animals. The Panel considers that no conclusions could be drawn from these references for the scientific substantiation of the claimed effect.

The Panel notes that bone disorders are not among the symptoms of biotin deficiency in humans.

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

3.2. Maintenance of normal teeth (ID 121)

A total of 21 references were cited to substantiate the claim. 13 were textbooks or opinions from scientific bodies in which the claimed effect was not stated. Seven references dealt with outcomes unrelated to the claimed effect, such as the effect of biotin on skin, hair and nails. One reference was related to biotin deficiency in animals. The Panel considers that no conclusions could be drawn from these references for the scientific substantiation of the claimed effect.

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

3.3. Maintenance of normal nails (ID 121, 2877)

A total of 23 references were cited to substantiate the claimed effect of which 13 were textbooks or opinions of scientific bodies in which the claimed effect was not stated and five were references related to other health effects. The Panel considers that no conclusions could be drawn from these references for the scientific substantiation of the claimed effect.

Five references described human studies which examined the effect of biotin supplementation on brittle fingernails.

Three uncontrolled, non-blinded studies were provided in which (a) women with nail hardness disorders were given 2.5 mg biotin daily for six to 10 months and nail quality was assessed by subject interview (Floersheim, 1989), (b) adolescents and adults with alopecia and nail quality disorders were given 2.5 mg biotin daily for six to 15 months and nail quality was assessed by subjective reporting (Floersheim, 1992), and (c) adults diagnosed with nail splitting or brittle nails were given 1 to 3 mg biotin daily for 1.5 to 7 months and nail quality was assessed using a questionnaire sent to patients and telephone survey (Hochman et al., 1993). The Panel notes that these studies were not blinded, did not control for factors other than biotin that might have influenced the outcome, that no objective methods were used to determine changes in nail quality, and the doses studied were considerably higher than the ones proposed in the conditions of use, all of which limit the value of the studies as a source of data. As a follow-up to the Floersheim study (1989), nail thickness was assessed using scanning electron microscopy in women with brittle nails of unknown aetiology (excluding women with a specific diagnosis of a nail dystrophy) given 2.5 mg biotin daily for six to 15 months (Colombo et al., 1990). The Panel notes that the study was not blinded, did not control for factors other than biotin that might have influenced the outcome, and that the dose studied was considerably higher than the ones proposed in the conditions of use, all of which limit the value of the study as a source of data.

A double-blind placebo controlled intervention (Gehring, 1996) included 60 subjects with reduced nail quality randomly assigned to consume either placebo (n=30) or 2.5 mg of biotin (n=30) daily for six months. Inclusion criteria were adults above 18 years of age with brittle, splintered or soft nails of unknown origin. Exclusion criteria were known nail disorders, such as mycosis, psoriasis and Lichen ruber, pregnancy, severe neurological, mental or internal disorders, biotin deficiency, concurrent medication and participation in other studies less then four weeks prior to the start of the intervention. Three subjects in each group were excluded from statistical analysis for different reasons. The swelling behaviour of nail keratin after incubation with sodium hydroxide (NaOH) and transonychial water loss were measured after three and six months. The Panel considers that the evidence provided does not establish that these assays are appropriate measures of nail quality. In addition, clinical judgement by the investigator and the subject was used. The Panel notes that no information was provided on the nature of the clinical examination carried out by the investigator or on the aspects of nail quality considered by the subjects, and that the dose studied was considerably higher than the doses proposed in the conditions of use, all of which limit the value of the study as a source of data.

In weighing the evidence, the Panel took into account that all but one of the studies were not blinded and did not control for factors other than biotin that might have influenced the outcome, that in three of the five studies no objective methods to determine changes in nail quality were used, that the evidence provided in the remaining study did not establish that the endpoints used in this study are appropriate measures of nail quality and that in all studies the doses studied were considerably higher than the ones proposed in the conditions of use.

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

3.4. Reduction of tiredness and fatigue (ID 119)

Four references were cited to substantiate the claim. Three were textbooks in which the claimed effect was not mentioned. One was a review on the role of B-vitamins in mitochondrial energy metabolism in which the claimed effect was not mentioned. The Panel considers that no conclusions could be drawn from these references for the scientific substantiation of the claimed effect.

Fatigue is also not among the symptoms of biotin deficiency (Mock, 2005).

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of biotin and the reduction of tiredness and fatigue.

3.5. Contribution to normal psychological functions (ID 120)

Depression is among the neurological symptoms of biotin deficiency observed in adults (Mock, 2005). In biotin-deficient infants, developmental delay, along with peculiar withdrawn behaviour, are characteristic of a neurological disorder resulting from lack of biotin (IoM, 1998).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of biotin and contribution to normal psychological functions.

4. Panel's comments on the proposed wording

4.1. Contribution to normal psychological functions (ID 120)

The Panel considers that the following wording reflects the scientific evidence: "Biotin 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 biotin 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.

CONCLUSIONS

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

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

Maintenance of normal skin and mucous membranes (ID 121)

- The claimed effect is "bone/teeth/hair/skin and nail health". The target population is assumed to be the general population.
- A claim on biotin and maintenance of normal skin and mucous membranes has already been assessed with a favourable outcome.

Maintenance of normal hair (ID 121)

- The claimed effect is "bone/teeth/hair/skin and nail health". The target population is assumed to be the general population.

- A claim on biotin and maintenance of normal hair has already been assessed with a favourable outcome.

Maintenance of normal bone (ID 121)

- The claimed effect is "bone/teeth/hair/skin and nail health". The target population is assumed to be the general population. Maintenance of normal bone is a beneficial physiological effect.

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

Maintenance of normal teeth (ID 121)

- The claimed effect is "bone/teeth/hair/skin and nail health". The target population is assumed to be the general population. Maintenance of normal teeth is a beneficial physiological effect.

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

Maintenance of normal nails (ID 121, 2877)

- The claimed effect is "bone/teeth/hair/skin and nail health" and "resistance and strength of nails". The target population is assumed to be the general population. Maintenance of normal nails is a beneficial physiological effect.

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

Reduction of tiredness and fatigue (ID 119)

- 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 not been established between the dietary intake of biotin and the reduction of tiredness and fatigue.

Contribution to normal psychological functions (ID 120)

- 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 biotin and contribution to normal psychological functions.

- The following wording reflects the scientific evidence: "Biotin contributes to normal psychological functions".

Contribution to normal macronutrient metabolism (ID 4661)

- The claimed effect is "role in protein and amino acid metabolism". The target population is assumed to be the general population.

- A claim on biotin and macronutrient metabolism 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 biotin 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-2008-906, EFSA-Q-2008-907, EFSA-Q-2008-908, EFSA-Q-2008-3610, EFSA-Q-2010-00614). 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[8] (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[9]

Foods are commonly involved in many different functions[10] 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.

[8] OJ L12, 18/01/2007
[9] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[10] 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 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 biotin, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
119	Biotin	Vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status Clarification provided Reduce fatigue and tiredness, particularly in situations of inadequate micronutrient status, due to role in macronutrient metabolism	- Ensures normal functioning of the body's organ tissues and systems, particularly in old age - Stimulates physical work capacities - Recommended in case of intense fatigue and during recovery
	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.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
120	Biotin	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 (e.g. co
	Conditions of use – Only for products with at least 100 % RDA of vitamins		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
121	Biotin	Bone/Teeth/ Hair / Skin and Nail health	Necessary for healthy teeth, bones, hair, skin and nails
	Conditions of use – Food supplement with 30 mg of biotin in the daily dose – Food supplement with 75 mg of biotin in the daily dose – 15% des empfohlenen Tagesbedarfs–pro Portion, 1 x am Tag – 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. – Mindestens 15 % RDA je 100 g oder 100 mL oder je Portion gemäß 90/496/EWG		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2877	Vitamine B8 : Vitamin B8 or vitamin H (biotin)	Resistance and strength of the nails	Contribute to improve nail's resistance

	Conditions of use – 0,15 mg/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4661	Biotin	Role in protein and amino acid metabolism	Biotin is needed for the proper metabolism of proteins / helps to build your proteins.
	Conditions of use – Capsule, syrup/ equivalent at maximum of 0,6 mcg biotin/ day, or as per individual conditions of use, during two weeks		