

## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to biotin and energy-yielding metabolism (ID 114, 117), macronutrient metabolism (ID 113, 114, 117), maintenance of skin and mucous membranes (ID 115), maintenance of hair (ID 118, 2876) and function of the nervous system (ID 116) 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</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 biotin and the following claimed effects: energy-yielding metabolism, macronutrient metabolism, maintenance of skin and mucous membranes, maintenance of hair, and function of the nervous system. 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, which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that biotin is sufficiently characterised.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of biotin and normal energy-yielding metabolism, normal macronutrient metabolism, maintenance of normal skin and mucous membranes, maintenance of normal hair and normal function of the nervous system.

The evidence provided does not establish that inadequate intake of biotin leading to impaired functions of the above-mentioned health relationships occurs in the general EU population.

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1 On request from the European Commission, Question No EFSA-Q-2008-900, EFSA-Q-2008-901, EFSA-Q-2008-902, EFSA-Q-2008-903, EFSA-Q-2008-904, EFSA-Q-2008-905, EFSA-Q-2008-3609 adopted on 02 July 2009.

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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, energy-yielding metabolism, macronutrient metabolism, skin and mucous membranes, hair, nervous system, health claims.

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## **BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION**

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## **TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION**

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## **EFSA DISCLAIMER**

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## **ACKNOWLEDGEMENTS**

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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>3</sup> 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 biotin, which is a 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 the 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<sup>4</sup> and Annex II of Directive 2002/46/EC<sup>5</sup>).

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 effect to human health

#### 2.1. Energy-yielding metabolism (ID 114, 117)

The claimed effects are “fat, carbohydrate, energy metabolism” and “fat metabolism and energy production”. The Panel assumes that the target population is the general population.

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

#### 2.2. Macronutrient metabolism (ID 113, 114, 117)

The claimed effects are “protein and amino acid metabolism”, “fat, carbohydrate, energy metabolism” and “fat metabolism and energy production”. The Panel assumes that the target population is the general population.

The Panel considers that normal macronutrient metabolism is beneficial to human health.

#### 2.3. Maintenance of skin and mucous membranes (ID 115)

The claimed effect is “normal structure and function of skin and mucosa”. The Panel assumes that the target population is the general population.

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<sup>3</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>4</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>5</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.

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

#### **2.4. Maintenance of hair (ID 118, 2876)**

The claimed effects are “hair growth & follicle formation” and “hair loss and regrowth”. The Panel assumes that the target population is the general population.

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

#### **2.5. Function of the nervous system (ID 116)**

The claimed effect is “neurological system function”. The Panel assumes that the target population is the general population.

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

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

Biotin is a cofactor for the acetyl CoA, propionyl CoA,  $\beta$ -methylcrotonyl CoA and pyruvate carboxylase enzymes, which are important in the synthesis of fatty acids, the catabolism of some branched-chain amino acids and the gluconeogenic pathway.

Pyruvate carboxylase catalyses the carboxylation of pyruvate to form oxaloacetate which 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 formation of malonyl-CoA which serves as a substrate for fatty acid elongation.

Propionyl CoA carboxylase carboxylates propionyl CoA to form D-methylmalonyl CoA which is racemised to the L-isomer and then transformed to succinyl CoA, which 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 consumption or parenteral nutrition. Thinning of hair and progression to loss of all hair, including eyebrows and lashes, has been reported. A scaly (seborrheic), red (eczematous) skin rash was present in the majority of cases. 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. Energy-yielding metabolism (ID 114, 117)**

Biotin is a cofactor for four carboxylase enzymes which are also involved in energy-yielding metabolism (IoM, 1998; Stryer, 1988).

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

### **3.2. Macronutrient metabolism (ID 113, 114, 117)**

Biotin is a cofactor for four carboxylase enzymes which are also involved in macronutrient metabolism (IoM, 1998; Stryer, 1988).

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

### **3.3. Maintenance of skin and mucous membranes (ID 115)**

Symptoms of biotin deficiency include a scaly (seborrheic), red (eczematous) skin which is reversible by administration of biotin (Mock, 2005). There is evidence that impaired fatty acid metabolism secondary to reduced activities of the biotin dependent carboxylases (especially acetyl CoA carboxylase) plays an aetiological role in the dermatological manifestation of biotin deficiency (Mock, 1991).

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

### **3.4. Maintenance of hair (ID 118, 2876)**

In addition to textbooks, animal studies and case reports, one reference was provided on the effect of high doses of biotin on alopecia and hair quality (Floersheim, 1992). The Panel notes that in this study no objective methods were used to determine the improvement in hair loss and hair quality.

Symptoms of biotin deficiency include thinning of hair and progression to loss of all hair, including eyebrows and lashes. Growth of normal hair generally appears after one or two months of treatment of the deficiency (Mock, 2005).

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

### **3.5. Function of the nervous system (ID 116)**

Biotin has a role in the metabolic pathway of all cells including brain and nerve cells.

Biotin deficiency symptoms include central nervous system abnormalities such as hypotonia, lethargy, and developmental delay in infants, and depression, hallucinations, and paraesthesia of the extremities in adults (FAO/WHO, 2004).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of biotin and normal function of the nervous system. However, the evidence provided does not

establish that inadequate intake of biotin leading to impaired function of the nervous system occurs in the general EU population.

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

##### **4.1. Energy-yielding metabolism (ID 114, 117)**

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

##### **4.2. Macronutrient metabolism (ID 113, 114, 117)**

The Panel considers that the following wording reflects the scientific evidence: "Biotin contributes to normal macronutrient metabolism."

##### **4.3. Maintenance of skin and mucous membranes (ID 115)**

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

##### **4.4. Maintenance of hair (ID 118, 2876)**

The Panel considers that the following wording reflects the scientific evidence: "Biotin contributes to the maintenance of normal hair."

##### **4.5. Function of the nervous system (ID 116)**

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

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

In order to bear the claims a food should be at least 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. No numerical Tolerable Upper Intake Level (UL) has been set for biotin owing to the lack of systematic oral intake dose-response studies of biotin (SCF, 2001).

#### **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.

##### **Energy-yielding metabolism (ID 114, 117)**

- The claimed effects are "fat, carbohydrate, energy metabolism" and "fat metabolism and energy production". 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 biotin and normal energy-yielding metabolism.

- The evidence provided does not establish that inadequate intake of biotin leading to impaired energy-yielding metabolism occurs in the general EU population.
- The following wording reflects the scientific evidence: “Biotin contributes to normal energy-yielding metabolism.”

#### **Macronutrient metabolism (ID 113, 114, 117)**

- The claimed effects are “protein and amino acid metabolism”, “fat, carbohydrate, energy metabolism” and “fat metabolism and energy production”. The target population is assumed to be the general population. Normal macronutrient metabolism is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of biotin and normal macronutrient metabolism.
- The evidence provided does not establish that inadequate intake of biotin leading to impaired macronutrient metabolism occurs in the general EU population.
- The following wording reflects the scientific evidence: “Biotin contributes to normal macronutrient metabolism.”

#### **Maintenance of skin and mucous membranes (ID 115)**

- The claimed effect is “normal structure and function of skin and mucosa”. The target population is assumed to be 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 biotin and the maintenance of normal skin and mucous membranes.
- The evidence provided does not establish that intake of biotin inadequate for the maintenance of normal skin and mucous membranes occurs in the general EU population.
- The following wording reflects the scientific evidence: “Biotin contributes to the maintenance of normal skin and mucous membranes.”

#### **Maintenance of hair (ID 118, 2876)**

- The claimed effects are “hair growth & follicle formation” and “hair loss and regrowth”. The target population is assumed to be the general population. Maintenance of normal hair is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of biotin and maintenance of normal hair.
- The evidence provided does not establish that intake of biotin inadequate for the maintenance of normal hair occurs in the general EU population.
- The following wording reflects the scientific evidence: “Biotin contributes to the maintenance of normal hair.”

#### **Function of the nervous system (ID 116)**

- The claimed effect is “neurological system function”. The target population is assumed to be the general population. Normal function of the nervous system is beneficial to human health.

- A cause and effect relationship has been established between the dietary intake of biotin and normal neurological function.
- The evidence provided does not establish that inadequate intake of biotin leading to impaired function of the nervous system occurs in the general EU population.
- The following wording reflects the scientific evidence: “Biotin contributes to the normal function of the nervous system.”

### 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-2008-900, EFSA-Q-2008-901, EFSA-Q-2008-902, EFSA-Q-2008-903, EFSA-Q-2008-904, EFSA-Q-2008-905, EFSA-Q-2008-3609). 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

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- Stryer L, 1988. *Biochemie*. Spektrum der Wissenschaft, Heidelberg.

## 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>6</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>7</sup>

Foods are commonly involved in many different functions<sup>8</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.

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<sup>6</sup> OJ L12, 18/01/2007

<sup>7</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>8</sup> 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
113	Biotin	Protein and amino acid metabolism	<ul style="list-style-type: none"> <li>- Biotin is needed for the proper metabolism of proteins</li> <li>- Biotin helps to build your proteins.</li> </ul>
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>– Must at least be a source of vitamin/s as per annex to regulation 1924/2006</li> <li>– Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: .02 miligram(s) Biotin Daily amount to be consumed to produce claimed effect: .02 miligram(s)</li> </ul>		
114	Biotin	Fat, carbohydrate, energy metabolism	<ul style="list-style-type: none"> <li>-Biotin helps release energy from fats</li> <li>-Biotin is needed for the body to help regulating carbohydrate supply</li> <li>-Biotin is needed for the proper metabolism of proteins/</li> <li>-Biotin helps to build your proteins.</li> </ul>
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>– Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: .02 miligram(s) biotin Daily amount to be consumed to produce claimed effect: .02 miligram(s)</li> <li>– Must at least be a source of vitamin/s as per annex to regulation 1924/2006</li> <li>– Es werden nur die Nährstoffe beworben, die lt. Nährwertkennzeichnungsverordnung (Anlage 1) mindestens 15 Prozent der empfohlenen Tagesdosis in 100 g oder 100 ml enthalten.</li> </ul>		
115	Biotin	Normal structure and function of skin and mucosa	Biotin helps to maintain healthy skin and mucosa.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>– Must at least be a source of vitamins as per annex to regulation 1924/2006</li> <li>– Minimum 15% RDA (0,023 mg)</li> <li>– Tagesbedarf gemäß NwKVO 150 µg pro Tag</li> <li>– 30 – 60 mcg pro Tag—Erwachsene</li> </ul>		

	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
<b>116</b>	Biotin	Neurological system function	Biotin is needed for normal mental function
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>– Minimum 15% RDA (0,023 mg) Grupa docelowa: osoby dorosle (po 18-tym roku zycia).</li> <li>– Must at least be a source of vitamin/s as per annex to regulation 1924/2006. Applicable to both children and adults</li> <li>– Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: .02 miligram(s) biotin Daily amount to be consumed to produce claimed effect: .02 miligram(s)</li> </ul>		
<b>117</b>	Biotin	Fat metabolism and energy production	Biotin contributes to normal fat metabolism and energy production. Biotin is involved in the metabolism of fats, carbohydrates and proteins. Biotin helps release energy from food.
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>– Must at least be a source of vitamin/s as per annex to regulation 1924/2006. Applicable to both children and adults</li> </ul>		
<b>118</b>	Biotin	Hair Growth & Follicle Formation	Biotin is essential for hair growth and hair follicle formation.
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>– Minimum 15% RDA</li> </ul>		
<b>2877</b>	Vitamine B8 : Vitamin B8 or vitamin H (biotin)	Hair loss and regrowth	Takes part in the regulation of sebum excess at the root of hair and thus contributes to limit hair loss and to stimulate their re-growth
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>– 0,15 mg/day</li> </ul>		