

## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to various food(s)/food constituent(s) and “energy and vitality” (ID 18, 26, 62, 105, 122, 145, 165, 3962, 4054, 4440), “invigoration of the body” (ID 2383, 2386, 2391, 2393, 2409, 2441, 2463, 2488, 3834, 3883), “general health” (ID 1313, 3348, 4182, 4613), “rejuvenation” (ID 3981, 4023), “tonic” (ID 1703, 3462, 3581, 4418), “stimulant” (ID 3190, 3506) and “metabolic benefits” (ID 4438) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>**

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

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims related to various food(s)/food constituent(s) and “energy and vitality”, “invigoration of the body”, “general health”, “rejuvenation”, “tonic”, “stimulant” and “metabolic benefits”. 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 claimed effects refer to “energy and vitality”, “invigoration of the body”, “general health”, “rejuvenation”, “tonic”, “stimulant” and “metabolic benefits”. The Panel considers that the claimed

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<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-805, EFSA-Q-2008-813, EFSA-Q-2008-849, EFSA-Q-2008-892, EFSA-Q-2008-909, EFSA-Q-2008-932, EFSA-Q-2008-952, EFSA-Q-2008-2050, EFSA-Q-2008-2439, EFSA-Q-2008-3116, EFSA-Q-2008-3119, EFSA-Q-2008-3124, EFSA-Q-2008-3126, EFSA-Q-2008-3142, EFSA-Q-2008-3174, EFSA-Q-2008-3196, EFSA-Q-2008-3221, EFSA-Q-2008-3922, EFSA-Q-2008-4079, EFSA-Q-2008-4191, EFSA-Q-2008-4233, EFSA-Q-2008-4307, EFSA-Q-2008-4550, EFSA-Q-2008-4599, EFSA-Q-2008-4678, EFSA-Q-2008-4696, EFSA-Q-2008-4735, EFSA-Q-2008-4766, EFSA-Q-2008-4893, EFSA-Q-2010-00371, EFSA-Q-2010-00391, EFSA-Q-2010-00393, EFSA-Q-2010-00566, adopted on 9 July 2010.

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<sup>3</sup> Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: 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.

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effects are not sufficiently defined. As no further details were provided in the proposed wordings or the clarifications provided by Member States, no specific claimed effects could be defined.

The Panel considers that these claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

**KEY WORDS**

Energy, vitality, invigoration, general health, rejuvenation, tonic, stimulant, and metabolic benefits, 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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## INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006<sup>4</sup> submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out<sup>5</sup>. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

## ASSESSMENT

The approach used in the evaluation of Article 13(1) health claims is explained in the briefing document for stakeholders published by EFSA<sup>6</sup>.

In assessing each specific food/health relationship that forms the basis of a health claim the NDA Panel considers the extent to which:

1. the food/constituent is defined and characterised;
2. the claimed effect is defined and is a beneficial physiological effect (“beneficial to human health”);
3. a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use).

Substantiation of the claim is dependent on a favourable outcome of the assessment of 1, 2 and 3 above. Thus, a cause and effect relationship is considered not to be established if the outcome of any one of these assessments is unfavourable.

For a claim, each relationship between a food/constituent and a claimed effect is assessed separately and individual assessments are combined, as appropriate, to form coherent opinions.

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

#### 1.1. “Energy and vitality” (ID 18, 26, 62, 105, 122, 145, 165, 3962, 4054, 4440)

The claimed effects are “energy”, “energy and vitality”, and “vitalizing”. The Panel assumes that the target population is the general population.

The Panel considers that the claimed effects are not sufficiently defined. As no further details were provided in the proposed wordings or the clarifications provided by Member States, no specific claimed effects could be defined.

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<sup>4</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

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

<sup>6</sup> See footnote 5

The Panel considers that these claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

**1.2. “Invigoration of the body” (ID 2383, 2386, 2391, 2393, 2409, 2441, 2463, 2488, 3834, 3883)**

The claimed effect is “invigoration of the body”. The Panel assumes that the target population is the general population.

The Panel considers that the claimed effect is not sufficiently defined. As no further details were provided in the proposed wordings or the clarifications provided by Member States, no specific claimed effect could be defined.

The Panel considers that this claimed effect is general and non-specific and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

**1.3. “General health” (ID 1313, 3348, 4182, 4613)**

The claimed effects are “general health”, “general health/contribution to a healthy and balanced diet”, “self well-being”, and “enhance general state of the organism/helps body for properly functioning”. The Panel assumes that the target population is the general population.

The Panel considers that the claimed effects are not sufficiently defined. As no further details were provided in the proposed wordings or the clarifications provided by Member States, no specific claimed effects could be defined.

The Panel considers that these claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

**1.4. “Rejuvenation” (ID 3981, 4023)**

The claimed effect is “rejuvenation”. The Panel assumes that the target population is the general population.

The Panel considers that the claimed effect is not sufficiently defined. As no further details were provided in the proposed wordings or the clarifications provided by Member States, no specific claimed effect could be defined.

The Panel considers that this claimed effect is general and non-specific and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

**1.5. “Tonic” (ID 1703, 3462, 3581, 4418)**

The claimed effects are “tonic for the support of physical capacities”, “tonic for the support of mental and well-being”, “reconstituent and tonic”, and “general tonic/vitamins and mineral supplementation from natural source”. The Panel assumes that the target population is the general population.

The Panel considers that the claimed effects are not sufficiently defined. As no further details were provided in the proposed wordings or the clarifications provided by Member States, no specific claimed effects could be defined.

The Panel considers that these claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

#### **1.6. “Stimulant” (ID 3190, 3506)**

The claimed effects are “stimulant” and “the unique composition and ratio of effective substances has general stimulating effects”. The Panel assumes that the target population is the general population.

The Panel considers that the claimed effects are not sufficiently defined. As no further details were provided in the proposed wordings or the clarifications provided by Member States, no specific claimed effects could be defined.

The Panel considers that these claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

#### **1.7. “Metabolic benefits” (ID 4438)**

The claimed effect is “metabolic benefits”. The Panel assumes that the target population is the general population.

The Panel considers that the claimed effect is not sufficiently defined. As no more details were provided in the proposed wordings or the clarifications provided by Member States, no specific claimed effect could be defined.

The Panel considers that this claimed effect is general and non-specific and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

### **CONCLUSIONS**

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

#### **“Energy and vitality” (ID 18, 26, 62, 105, 122, 145, 165, 3962, 4054, 4440)**

- The claimed effects are “energy”, “energy and vitality”, and “vitalizing”. The target population is assumed to be the general population.
- The claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

#### **“Invigoration of the body” (ID 2383, 2386, 2391, 2393, 2409, 2441, 2463, 2488, 3834, 3883)**

- The claimed effect is “invigoration of the body”. The target population is assumed to be the general population.
- The claimed effect is general and non-specific and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

#### **“General health” (ID 1313, 3348, 4182, 4613)**

- The claimed effects are “general health”, “general health/contribution to a healthy and balanced diet”, “self well-being”, “enhance general state of the organism/helps body for properly functioning”. The target population is assumed to be the general population.
- The claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

### **“Rejuvenation” (ID 3981, 4023)**

- The claimed effect is “rejuvenation”. The target population is assumed to be the general population.
- The claimed effect is general and non-specific and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

### **“Tonic” (ID 1703, 3462, 3581, 4418)**

- The claimed effects are “tonic for the support of physical capacities”, “tonic for the support of mental and well-being”, and “reconstituent and tonic”. The target population is assumed to be the general population.
- The claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

### **“Stimulant” (ID 3190, 3506)**

- The claimed effects are “stimulant” and “the unique composition and ratio of effective substances has general stimulating effects”. The target population is assumed to be the general population.
- The claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

### **“Metabolic benefits” (ID 4438)**

- The claimed effect is “metabolic benefits”. The target population is assumed to be the general population.
- The claimed effect is general and non-specific and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

## **DOCUMENTATION PROVIDED TO EFSA**

Health claims pursuant to Article 13(1) of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-805, EFSA-Q-2008-813, EFSA-Q-2008-849, EFSA-Q-2008-892, EFSA-Q-2008-909, EFSA-Q-2008-932, EFSA-Q-2008-952, EFSA-Q-2008-2050, EFSA-Q-2008-2439, EFSA-Q-2008-3116, EFSA-Q-2008-3119, EFSA-Q-2008-3124, EFSA-Q-2008-3126, EFSA-Q-2008-3142, EFSA-Q-2008-3174, EFSA-Q-2008-3196, EFSA-Q-2008-3221, EFSA-Q-2008-3922, EFSA-Q-2008-4079, EFSA-Q-2008-4191, EFSA-Q-2008-4233, EFSA-Q-2008-4307, EFSA-Q-2008-4550, EFSA-Q-2008-4599, EFSA-Q-2008-4678, EFSA-Q-2008-4696, EFSA-Q-2008-4735, EFSA-Q-2008-4766, EFSA-Q-2008-4893, EFSA-Q-2010-00371, EFSA-Q-2010-00391, EFSA-Q-2010-00393, EFSA-Q-2010-00566). 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>.

## 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>7</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>8</sup>

Foods are commonly involved in many different functions<sup>9</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

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<sup>7</sup> OJ L12, 18/01/2007

<sup>8</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>9</sup> The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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

#### **SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE**

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 various food(s)/food constituent(s) claiming general and non-specific health effects, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
18	Vitamin A	Energy and Vitality	Necessary to maintain energy and general vitality
	<b>Conditions of use</b> - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.  Agency guidance for supplements is that products containing beta-carotene should carry the label advisory statement "[Beta-carotene] should not be taken by heavy smokers."		
	<b>No clarification provided by Member States</b>		
ID	Food or Food constituent	Health Relationship	Proposed wording
26	Vitamin B1	Energy and Vitality	Necessary to maintain energy and general vitality
	<b>Conditions of use</b> - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.		
	<b>No clarification provided by Member States</b>		
ID	Food or Food constituent	Health Relationship	Proposed wording
62	Vitamin B5	Energy and Vitality	Necessary to maintain energy and general vitality
	<b>Conditions of use</b> - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.		
	<b>No clarification provided by Member States</b>		
ID	Food or Food constituent	Health Relationship	Proposed wording
105	Vitamin B12	Energy and Vitality	Necessary to maintain energy and general vitality
	<b>Conditions of use</b> - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.		
	<b>No clarification provided by Member States</b>		
ID	Food or Food constituent	Health Relationship	Proposed wording
122	Biotin	Energy and Vitality	Necessary to maintain energy and general vitality
	<b>Conditions of use</b> - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or		

	[name of mineral/s]" as per Annex to Regulation 1924/2006.		
	<b>No clarification provided by Member States</b>		
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
145	Vitamin C	Energy and Vitality	Necessary to maintain energy and general vitality
	<b>Conditions of use</b> - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.  Agency guidance for supplements is that products containing >1000 mg of Vitamin C should carry the label advisory statement "This amount of Vitamin C may cause mild stomach upset in sensitive individuals"		
	<b>No clarification provided by Member States</b>		
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
165	Vitamin E	Energy and Vitality	Necessary to maintain energy and general vitality
	<b>Conditions of use</b> - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.		
	<b>No clarification provided by Member States</b>		
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
1313	Vegetables of 5 colors	General health. Contribution to a healthy and balanced diet	Eating a variety of colorful vegetables helps to protect your health. Eating vegetables of all the available colors helps to get all the nutrients and protective substances that will contribute to the wellbeing of your body.
		<u>Clarification provided</u> Contribute and support general health via the action of phytochemicals and fibre	
<b>Conditions of use</b> - none provided			
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
1703	Royal jelly	Reconstituent and tonic	Reconstituent and tonic
	<b>Conditions of use</b> - 500 mg/sachet		
	<b>No clarification provided by Member States</b>		
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
2383	Acorus Calamus (Sweet flag, sweet rush)	Invigoration of the body	1. Stimulating properties  2. A generally restorative product for those who wish to suppress the addiction, including smoking addiction

			<p>3. For the health of respiratory organs, promotion of cough-up and body's resistance (resistance abilities)</p> <p>4. Contains herbs with stimulating and mood-improving properties</p>
<p><b>Conditions of use</b></p> <p>- Root: 0,1 - 1,8 g / Used as part of a multibotanical combination</p>			
<p><b>No clarification provided by Member States</b></p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
2386	Alchemilla vulgaris (Lady's Mantle )	Invigoration the body	A tasty and healthy drink, the herbs present in it contain vitamins, minerals, essential oils, and flavonoids which beneficially affect the state of health, soothe and strengthen
<p><b>Conditions of use</b></p> <p>- Used as part of a multibotanical combination</p>			
<p><b>No clarification provided by Member States</b></p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
2391	Angelica sinensis (Angelica)	Invigoration the body	A generally restorative product for the maintenance of body's functions — strengthens the immunity, improves the state of cardiovascular system, tones up the body, stimulates mental work capacities, increases body's adaptation in extreme and stressful situations
<p><b>Conditions of use</b></p> <p>- Root: 0,4- 1,25g / Used as part of a multibotanical combination</p>			
<p><b>No clarification provided by Member States</b></p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
2393	Apium graveolens (Celery)	Invigoration the body	A generally restorative tea which is rich in vitamins, minerals, antioxidants and essential herbal oils and helps the body overcome stress and exertion, prevents setting in of changes associated with age, improves the immunity

	<b>Conditions of use</b> - Leaf: 30 mg / Used as part of a multibotanical combination		
	<b>No clarification provided by Member States</b>		
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
<b>2409</b>	Centaurium erythraea (Centaury)	Invigoration the body	A generally restorative product for those who wish to suppress the addiction, including smoking addiction
	<b>Conditions of use</b> - 36 mg / Used as part of a multibotanical combination		
	<b>No clarification provided by Member States</b>		
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
<b>2441</b>	Euphrasia officinalis (Eyebright)	Invigoration of the body	A generally restorative product for those who wish to suppress the addiction, including smoking addiction
	<b>Conditions of use</b> - Herb: 36 mg / Used as part of a multibotanical combination		
	<b>No clarification provided by Member States</b>		
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
<b>2463</b>	Medicago lupulina / M.sativa	Invigoration the body	Contains herbs with body strengthening and restorative properties
	<b>Conditions of use</b> - Herb: 740 mg / Used as part of a multibotanical combination		
	<b>No clarification provided by Member States</b>		
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
<b>2488</b>	Salix alba (Willow)	Invigoration the body	Contains herbs with body strengthening and restorative properties
	<b>Conditions of use</b> - Bark: 600 mg / Used as part of a multibotanical combination		
	<b>No clarification provided by Member States</b>		
<b>ID</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
<b>3190</b>	Royal jelly, lyophilized	The unique composition and ratio of effective substances has general stimulating effects.- upresnit vplyv-stimulacny vplyv na psychicke funkcie alebo telesne funkcie?	It nourishes the human body and supplies energy. It supplies vitamins and minerals from natural sources. It has positive effects during menopause and for overall rejuvenation of the skin and human body.

		<p><u>Clarification provided</u></p> <p>The unique composition and ratio of effective substances has general stimulating effects, it improves the immune system and most biological functions</p>	
<p><b>Conditions of use</b></p> <p>- Not suitable for people sensitive to bee products. Not intended for children and pregnant women. To use 20 mg of lyophilized royal jelly once per day within the period of one month.</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
3348	ELEUTHEROCOCCUS SENTICOSUS MAXIM.	Self well-being.	Helps to obtain a relaxation effect and regain a natural good temper.
<p><b>Conditions of use</b></p> <p>- Dried extract (tit. eleutheroside E min. 0.5%): 5-6 mg/kg/day, divided in 2 doses (morning and afternoon)</p>			
<p><b>No clarification provided by Member States</b></p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
3462	MUIRA PUAMA	Tonic for the support of physical capacities.	Helps in case of augmented request of nutrients. Helps in case of augmented request of nutrients. Helps the physical and mental resistance.
<p><b>Conditions of use</b></p> <p>- Leaves, stem, and roots: 0.5-1.5 g/day for two weeks</p>			
<p><b>No clarification provided by Member States</b></p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
3506	Piper longum	Stimulant	None provided
<p><b>Conditions of use</b></p> <p>- Fruit 0.5-3g / day</p>			
<p><b>No clarification provided by Member States</b></p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
3581	SCHISANDRA CHINENSIS BAILL.	Tonic for the support of mental and well-being	Contributes to recover physical and mental well-being. Helps the physical and mental resistance.
<p><b>Conditions of use</b></p> <p>- 400-450 mg powdered herb cps three times daily or 1-2 ml of 1:3 EtOH tincture three times daily</p>			
<p><b>No clarification provided by Member States</b></p>			

ID	Food or Food constituent	Health Relationship	Proposed wording
3834	Urtica dioica (Common Name : Nettle)	Invigoration of the body	Support the body's vitality/ helps to make you feel more energetic
	<b>Conditions of use</b> - Aerial parts, root / Usual consumption as traditional foodstuff in a normal diet / The equivalent of 4 g nettle root per day		
	<b>No clarification provided by Member States</b>		
ID	Food or Food constituent	Health Relationship	Proposed wording
3883	Rosmarinus officinalis (Common Name : Rosemary)	Invigoration of the body	helps to strengthen the body/ helps you feel more energetic
	<b>Conditions of use</b> - Leaf / Usual consumption as traditional foodstuff in a normal diet / The equivalent of 4-6 g of herb per day - Leaf / Usual consumption as traditional foodstuff in a normal diet / The equivalent of 2 g of herb per day		
	<b>No clarification provided by Member States</b>		
ID	Food or Food constituent	Health Relationship	Proposed wording
3962	Asparagus racemosus ROOT	Energy <u>Clarification provided</u> Its anodyne and tonic qualities give strength and energy. (note to EFSA: this can be measured).	Helps to maintain strength and energy levels. Helps increase strength and energy levels.
	<b>Conditions of use</b> - Powder 2.0-0.1g/day; aqueous extract 1.0-0.05g/day All over 2 years old: 2-4 years ¼ adult dose, 4-10 years half adult dose		
ID	Food or Food constituent	Health Relationship	Proposed wording
3981	Asphaltum/Shilajit – purified	Rejuvenation <u>Clarification provided</u> Enhances the feeling of strength	Has a rejuvenating effect
	<b>Conditions of use</b> - Powder: 1.0-0.05g/day All over 2 years old: 2-4 years ¼ adult dose, 4-10 years half adult dose		
ID	Food or Food constituent	Health Relationship	Proposed wording
4023	Commiphora mukul PURIFIED EXUDATE	Rejuvenation <u>Clarification provided</u> Enhances the feeling of strength	Has a rejuvenating effect on all tissues.

<p><b>Conditions of use</b></p> <p>- Powder: 0.75-0.05g/day. Unsupervised long-term use of more than 250-500mg/day is not recommended during pregnancy. May occasionally loosen the bowels Do not use in case of diarrhoea.</p> <p>All over 2 years old: 2-4 years ¼ adult dose, 4-10 years half adult dose.</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
4054	Glycyrrhiza glabra ROOT	<p>Energy</p> <p><u>Clarification provided</u></p> <p>Its sweet, tonic and alterative properties support energy levels.</p>	Helps maintain energy levels
<p><b>Conditions of use</b></p> <p>- Powder: 4.0-0.2g/day ; aqueous extract 2.0-0.1g/day . Caution in long-term use. Not more than 3g/day in pregnancy.</p> <p>All over 2 years old: 2-4 years ¼ adult dose, 4-10 years half adult dose</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
4182	Tribulus terrestris FRUIT	<p>General health</p> <p><u>Clarification provided</u></p> <p>Its digestive, aphrodisiac and tonic effects help maintain energy levels.</p>	Helps maintain body and muscle tone and energy levels.
<p><b>Conditions of use</b></p> <p>- Powder: 0.6-0.03g/day; aqueous extract: 0.3-0.015g/day.</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
4418	Hordeum vulgare-Herba-Green Barley	General tonic Vitamins and mineral supplementation from natural source	Vitamins, enzymes and mineral supplementation from natural source
<p><b>Conditions of use</b></p> <p>- Oral administration / Powder, sachets, 2 sachets a day</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
4438	Medicago sativa-Herba-Alfalfa	Metabolic benefits	Improves the metabolism
<p><b>Conditions of use</b></p> <p>- Oral administration / Powder</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
4440	Medicago sativa L.-Flowering herb-Alfalfa	Vitalizing	Vitamin and mineral supplement in case of psycho-physical exhaustion, exhaustion of sportsmen, in convalescence/ Vitaminization cure for

			children.
<b>Conditions of use</b> - Children: 1-2 years: 1 ml 2 times a day; 3-7 years: 2 ml 2 times a day; Up to 7 years and adults: 3 ml 2 times a day.			
ID	Food or Food constituent	Health Relationship	Proposed wording
4613	Ribes nigrum fructus, Rosa canina fructus (blackcurrant fruits, wild dog rose fruits)	Enhance general state of the organism / Helps body for properly functioning	helps to eliminate weakness and fortify the body / maintain general well/being
<b>Conditions of use</b> - children younger as 2 years: 1 teaspoon per day (2,5 g) / -children 2-6 years: 2 teaspoon per day (5 g) / -adults: 6 teaspoon per day (15 g) / A usually cure can be taken 6-8 weeks.			