

## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to magnesium and electrolyte balance (ID 238), energy-yielding metabolism (ID 240, 247, 248), neurotransmission and muscle contraction including heart muscle (ID 241, 242), cell division (ID 365), maintenance of bone (ID 239), maintenance of teeth (ID 239), blood coagulation (ID 357) and protein synthesis (ID 364) 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 magnesium and the following claimed effects: electrolyte balance, energy-yielding metabolism, neurotransmission and muscle contraction including heart muscle, cell division, maintenance of bone, maintenance of teeth, blood coagulation and protein synthesis. 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 magnesium, which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that magnesium is sufficiently characterised.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of magnesium and electrolyte balance, normal energy-yielding metabolism, normal neurotransmission and muscle contraction including heart muscle, normal cell division, maintenance of normal bone, maintenance of normal teeth, and normal protein synthesis.

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1 On request from the European Commission, Question No EFSA-Q-2008-1025, EFSA-Q-2008-1026, EFSA-Q-2008-1027, EFSA-Q-2008-1028, EFSA-Q-2008-1029, EFSA-Q-2008-1034, EFSA-Q-2008-1035, EFSA-Q-2008-1144, EFSA-Q-2008-1151, EFSA-Q-2008-1152 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 magnesium as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of magnesium and normal blood coagulation.

**KEY WORDS**

Magnesium, minerals, electrolyte balance, energy-yielding metabolism, neurotransmission, muscle, heart, cell division, bone, teeth, blood coagulation, protein synthesis, health claims.

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

See Appendix A

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

See Appendix A

## **EFSA DISCLAIMER**

See Appendix B

## **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 magnesium, which is a well recognised nutrient and is measurable in foods by established methods.

Magnesium occurs naturally in foods and is authorised for addition to foods (Annex I of Regulation (EC) No 1925/2006<sup>4</sup> and Annex I of Directive 2002/46/EC<sup>5</sup>). This evaluation applies to magnesium naturally present in foods and to 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, magnesium, which is the subject of the health claims is sufficiently characterised.

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

#### 2.1. Electrolyte balance (ID 238)

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

The Panel considers that electrolyte balance is beneficial to human health.

#### 2.2. Energy-yielding metabolism (ID 240, 247, 248)

The claimed effects are “energy metabolism/normal cellular energy supply”, “magnesium is an essential cofactor for more than 300 enzymes involved in biosynthetic processes and energy metabolism”, “normal energy metabolism”. The Panel assumes that the target population is the general population.

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

#### 2.3. Neurotransmission and muscle contraction including heart muscle (ID 241, 242)

The claimed effects are “normal muscle contraction including normal heartbeat” and “nerve transmission/function”. The Panel assumes that the target population is the general population.

The Panel considers that normal neurotransmission and muscle contraction including heart muscle are beneficial to human health.

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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.

#### **2.4. Cell division (ID 365)**

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

The Panel notes that cell division is a crucial process for tissue growth and development and for tissue maintenance through cell turnover.

The Panel considers that normal cell division is beneficial to human health.

#### **2.5. Maintenance of bone (ID 239)**

The claimed effect is “bone and teeth structure”. The Panel assumes that the target population is the general population.

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

#### **2.6. Maintenance of teeth (ID 239)**

The claimed effect is “bone and teeth structure”. The Panel assumes that the target population is the general population.

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

#### **2.7. Blood coagulation (ID 357)**

The claimed effect is “normal blood clotting”. The Panel assumes that the target population is the general population.

The Panel considers that normal blood coagulation is beneficial to human health.

#### **2.8. Protein synthesis (ID 364)**

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

The Panel considers that normal protein synthesis is beneficial to human health.

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

Magnesium is an essential nutrient and serves as a cofactor for over 300 enzymes involved in biosynthetic processes. It is part of the Mg-ATP complex, is essential for oxidative phosphorylation and has roles in energy metabolism, mineral homeostasis, calcium metabolism, and neuromuscular and endocrine function (IoM, 1997; SCF, 2001; Volpe, 2006).

In the human body, 50 to 60% of magnesium is located in the bone. Part of it is readily exchangeable with serum and therefore bone represents a magnesium store. The remaining magnesium is mainly intracellular; extracellular magnesium represents only 1% of the total magnesium content of the body.

#### **3.1. Electrolyte balance (ID 238)**

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus on the role of magnesium in electrolyte balance (IoM, 1997; EVM, 2003; Rude and Shils, 2006).

Soft tissue magnesium functions as a cofactor of many enzymes involved in the maintenance of the electrical potential of nerve tissue and cell membranes. Magnesium deficiency always includes secondary electrolyte disturbances. Hypomagnesaemia is often associated with hypocalcaemia and

calcium homeostasis is controlled in part by a Mg-requiring mechanism which releases parathyroid hormone.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of magnesium and electrolyte balance.

### **3.2. Energy-yielding metabolism (ID 240, 247, 248)**

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus on the role of magnesium in energy-yielding metabolism (SCF, 2001; IoM, 1997)

The Panel concludes that a cause and effect relationship has been established between the dietary intake of magnesium and normal energy-yielding metabolism.

### **3.3. Neurotransmission and muscle contraction including heart muscle (ID 241, 242)**

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus on the role of magnesium in nerve transmission and muscle contraction, including heart muscle contraction (IoM, 1997; FAO/WHO, 2004; EVM, 2002; DoH, 1991).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of magnesium and normal neurotransmission and muscle contraction including heart muscle.

### **3.4. Cell division (ID 365)**

Magnesium is able to form complexes with nucleic acids. The negatively charged ribose phosphate structure of nucleic acids has a high affinity for magnesium. The resulting stabilisation of numerous ribonucleotides and deoxyribonucleotides induces physicochemical changes that affect DNA maintenance, duplication and transcription (Rude and Shils, 2006).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of magnesium and cell division.

### **3.5. Maintenance of bone (ID 239)**

Some 50 to 60% of the total body magnesium content of approximately 25 g in the normal adult resides in bones and teeth. One-third of skeletal magnesium is exchangeable, and it is this fraction that may serve as a reservoir for maintaining a normal extracellular magnesium concentration. The magnesium in bones and tooth enamel and dentin is not an integral part of the hydroxyapatite crystal structure (like calcium and phosphorus); rather, it is adsorbed on the surface of the crystal. Magnesium deficiency in animals results in decreased bone strength and volume and impaired bone and tooth development. Magnesium deficiency in humans causes hypocalcaemia and vitamin D abnormalities (Volpe, 2006).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of magnesium and maintenance of normal bone.

### **3.6. Maintenance of teeth (ID 239)**

Some 50 to 60% of the total body magnesium content of approximately 25 g in the normal adult resides in bones and teeth. One-third of skeletal magnesium is exchangeable, and it is this fraction that may serve as a reservoir for maintaining a normal extracellular magnesium concentration. The magnesium in bones and tooth enamel and dentin is not an integral part of the hydroxyapatite crystal structure (like calcium and phosphorus); rather, it is adsorbed on the surface of the crystal. Magnesium deficiency in animals results in decreased bone strength and volume and impaired bone

and tooth development. Magnesium deficiency in humans causes hypocalcaemia and vitamin D abnormalities.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of magnesium and maintenance of teeth.

### **3.7. Blood coagulation (ID 357)**

The normal mechanism for blood coagulation is a complex series of events involving the interaction of the injured blood vessel, platelets, and a number of various coagulation factors circulating in the blood.

The only reference provided does not refer to the role of magnesium on blood coagulation. The magnesium cation might act indirectly on this function through its effects on calcium. However, impaired blood coagulation is not an established symptom of magnesium deficiency.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of magnesium and normal blood coagulation.

### **3.8. Protein synthesis (ID 364)**

Magnesium is an essential cofactor of enzymes involved in protein synthesis (SCF, 2001; FAO/WHO, 2004). Protein synthesis is reported to be sensitive to magnesium depletion (IoM, 1997).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of magnesium and normal protein synthesis.

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

### **4.1. Electrolyte balance (ID 238)**

The Panel considers that the following wording reflects the scientific evidence: "Magnesium contributes to electrolyte balance".

### **4.2. Energy-yielding metabolism (ID 240, 247, 248)**

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

### **4.3. Neurotransmission and muscle contraction including heart muscle (ID 241, 242)**

The Panel considers that the following wordings reflect the scientific evidence: "Magnesium contributes to normal muscle function including the heart muscle", "magnesium contributes to normal nerve function".

### **4.4. Cell division (ID 365)**

The Panel considers that the following wording reflects the scientific evidence: "Magnesium contributes to normal cell division".

### **4.5. Maintenance of bone (ID 239)**

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



#### **4.6. Maintenance of teeth (ID 239)**

The Panel considers that the following wording reflects the scientific evidence: “Magnesium contributes to the maintenance of normal teeth”.

#### **4.7. Protein synthesis (ID 364)**

The Panel considers that the following wording reflects the scientific evidence: “Magnesium contributes to normal protein synthesis”.

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

The Panel considers that in order to bear the claim a food should be at least a source of magnesium 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 Tolerable Upper Intake Levels (UL) have been established for magnesium normally present in food and beverages. An UL of 250 mg Mg/day for older children and adults has been established for readily dissociable magnesium salts and compounds like MgO in nutritional supplements, waters or added to food and beverages (SCF, 2001).

### **CONCLUSIONS**

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

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

#### **Electrolyte balance (ID 238)**

- The claimed effect is “electrolyte balance”. The target population is assumed to be the general population. Electrolyte balance is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of magnesium and electrolyte balance.
- The following wording reflects the scientific evidence: “magnesium contributes to electrolyte balance”.

#### **Energy-yielding metabolism (ID 240, 247, 248)**

- The claimed effects are “energy metabolism/ normal cellular energy supply”, “magnesium is an essential cofactor for more than 300 enzymes involved in biosynthetic processes and energy metabolism”, “normal energy metabolism”. 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 magnesium and normal energy-yielding metabolism.
- The following wording reflects the scientific evidence: “magnesium contributes to normal energy metabolism”.

#### **Neurotransmission and muscle contraction including heart muscle (ID 241, 242)**

- The claimed effects are “normal muscle contraction including normal heartbeat” and “nerve transmission/function”. The target population is assumed to be the general population. Normal neurotransmission and muscle contraction including heart muscle are beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of magnesium and neurotransmission and muscle contraction including heart muscle.

- The following wordings reflect the scientific evidence: “magnesium contributes to muscle function including the heart muscle”, “magnesium contributes to nerve function”.

#### **Cell division (ID 365)**

- The claimed effect is “cell division”. The target population is assumed to be the general population. Normal cell division is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of magnesium and cell division.
- The following wording reflects the scientific evidence: “magnesium contributes to cell division”.

#### **Maintenance of bone (ID 239)**

- The claimed effect is “bone and teeth structure”. The target population is assumed to be the general population. Maintenance of normal bone is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of magnesium and maintenance of normal bone.
- The following wording reflects the scientific evidence: “magnesium contributes to the maintenance of normal bone”.

#### **Maintenance of teeth (ID 239)**

- The claimed effect is “bone and teeth structure”. The target population is assumed to be the general population. Maintenance of normal teeth is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of magnesium and maintenance of normal teeth.
- The following wording reflects the scientific evidence: “magnesium contributes to the maintenance of normal teeth”.

#### **Blood coagulation (ID 357)**

- The claimed effect is “normal blood clotting”. The target population is assumed to be the general population. Normal blood coagulation is beneficial to human health.
- A cause and effect relationship has not been established between the dietary intake of magnesium and normal blood coagulation.

#### **Protein synthesis (ID 364)**

- The claimed effect is “protein synthesis”. The target population is assumed to be the general population. Normal protein synthesis is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of magnesium and normal protein synthesis.
- The following wording reflects the scientific evidence: “magnesium contributes to normal protein synthesis”.

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

- In order to bear the claims a food should be at least a source of magnesium 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-2008-1025, EFSA-Q-2008-1026, EFSA-Q-2008-1027, EFSA-Q-2008-1028, EFSA-Q-2008-1029, EFSA-Q-2008-1034, EFSA-Q-2008-1035, EFSA-Q-2008-1144, EFSA-Q-2008-1151, EFSA-Q-2008-1152). 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>

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- DoH (Department of Health), 1991. Dietary Reference Values for Food Energy and Nutrients for the United Kingdom. Report of the Panel on Dietary Reference Values. Report on Health and Social Subjects No. 41. DH: The Stationery Office.
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- SCF (Scientific Committee on Food), 2001. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of magnesium.
- Volpe SL, 2006. Magnesium. In: Bowman BA and Russell RM (eds). Present knowledge in nutrition, 9<sup>th</sup> ed. ILSI Press, Washington DC, 400-408.

## 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.

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:

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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).

- (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 magnesium, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
238	Magnesium	Electrolyte balance	Magnesium is necessary for electrolyte balance.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 300 mg per day</li> <li>- MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing &gt;400mg Magnesium should carry the label statement '[This amount of Magnesium] may cause mild stomach upset in sensitive individuals.'Applicable to both children and adults</li> <li>- Person group : keine Einschränkung ; Amount of consumption: 45 mg Mg / 120 mg Ca/ 300 mg K ; period of consumption Nahrungsergänzungsmittel, täglicher Verzehr ; Upper limit (value):300 mg</li> <li>- MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG</li> <li>- 2X175 mg=2192 mg Magnesiumcitrat</li> </ul>		
239			
	Magnesium	Bone and teeth structure	Magnesium is needed to build healthy bones and teeth. Magnesium helps to build and maintain strong bones and teeth
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Must at least be a source of mineral/s as per annex to regulation 1924/2006 (amount to evaluate by EFSA)</li> <li>- 300 mg per day</li> <li>- Does claim rely on the presence/absence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance <ul style="list-style-type: none"> <li>Number of nutrients/other substances that are essential to claimed effect: 1</li> <li>Names of nutrient/other substances and Quantity in Average daily serving: 100mg magnesium</li> <li>Weight of average daily food serving: 200 miligram(s)</li> <li>Daily amount to be consumed to produce claimed effect: 300 miligram(s)</li> <li>Number of food portions this equates to in everyday food portions: 2</li> <li>Are there factors that could interfere with bioavailability: Yes</li> <li>Please give reason: do not store above 25 degrees C</li> <li>Length of time after consumption for claimed effect to become apparent: It is apparent after a period of regular use.</li> <li>Number of days: 7</li> </ul> </li> </ul>			



	<p>Daily amount to be consumed to produce claimed effect: 270 miligram(s)</p> <p>Are there factors that could interfere with bioavailability: No</p> <p>Length of time after consumption for claimed effect to become apparent: Habitual intake</p> <p>Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No</p> <ul style="list-style-type: none"> <li>- Oat bran and flakes with magnesium content of 130mg/100g, 65mg/dl (serving)Phytic acid in cereals may weaken the absorption and utilisation of magnesium</li> <li>- Food supplement with 100-350mg of magnesium in the daily dose</li> <li>- 15% RDA per 100 g</li> <li>- MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing &gt;400mg Magnesium should carry the label statement '[This amount of Magnesium] may cause mild stomach upset in sensitive individuals. Applicable to both children and adults</li> <li>- 300 mg / d—Erwachsene</li> <li>- Tagesbedarf gemäß NwKVO 300 mg pro Tag</li> <li>- MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG</li> <li>- 15% RDA in 100g Lebensmittel = 56,25 mg /100g Lebensmittel ; person group : Erwachsene ; <i>Amount of consumption</i> 375 mg</li> <li>- 2X175 mg=2192 mg Magnesiumcitrat</li> <li>- Jugendliche, Erwachsene ; Amount of consumption 200 mg ; Upper limit (value) 400 mg</li> <li>- Jugendliche, Erwachsene ; Amount of consumption 100 – 350 mg ; Upper limit (value) 350 mg</li> <li>- 53% AJR</li> </ul>		
<b>240</b>	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Magnesium	Energy metabolism/Normal cellular energy supply	Magnesium is essential for use of energy by the body.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing &gt;400mg Magnesium should carry the label statement '[This amount of Magnesium] may cause mild stomach upset in sensitive individuals.'Applicable to both children and adults</li> <li>- 300 mg per day</li> <li>- 300 mg / d—Erwachsene</li> <li>- 2X175 mg=2192 mg Magnesiumcitrat</li> <li>- Jugendliche, Erwachsene. Amount of consumption: 100 – 350 mg ; Upper limit (value) 350 mg</li> </ul>		

	- MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG		
241	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Magnesium	Normal muscle contraction including normal heartbeat	Magnesium is necessary for muscle function
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 6 to 10 mg of magnesium per kg body weight per day. 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 &gt;0.5 mg magnesium should carry the label advisory statement "this amount of magnesium may cause mild stomach upset in sensitive individuals"</li> <li>- 300 mg per day</li> <li>- Jugendliche, Erwachsene. Amount of consumption: 100 – 350 mg ; Upper limit (value) 350 mg</li> <li>- Jugendliche, Erwachsene. Amount of consumption: 200 mg ; Upper limit (value) 400 mg</li> <li>- 150 mg minimum daily is suggested in food supplements. The UK RNI is 270 mg daily for women, 300 mg daily for men. High doses of magnesium over time can cause nausea, diarrhoea and calcium depletion. Supplements containing &gt;400mg magnesium should carry the label advisory statement "this amount of magnesium may cause mild stomach upset in sensitive individuals"</li> <li>- Source of / 15% of RDA per 100 g Agency guidance for supplements is that products containing &gt;400mg magnesium should carry the label advisory statement "this amount of magnesium may cause mild stomach upsets in sensitive individuals"</li> <li>- Oat bran and flakes with magnesium content of 130mg/100g, 65mg/dlPhytic acid may interfere with the absorption of calcium.</li> <li>- Food supplement with 100-300mg of magnesium in the daily dose.</li> <li>- Food supplement with 100-350mg of magnesium in the daily dose</li> <li>- Juices with magnesium content of 60mg/100g, 120mg/serving</li> <li>- Daily amount to be consumed to produce claimed effect: 270.miligram(s)</li> <li>- Are there factors that could interfere with bioavailability: No</li> <li>- Length of time after consumption for claimed effect to become apparent: Habitual intake</li> <li>- Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No</li> <li>- 300 mg of magnesium - a recommended daily dose is recommended to divide into two daily doses. It is used within the period of one month, to be repeated 2 -3 times per year as necessary. Suitable for diabetic patients.</li> <li>- MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that Products containing &gt;400mg Magnesium should carry the label statement '[This amount of Magnesium] may cause mild stomach upset in sensitive individuals.' Applicable to both children and adults</li> <li>- 300 mg / d—Erwachsene</li> <li>- Drink with 0.84mg/100g of iron, 2.1mg/serving, 4.2mg/daily serving and 18mg/100g of magnesium, 45mg/serving, 90mg/daily serving</li> </ul>			

	<ul style="list-style-type: none"> <li>- Jugendliche, Erwachsene; Upper level 400 mg</li> <li>- Es werden nur die Nährstoffe beworben, die lt. Nährwertkennzeichnungs-verordnung (Anlage 1) mindestens 15 Prozent der empfohlenen Tagesdosis in 100 g oder 100 ml enthalten.</li> <li>- MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG</li> <li>- Amount, period of consumption : Kalium in Verbindung mit Magnesium ist essentiell für eine rhythmische Herzarbeit und ordnungsgemäße Kontraktion von Herzmuskelzellen.</li> <li>- Amount, period of consumption : ab 50 mg/l Magnesium (siehe EG-Mineralwasser-Richtlinie)</li> </ul>		
242	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Magnesium	Nerve transmission/ function	Magnesium is necessary for nerve/ nervous system function.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 300 mg per day</li> <li>- MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that Products containing &gt;400mg Magnesium should carry the label statement '[This amount of Magnesium] may cause mild stomach upset in sensitive individuals.'Applicable to both children and adults</li> <li>- 300 mg / d—Erwachsene</li> <li>- Jugendliche, Erwachsene ; Amount, period of consumption :200 mg ; Upper level 400 mg</li> <li>- Amount, period of consumption : ab 50 mg/l Magnesium (siehe EG-Mineralwasser-Richtlinie)</li> <li>- 2X175 mg=2192 mg Magnesiumcitrat</li> </ul>		
247	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Magnesium	Magnesium is an essential cofactor for more than 300 enzymes involved in biosynthetic processes and energy metabolism.	For energy metabolism.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Claim to be only used for Foods for sport people under the Dir. 89/398/EEC. The DRA for magnesium is 420 mg (M) and 320 mg (F). CEDAP recommendations for sports people: magnesium is 150 mg/1000 kcal energy spent. Agency guidance for supplements is that products containing &gt;0.5 mg of should carry the label advisory statement "Long term intake of this amount of maganese may lead to muscle pain and fatigue"</li> <li>- Jugendliche, Erwachsene ; Amount of consumption 200 mg ; Upper level 400 mg</li> <li>- Jugendliche, Erwachsene ; Amount of consumption 100 – 350 mg ; Upper level 350 mg</li> </ul>		

248	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Magnesium	Normal energy metabolism	Magnesium supports energy metabolism
<b>Conditions of use</b>			
- The product must contain at least 15% of the RDA ; Agency guidance for supplements is that products containing > 400mg of magnesium should carry the label advisory statement "[This amount of Magnesium]* may cause mild stomach upset in sensitive individuals."			
357	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Magnesium	Normal blood clotting	Magnesium is necessary for normal blood clotting.
<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 >400 mg of magnesium should carry the label advisory statement "This amount of magnesium may cause mild stomach upsets in sensitive individuals"			
364	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Magnesium	Protein synthesis	Magnesium contributes to the protein synthesis in the body.
<b>Conditions of use</b>			
- -			
365	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Magnesium	Cell division	Magnesium contributes to the cell division.
<b>Conditions of use</b>			
- -			