

## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to vitamin D and maintenance of bone and teeth (ID 150, 151, 158), absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations (ID 152, 157), cell division (ID 153), and thyroid function (ID 156) 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 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to vitamin D and the following claimed effects: maintenance of bone and teeth, absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations, cell division, and thyroid function. 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 vitamin D, which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that the food constituent, vitamin D, which is the subject of the health claims, is sufficiently characterised.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin D and maintenance of normal bone and teeth, absorption and utilisation of calcium and phosphorus and normal blood calcium concentrations, and normal cell division.

The Panel considers that, in order to bear the claims, a food should be at least a source of vitamin D as per Annex to Regulation 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 intake of vitamin D and thyroid function.

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1 On request from the European Commission, Question No EFSA-Q-2008-937, EFSA-Q-2008-938, EFSA-Q-2008-939, EFSA-Q-2008-940, EFSA-Q-2008-943, EFSA-Q-2008-944, EFSA-Q-2008-945 adopted on 02 July 2009.

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**KEY WORDS**

Vitamin D, bone, teeth, calcium absorption, phosphorus absorption, calcium blood concentrations, cell division, thyroid function, health claims.

**TABLE OF CONTENTS**

Summary .....	1
Table of contents .....	3
Background as provided by the European Commission.....	4
Terms of Reference as provided by the European Commission .....	4
EFSA Disclaimer.....	4
Acknowledgements .....	4
Information as provided in the consolidated list .....	5
Assessment .....	5
1. Characterisation of the food/constituent.....	5
2. Relevance of the claimed effect to human health.....	5
2.1. Maintenance of bone and teeth (ID 150, 151, 158).....	5
2.2. Absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations (ID 152, 157) .....	5
2.3. Cell division (ID 153) .....	5
2.4. Thyroid function (ID 156) .....	6
3. Scientific substantiation of the claimed effect.....	6
3.1. Maintenance of bone and teeth (ID 150, 151, 158).....	6
3.2. Absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations (ID 152, 157) .....	7
3.3. Cell division (ID 153) .....	7
3.4. Thyroid function (ID 156) .....	7
4. Panel’s comments on the proposed wordings.....	7
4.1. Maintenance of bone and teeth (ID 150, 151, 158).....	7
4.2. Absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations (ID 152, 157) .....	7
4.3. Cell division (ID 153) .....	8
5. Conditions and possible restrictions of use .....	8
Conclusions .....	8
Documentation provided to EFSA .....	9
References .....	9
Appendices .....	11

**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

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The members of the Claims Sub-Working Group on Bone/Teeth/Connective Tissue: Rikke Andersen, Olivier Bruyère, Albert Flynn, Ingegerd Johansson, Jukka Meurman and Hildegard Przyrembel.

## INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation 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 claim is vitamin D which is a well recognised nutrient and is measurable in foods by established methods. Vitamin D occurs naturally in foods as vitamin D<sub>2</sub> (ergocalciferol) and vitamin D<sub>3</sub> (cholecalciferol). Different forms of vitamin D are authorised for addition to foods and for use in food supplements (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 vitamin D naturally present in foods and those forms authorised for addition to foods and for use in food supplements (Annex II of the Regulation (EC) No 1925/2006 and Annex II of Directive 2002/46/EC).

The Panel considers that the food constituent, vitamin D, which is the subject of the health claim, is sufficiently characterised.

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

#### 2.1. Maintenance of bone and teeth (ID 150, 151, 158)

The claimed effects are “bone health/ bone strength, includes bone structure, bone mineralisation, bone density”, “teeth mineralization”, and “normal bone and tooth formation”. The Panel assumes that the target population is the general population.

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

#### 2.2. Absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations (ID 152, 157)

The claimed effects are “absorption and utilisation of calcium, phosphorus”, and “normal blood calcium levels”. The Panel assumes that the target population is the general population.

The Panel considers that normal absorption and utilisation of calcium and phosphorus and the maintenance of normal blood calcium concentrations are beneficial to human health.

#### 2.3. Cell division (ID 153)

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.

<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. Thyroid function (ID 156)

The claimed effect is that vitamin D is “endocrine / thyroid metabolism”. The Panel assumes that the target population is the general population.

The Panel considers that normal thyroid function is beneficial to human health.

## 3. Scientific substantiation of the claimed effect

Vitamin D can be obtained from dietary sources or can be synthesised in the body by exposure to UV-radiation from the sun. Even though it is more suitable to refer to vitamin D as a hormone, vitamin D resembles true vitamins, since humans deprived of solar exposure depend on a food source. Synthesis of vitamin D in the skin by the action of sunlight is insufficient to meet requirements in European countries, especially during winter months when there is little sunlight exposure.

Vitamin D is biologically inactive and requires successive hydroxylations; first in the liver, where 25-hydroxyvitamin D (25-OHD) is formed, and the next hydroxylation in the kidneys form 1,25-dihydroxyvitamin D (1,25-(OH)<sub>2</sub>D), which is the biologically active form of vitamin D. 1,25-(OH)<sub>2</sub>D interacts with a specific nuclear receptor in its target tissues that results in a biological response. The major target tissues for 1,25-(OH)<sub>2</sub>D are the intestine and bone; however, nuclear receptors for 1,25-(OH)<sub>2</sub>D have been identified in several other tissues and in cultured tumour cells. Serum concentration of 25-OHD is accepted as a valid marker of vitamin D status.

The principal physiological function of vitamin D in all vertebrates including humans is to maintain serum calcium and phosphorus concentrations in a range that supports cellular processes, neuromuscular function, and bone ossification. Vitamin D accomplishes this goal by enhancing the efficiency of the small intestine to absorb dietary calcium and phosphorus, and by mobilising calcium and phosphorus from the bone.

Vitamin D also has other functions in tissues not primarily related to mineral metabolism. One example is the haematopoietic system, in which vitamin D affects cell differentiation and proliferation including such effects also in cancer cells. Vitamin D furthermore participates in the process of insulin secretion. The active metabolite of vitamin D, 1,25(OH)<sub>2</sub>D, regulate the transcription of a large number of genes through binding to a transcription factor, the vitamin D receptor (VDR) (SCF, 2002).

### 3.1. Maintenance of bone and teeth (ID 150, 151, 158)

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus on the role of vitamin D in growth, development and maintenance of bone and teeth. It is well established that adequate status for vitamin D is required for efficient calcium absorption and for the maintenance of normal blood concentrations of calcium and phosphate that are in turn needed for the normal mineralisation of bone and teeth. Adequate intake of vitamin D is needed to achieve a vitamin D status that is sufficient for normal bone and teeth mineralisation throughout childhood and adolescence and for bone maintenance in adults and the elderly. Sub-optimal vitamin D status has been shown to reduce bone mineral accretion in children and adolescents, and to accelerate bone loss in adults and older people. Recommended intakes of vitamin D to meet requirements for growth, development and maintenance of bones and teeth have been established for all life-stage groups by several expert committees. Sub-optimal vitamin D status has been reported in subgroups of children, adolescents, adults and the elderly in a number of European countries, particularly in winter months, indicative of inadequate vitamin D intake (AFSSA, 2001; Cranney et al., 2007; Davies et al., 2005; EVM, 2002; FAO/WHO 2001; IoM, 1997; Greer et al., 2006; Holick, 2004 and 2005; Norman et al., 2007; Ovesen et al., 2003; SCF, 1993, SCF 2002).

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

### **3.2. Absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations (ID 152, 157)**

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that it is well established that adequate status for vitamin D is required for efficient calcium absorption and for the maintenance of normal blood concentrations of calcium and phosphorus. The principal physiological function of vitamin D in vertebrates, including humans, is to maintain intracellular and extracellular calcium concentrations within a physiologically acceptable range. Vitamin D accomplishes this goal through the hormonal form 1,25-(OH)<sub>2</sub>D, which acts through a nuclear receptor to enhance the efficiency of the small intestine to absorb dietary calcium and phosphorus, to mobilise calcium and phosphorus from bone, and to reabsorb calcium in the kidney (IoM, 1997; SCF, 2002).

Adequate intake of vitamin D is needed to achieve a vitamin D status that is sufficient for normal absorption/utilisation of calcium and phosphorus. Vitamin D deficiency has been shown to cause the mineralisation defects that result in rickets among children and osteomalacia among adults. Recommended intakes of vitamin D to meet requirements for normal absorption/utilisation of calcium and phosphorus have been established for all life-stage groups by several expert committees (Gibney, 2002; Holick, 2005).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin D and normal absorption of calcium and phosphorus and the maintenance of normal blood calcium concentrations.

### **3.3. Cell division (ID 153)**

In many tissues, vitamin D has important functions in regulation of cell proliferation and differentiation (SCF, 2002). It alters the growth and differentiation of numerous normal and pathological cell types by several mechanisms. Vitamin D slows cell cycle progression, affecting many regulators of this process (Samuel and Sitrin, 2008).

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

### **3.4. Thyroid function (ID 156)**

Three references were cited to substantiate the claimed effect. These references referred to intervention studies in patients with end-stage renal disease and patients who underwent total thyroidectomy and were not related to the claimed effect. The Panel notes that the references cited did not provide any scientific data that could be used to substantiate the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin D and normal thyroid function.

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

### **4.1. Maintenance of bone and teeth (ID 150, 151, 158)**

The Panel considers that the following wording reflects the scientific evidence: "Vitamin D contributes to the maintenance of normal bones and teeth".

### **4.2. Absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations (ID 152, 157)**

The Panel considers that the following wording reflects the scientific evidence: "Vitamin D contributes to normal absorption/utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations".

#### **4.3. Cell division (ID 153)**

The Panel considers that the following wording reflects the scientific evidence: “Vitamin D contributes to normal cell division”.

#### **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 vitamin D as per Annex to Regulation (EC) 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

#### **CONCLUSIONS**

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

- The food constituent, vitamin D, which is the subject of the health claim is sufficiently characterised.

#### **Maintenance of bone and teeth (ID 150, 151, 158)**

- The claimed effects are “bone health/ bone strength, includes bone structure, bone mineralisation, bone density”, “teeth mineralization”, and “normal bone and tooth formation”. The target population is assumed to be the general population. Maintenance of normal bone and teeth is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin D and maintenance of normal bone and teeth.
- The following wording reflects the scientific evidence: “Vitamin D contributes to the maintenance of normal bones and teeth”.

#### **Absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations (ID 152, 157)**

- The claimed effects are “absorption and utilisation of calcium, phosphorus” and “normal blood calcium levels”. The target population is assumed to be the general population. Normal absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations are beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin D and normal absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations.
- The following wording reflect the scientific evidence: “Vitamin D contributes to normal absorption/utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations”.

#### **Cell division (ID 153)**

- 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 vitamin D and normal cell division.
- The following wording reflect the scientific evidence: “Vitamin D contributes to normal cell division”.

#### **Thyroid function (ID 156)**

- The claimed effect is that vitamin D is “endocrine / thyroid metabolism”. The target population is assumed to be the general population. Normal thyroid function is beneficial to human health.
- A cause and effect relationship has not been established between the dietary intake of vitamin D and normal thyroid function.

### Conditions and possible restrictions of use

- In order to bear the claims a food should be at least a source of vitamin D as per Annex to Regulation (CE) 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-2008-937, EFSA-Q-2008-938, EFSA-Q-2008-939, EFSA-Q-2008-940, EFSA-Q-2008-943, EFSA-Q-2008-944, EFSA-Q-2008-945). 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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- SCF (Scientific Committee on Food), 2002. Opinion on the Tolerable Upper Intake Level of Vitamin D.

## 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

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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).

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 vitamin D, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
150	Vitamin D	Bone health/ bone strength Includes bone structure, bone mineralisation, bone density	Vitamin D is needed/important for the structure of bones/healthy bones. Vitamin D helps build and maintain strong/healthy bones. Vitamin D is necessary for adequate bone density.
<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: 5 microgram(s) vitamin D Daily amount to be consumed to produce claimed effect: 5 microgram(s) Length of time after consumption for claimed effect to become apparent: Regular consumption Other conditions for use: comply with "source of" nutrition claim in 1924/2006/EC</li> <li>- Daily amount to be consumed to produce claimed effect: 10 microgram(s) Are there factors that could interfere with bioavailability: No Length of time after consumption for claimed effect to become apparent: Habitual intake Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Yes State the maximum limit in mg/kg body weight/day: .02. Please note, regarding question 0.02mg is the safe upper limit regardless of body weight i.e. safe upper limit is 50ug (0.02mg) per day. Also, please note, supplemental intakes of up to 25ug/day appear to be well tolerated, and higher levels (45ug/day) may also be tolerated in the short term. In some cases, these high intakes may be necessary to prevent / treat deficiency. Potential adverse health effects: Excessive intakes can result in hypervitaminosis D Describe subgroups this limit applies to: This applies to the general population but infants, patients who are abnormally sensitive to vitamin D and patients with idiopathic hypercalcaemia may be more at risk.</li> <li>- 15-30 µg= 600-1200 I.E.</li> <li>- MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults Typical adults dosage: 5 – 100 mcg daily. .</li> <li>- 0.75 mcg</li> <li>- MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG</li> <li>- 15% RDA of Vitamin D, 90/496/EEC</li> <li>- 500-1000 mg Calcium als Calciumcitrat, 10 µg Vitamin D, 8-16 mg Zink</li> <li>- Presence of a nutrient or other substance Number of nutrients/other substances that are essential to claimed effect: 2 Names of nutrient/other substances and Quantity in Average daily serving: 209 mg calcium, 0.97 micrograms vitamin D Weight of average daily food serving: 25 gram(s) Daily amount to be consumed to produce claimed effect: 22.5 gram(s) Number of food portions this equates to in everyday food portions: 1 Are there factors that could interfere with bioavailability: No Length of time after consumption for claimed effect to become apparent: the claim is a long term effect Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No Where applicable outline nutritional composition (g per 100g) of food: Total Fat: 4.40 Saturated Fat: 3.00 Trans Fat: .00 Sugar: 1.20 Salt: .50 Sodium: .20 Other conditions for use: The product should be consumed as part of a balanced and varied diet with exercise.</li> <li>- The product shall be a source of vitamin D. Normal daily intake of the product shall provide at least 15% of RDI.</li> </ul>			

	- 5 µg per day		
151	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin D	Teeth mineralization	Vitamin D is needed for teeth mineralization. Vitamin D is important for the structure of healthy teeth. Vitamin D contributes to promote teeth mineralization.
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- 15-30 µg= 600-1200 I.E.</li> <li>- MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006</li> <li>- 500-1000 mg Calcium als Calciumcitrat, 10 µg Vitamin D, 8-16 mg Zink</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: 5 microgram(s) vitamin D Daily amount to be consumed to produce claimed effect: 5 microgram(s) Length of time after consumption for claimed effect to become apparent: Regular consumption Other conditions for use: Comply with "source of" nutrition claim in 1924/2006/EC</li> <li>- MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG</li> </ul>		
152	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin D	Absorption and utilisation of Calcium, Phosphorus	Vitamin D helps to absorb calcium in the gastrointestinal tract and keeps a balance of calcium in the organism. Vitamin D is necessary for the absorption and utilisation of calcium and phosphorus. Vitamin D is necessary for Calcium up-take in bones.
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- Vitamin D enriched milks, buttermilks, yoghurts and buttermilks with vitamin D content of 0.5 mg/100g, 1mg/serving</li> <li>- Food supplement with 5-10µg of vitamin D in the daily dose</li> <li>- Tagesbedarf gemäß NwKVO 5 µg pro Tag (8)</li> <li>- 5 µg per day</li> <li>- Must at least be a source of vitamin/s as per annex to regulation1924/2006 (amount to evaluate by EFSA)</li> <li>- Number of nutrients/other substances that are essential to claimed effect: 2 Names of nutrient/other substances and Quantity in Average daily serving: 0.9 micrograms vitamin D, 144 mg calcium Weight of average daily food serving: 90 gram(s) Daily amount to be consumed to produce claimed effect: 500 gram(s) Number of food portions this equates to in everyday food portions: 1 Are there factors that could interfere with bioavailability: Don't Know Length of time after consumption for claimed effect to become apparent: Dependent on the individual's nutritional status Other conditions for use: Product should</li> </ul>		

	<p>be consumed in the context of a healthy diet and lifestyle</p> <ul style="list-style-type: none"> <li>- Number of nutrients/other substances that are essential to claimed effect: 2 Names of nutrient/other substances and Quantity in Average daily serving: 3 micrograms vitamin D, 408 mg calcium Weight of average daily food serving: 300 mililitre(s) Daily amount to be consumed to produce claimed effect: 1.77 litres(s) Number of food portions this equates to in everyday food portions: 1 Length of time after consumption for claimed effect to become apparent: Dependent on the individual's nutritional status Other conditions for use: Product should be consumed in the context of a healthy diet and lifestyle</li> <li>- Daily amount to be consumed to produce claimed effect: 10 microgram(s) Are there factors that could interfere with bioavailability: No Length of time after consumption for claimed effect to become apparent: Habitual intake Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Yes State the maximum limit in mg/kg body weight/day: Please note 0.02mg is the maximum limit regardless of body weight i.e maximum limit is 50ug (0.02mg) per day. Also, please note, supplemental intakes of up to 25ug/day appear to be well tolerated, and higher levels (45ug/day) may also be tolerated in the short term. In some cases, these high intakes may be necessary to prevent / treat deficiency. Potential adverse health effects: Excessive intakes can result in hypervitaminosis D. Describe subgroups this limit applies to: This applies to the general population, but infants, patients who are abnormally sensitive to vitamin D and patients with idiopathic hypercalciuria and hypercalcaemia may be more at risk.</li> <li>- Must at least be a source of vitamin/s as per annex to regulation 1924/2006 (amount to evaluate by EFSA)</li> <li>- MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG</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: 2 Names of nutrient/other substances and Quantity in Average daily serving: 3 micrograms vitamin D, 408 milligrams calcium Weight of average daily food serving: 90 gram(s) Daily amount to be consumed to produce claimed effect: 500 gram(s) Number of food portions this equates to in everyday food portions: 1 Length of time after consumption for claimed effect to become apparent: Dependent on the individual's nutritional status Other conditions for use: Product should be consumed in the context of a healthy diet and lifestyle</li> </ul>		
<b>153</b>	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin D	Cell division	Vitamin D contributes to normal cell division.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 500-1000 mg Calcium als Calciumcitrat, 10 µg Vitamin D, 8-16 mg Zink</li> <li>- 15-30 µg= 600-1200 I.E.</li> <li>- Applicable to both children and adults 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: 5 microgram(s) vitamin D Daily amount to be consumed to produce claimed effect: 5 microgram(s) Length of time after consumption for claimed effect to become apparent: Regular consumption Other conditions for use: comply with "source of" nutrition claim in 1924/2006/EC</li> <li>- MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG</li> </ul>		

	Food or Food component	Health Relationship	Proposed wording
156	Vitamin D	Endocrine / thyroid metabolism	Vitamin D is needed for the normal / proper function of the thyroid. Vitamin D is needed for the proper regulation of blood calcium levels.
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- Typical adults dosages 5 – 50 mcg daily for vitamin D2, (ergocalciferol, and up to 100 mcg daily for vitamin D3 (cholecalciferol). 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.</li> </ul>		
157	Vitamin D	Normal blood calcium levels	Vitamin D is necessary for the normal absorption and utilization of calcium and phosphorus.
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- Guidance level is 25mcg/day or less (FSA)&gt;.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.</li> </ul>		
158	Vitamin D	Normal bone and tooth formation	Vitamin D is necessary for normal bone and tooth formation.
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- Guidance level is 25mcg/day or less (FSA)&gt; 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.</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>- Number of nutrients/other substances that are essential to claimed effect: 2 Names of nutrient/other substances and Quantity in Average daily serving: 3 micrograms vitamin D, 408 mg calcium Weight of average daily food serving: 300 mililitre(s) Daily amount to be consumed to produce claimed effect: 300 litres(s) Number of food portions this equates to in everyday food portions: 1 Length of time after consumption for claimed effect to become apparent: depends on the individual's nutritional Other conditions for use: Product should be consumed in the context of a healthy diet and lifestyle</li> <li>- Number of nutrients/other substances that are essential to claimed effect: 2 Names of nutrient/other substances and Quantity in Average daily serving: 1 microgram vitamin D, 160 miligrams calcium Weight of average daily food serving: 100 gram(s) Daily amount to be consumed to produce claimed effect: 100 gram(s) Number of food portions this equates to in everyday food portions: 1 Length of time after consumption for claimed effect to become apparent: depends on the individual's nutritional status Other conditions for use: Product should be consumed in the context of a healthy diet and lifestyle</li> </ul>		