

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to calcium and maintenance of bones and teeth (ID 224, 230, 231, 354, 3099), muscle function and neurotransmission (ID 226, 227, 230, 235), blood coagulation (ID 230, 236), energy-yielding metabolism (ID 234), function of digestive enzymes (ID 355), and maintenance of normal blood pressure (ID 225, 385, 1419) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

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

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 calcium and the following claimed effects: maintenance of bones and teeth, muscle function and neurotransmission, blood coagulation, energy-yielding metabolism, function of digestive enzymes, and maintenance of a normal blood pressure. 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 calcium, which is a well recognised nutrient and it is measurable in foods by established methods. The Panel considers that calcium is sufficiently characterised.

The Panel concludes that a cause and effect relationship has been established between calcium and maintenance of normal bones and teeth, normal muscle function and neurotransmission, normal blood coagulation, normal energy-yielding metabolism, and normal function of digestive enzymes.

1 On request from the European Commission, Question No EFSA-Q-2008-1011, EFSA-Q-2008-1012, EFSA-Q-2008-1013, EFSA-Q-2008-1014, EFSA-Q-2008-1017, EFSA-Q-2008-1018, EFSA-Q-2008-1021, EFSA-Q-2008-1022, EFSA-Q-2008-1023, EFSA-Q-2008-1141, EFSA-Q-2008-1142, EFSA-Q-2008-1172, EFSA-Q-2008-2156, EFSA-Q-2008-3831, 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 calcium 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 the evidence provided is insufficient to establish a cause and effect relationship between the intake of calcium and the maintenance of a normal blood pressure.

KEY WORDS

Calcium, bones, mineralisation, teeth, muscle, neurotransmission, blood pressure, digestive enzymes, colorectal cells, 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

See Appendix B

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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 1924/2006³ 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 calcium, which is a well recognised nutrient and is measurable in foods by established methods. Calcium occurs naturally in foods in many forms which are generally well utilised by the body. Different forms of calcium are authorised for addition to foods and for use in food supplements (Annex II of the Regulation (EC) No 1925/2006⁴ and Annex II of Directive 2002/46/EC⁵). This evaluation applies to calcium 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, calcium, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Maintenance of bone and teeth (ID 224, 230, 231, 354, 3099)

The claimed effects are “bone health”, “bone strength (includes bone structure, bone mineralisation, bone density)”, “structure of teeth”, “bones and teeth” and “dental health”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that the claimed effects relate to the maintenance of normal bones and teeth.

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

2.2. Muscle function and neurotransmission (ID 226, 227, 230, 235)

The claimed effects are “muscle function”, “nerve transmission/function”, “nerves and muscle”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that the claimed effects relate to normal muscle function and neurotransmission.

The Panel considers that normal muscle function and neurotransmission are beneficial to human health.

³ 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.

⁴ 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.

⁵ 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.

2.3. Blood coagulation (ID 230, 236)

The claimed effect is “needed for normal blood coagulation (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.

2.4. Energy-yielding metabolism (ID 234)

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

In the context of the proposed wordings, the Panel notes that the claimed effect relates to the conversion of energy from foods into energy in the form of ATP which may be readily used by the body.

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

2.5. Normal function of digestive enzymes (ID 355)

The claimed effect is “support the normal functioning of digestion enzymes”. The Panel assumes that the target population is the general population.

Digestive enzymes are protein molecules that catalyse the breakdown of large food molecules into smaller molecules to facilitate their absorption by the small intestine. They are secreted by the salivary glands, the glands in the stomach, the pancreas, and the glands in the small intestine. Failure to digest and absorb dietary nutrients leads to malabsorption.

The Panel considers that the normal function of digestive enzymes is beneficial to human health.

2.6. Maintenance of normal blood pressure (ID 225, 385, 1419)

The claimed effects are “blood pressure”, “cardiovascular system” and “healthy heart”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that the claimed effect relates to the maintenance of a normal blood pressure.

Blood pressure (BP) is the pressure (force per unit area) exerted by circulating blood on the walls of blood vessels. Elevated BP, by convention above 140mmHg (systolic) and/or 90mmHg (diastolic), may compromise the normal function of the arteries.

The Panel considers that maintaining a normal blood pressure is beneficial to human health.

3. Scientific substantiation of the claimed effect

More than 99% of the total calcium in the body is located in bones and teeth and contributes to their mass, structure and strength. Besides this structural role, calcium acts as an intracellular messenger and as a cofactor for extracellular enzymes and proteins (IoM, 1997).

3.1. Maintenance of bone and teeth (ID 224, 230, 231, 354, 3099)

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus on the roles of calcium in the maintenance of normal bones and teeth.

Calcium is an important structural component of bone and teeth. Adequate calcium intake throughout childhood and adolescence is needed to achieve maximum peak bone mass in young adulthood which is an important determinant of bone mineral status in later life. The growth, development and maintenance of bone and teeth is related to the quantity of dietary calcium consumed and recommended intakes of calcium to meet requirements for growth, development and maintenance of bone at all ages have been established by various authorities. Inadequate dietary calcium intake may contribute to impaired bone development in early life and to the accelerated loss of bone mass in adults and in older people. Available evidence indicates that calcium intakes may be inadequate in sub-groups of the population in some EU countries, especially children, women and older people (AAP, 1999; AFSSA, 2001; Branca, 1997; COMA, 1991; DGE, 2000; Elmadfa and Weichselbaum, 2004; FAO/WHO, 2001; FNB, 1999; Food Safety Authority of Ireland, 1999; Greer, 2006; JHCI, 2003; IoM, 1997, National Health and Medical Research Council, 2006; Nordic Council of Ministers, 2004; SCF, 2003; Theobald, 2005; WHO, 2003).

The Panel considers that a cause and effect relationship has been established between the dietary intake of calcium and the maintenance of normal bones and teeth.

3.2. Muscle function and neurotransmission (ID 226, 227, 230, 235)

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus on the role of calcium in muscle function and neurotransmission (IoM, 1997; JHCI, 2003).

Normal muscle function (including the heart) and neurotransmission require adequate calcium concentrations within the cells and in the extracellular fluid (ECF). Serum calcium, which is in exchange with ECF and intracellular calcium, is tightly regulated by homeostatic mechanisms and largely independent of dietary intake. In the absence of disease, serum, ECF and intracellular calcium concentrations are virtually never low because of dietary calcium deficiency. This is because the very large calcium reserve in the skeleton prevents significant decreases of calcium in serum, ECF and intracellularly practically without limit (Weaver and Heaney, 2006).

The Panel considers that a cause and effect relationship has been established between calcium and normal muscle function and neurotransmission. However, the evidence provided does not establish that inadequate intake of calcium leading to impaired muscle function and neurotransmission occurs in the general EU population.

3.3. Blood coagulation (ID 230, 236)

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus on the role of calcium in normal blood coagulation.

Calcium is necessary to stabilise or allow maximal activity for a number of blood clotting enzymes. However, the normal activity of these enzymes is not significantly affected by changes in extracellular calcium concentrations or by dietary calcium deficiency, and is practically independent of dietary calcium intake (Weaver and Heaney, 2006).

The Panel considers that a cause and effect relationship has been established between calcium and normal blood coagulation. However, the evidence provided does not establish that inadequate intake of calcium leading to impaired blood coagulation occurs in the general EU population.

3.4. Energy-yielding metabolism (ID 234)

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus on the role of calcium in the stabilisation and activity of certain enzymes involved in energy metabolism, such as glyceraldehyde phosphate dehydrogenase, pyruvate dehydrogenase, and α -ketoglutarate dehydrogenase. However, the normal activity of these enzymes is not significantly affected by changes in extracellular calcium concentrations or by dietary calcium deficiency, and is practically independent of dietary calcium intake (Weaver and Heaney, 2006).

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

3.5. Function of digestive enzymes (ID 355)

The list of references provided consists of one review, one report, one manual and one book chapter.

The information included in well-recognised monographs and manuals does not support a role for dietary calcium in the function of several enzymes, since such functions are not affected by changes in plasma concentrations of calcium or by dietary calcium intake (Berdanier et al., 2002; British Nutrition Foundation Taskforce, 1989; Gurr et al., 1999; EVM, 2002; Bowman and Russell, 2007; Gibney et al., 2002; Caballero et al., 2005). However, several digestive enzymes (e.g. lipase) require a chemical association between calcium and enzyme protein(s) for full catalytic activity to occur.

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

3.6. Maintenance of normal blood pressure (ID 225, 385, 1419)

Some mechanisms have been proposed for an effect of dietary calcium on blood pressure on the basis of experimental animal models of hypertension (Hatton and McCarron, 1994).

The effects of dietary calcium intake on blood pressure have also been investigated in humans. A meta-analysis of 23 observational epidemiological studies (total of 38,950 subjects) showed a weak significant negative association between habitual calcium intake and blood pressure, i.e. -0.39 mmHg systolic and -0.34 mmHg diastolic per 100 mg of dietary calcium per day (Cappuccio et al., 1995; Birkett, 1998). In contrast, in a more recent study, dietary calcium intake was positively associated with changes in blood pressure over 8 years in 1,714 middle-aged men from the Chicago Western Electric Study (Stamler et al., 2002). The mean calcium intake in this cohort was 1,019 (SD 446) mg/d. Calcium intake was not related to blood pressure in 3,239 participants aged 55 years and over in the Rotterdam Study, except for a subgroup of hypertensive subjects where an inverse association was found (Geleijnse et al, 1996). Wang et al. (2008) examined the relationship of dietary calcium intake with incident hypertension in 28,886 US women. Daily calcium intake ranged from <558 mg (bottom quintile) to >1000 mg (upper quintile). The risk of hypertension was 11-13% lower in subjects with a calcium intake >679 mg/day. The Panel notes that results from observational studies on the relationship between dietary calcium intake and blood pressure are inconsistent.

The evidence provided by several meta-analyses of randomised controlled trials (Allender et al., 1996; Bucher et al., 1996; Griffith et al., 1999; Van Mierlo et al., 2006) indicate a small beneficial effect of calcium supplementation on blood pressure. Reductions of up to 2 mmHg systolic and 1 mmHg diastolic have been achieved with calcium doses around 1 g per day (range 400-2000 mg/d). Findings,

however, are heterogeneous with around 30% of the studies showing an increase rather than a decrease in systolic blood pressure during calcium supplementation (Van Mierlo et al., 2006). Also, the evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is no consensus on the effects of dietary calcium on blood pressure in humans (Appel et al., 2006; Mancia et al., 2007). The American Heart Association in their scientific statement on dietary approaches to prevent and treat hypertension considered data insufficient to recommend supplemental calcium as a means to lower blood pressure (Appel et al., 2006). In 2007, the European Society of Hypertension and of the European Society of Cardiology published their joint Guidelines for the Management of Arterial Hypertension. The Committee stated that the evidence for a blood pressure lowering effect of supplemental calcium is equivocal (Mancia et al., 2007).

In weighing the evidence, the Panel took into account that the evidence contained in consensus opinions/reports from authoritative bodies and reviews is equivocal, that there is no consensus on the effects of dietary calcium on blood pressure in humans, that results from observational studies on the relationship between dietary calcium intake and blood pressure are inconsistent, and that around 30% of the intervention studies show an increase rather than a decrease in systolic blood pressure during calcium supplementation.

The Panel considers that the evidence presented is insufficient to establish a cause and effect relationship between the dietary intake of calcium and the maintenance of a normal blood pressure.

4. Panel's comments on the proposed wordings

4.1. Maintenance of bone and teeth (ID 224, 230, 231, 354, 3099)

The Panel considers that the following wordings reflect the scientific evidence: "Calcium is needed for the maintenance of normal bones and teeth".

4.2. Muscle function and neurotransmission (ID 226, 227, 230, 235)

The Panel considers that the following wordings reflect the scientific evidence: "Calcium contributes to normal muscle function and neurotransmission"

4.3. Blood coagulation (ID 230, 236)

The Panel considers that the following wordings reflect the scientific evidence: "Calcium contributes to normal blood clotting"

4.4. Energy metabolism (ID 234)

The Panel considers that the following wordings reflect the scientific evidence: "Calcium contributes to normal energy metabolism"

4.5. Function of digestive enzymes (ID 355)

The Panel considers that the following wordings reflect the scientific evidence: "Calcium contributes to the normal function of digestive enzymes"

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 calcium as per Annex to Regulation (EC) 1924/2006. Such amounts can be easily consumed as part of a balanced

diet. No Tolerable Upper Intake Levels (UL) have been established for calcium in children and adolescents; the UL for calcium in adults is 2500 mg/day (SCF, 2003).

CONCLUSIONS

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

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

Maintenance of bones and teeth (ID 224, 230, 231, 354, 3099)

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

Muscle function and neurotransmission (ID 226, 227, 230, 235)

- The claimed effects are “muscle function”, “nerve transmission/function”, “nerves and muscle”. The target population is assumed to be the general population. Normal muscle function and neurotransmission are beneficial to human health.
- A cause and effect relationship has been established between calcium and normal muscle function and neurotransmission in healthy subjects.
- The evidence provided does not establish that inadequate intake of calcium leading to impaired muscle function and neurotransmission occurs in the general EU population.
- The following wording reflects the scientific evidence: “Calcium contributes to normal muscle function and neurotransmission”.

Blood coagulation (ID 230, 236)

- The claimed effect is “blood coagulation (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 been established between calcium and normal blood coagulation.
- The evidence provided does not establish that inadequate intake of calcium leading to impaired blood coagulation occurs in the general EU population.
- The following wording reflects the scientific evidence: “Calcium contributes to normal blood clotting”.

Energy-yielding metabolism (ID 234)

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

Function of digestive enzymes (ID 355)

- The claimed effect is “support the normal functioning of digestion enzymes”. The target population is assumed to be the general population. Normal function of digestive enzymes is beneficial to human health.
- A cause and effect relationship has been established between calcium and the normal function of digestive enzymes.
- The evidence provided does not establish that inadequate intake of calcium leading to impaired function of digestive enzymes occurs in the general EU population.
- The following wording reflects the scientific evidence: “calcium contributes to the normal function of digestive enzymes”.

Maintenance of normal blood pressure (ID 225, 385, 1419)

- The claimed effects are “blood pressure”, “cardiovascular system” and “healthy heart”. The target population is assumed to be the general population. Maintenance of a normal blood pressure is beneficial to human health.
- The evidence presented is insufficient to establish a cause and effect relationship between the dietary intake of calcium and the maintenance of a normal blood pressure.

Conditions and possible restrictions of use

- In order to bear the claim a food should be at least a source of calcium as per Annex to Regulation 1924/2006. Such amounts can be easily consumed as part of a balanced diet.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1011, EFSA-Q-2008-1012, EFSA-Q-2008-1013, EFSA-Q-2008-1014, EFSA-Q-2008-1017, EFSA-Q-2008-1018, EFSA-Q-2008-1021, EFSA-Q-2008-1022, EFSA-Q-2008-1023, EFSA-Q-2008-1141, EFSA-Q-2008-1142, EFSA-Q-2008-1172, EFSA-Q-2008-2156, EFSA-Q-2008-3831). 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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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 foods⁶ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁷

Foods are commonly involved in many different functions⁸ 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.

⁶ OJ L12, 18/01/2007

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

⁸ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

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

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.

- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to calcium, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
224	Calcium	Bone health/ bone strength (includes bone structure, bone mineralisation, bone density), structure of teeth	Calcium is needed/important for the structure of bones/healthy bones; -Calcium is needed to maintain strong/healthy bones; - Calcium is needed/important for the structure of teeth/healthy teeth; -Calcium is needed to maintain strong/healthy teeth
<p>Conditions of use</p> <ul style="list-style-type: none"> - 1000mg/d* - ab 150 mg/l Calcium (siehe EG-Mineralwasser-Richtlinie) - Tagesbedarf gemäß NwKVO 800 mg pro Tag - Erwachsene 800 Gramm (g) mind. 120 mg / 100g // 100 ml - 15% RDA of calcium, 90/496/EEC - 30 % des empfohlenen Tagesbedarfs pro Tagesration - Food supplements with 400-800mg of calcium (calcium carbonate) in the daily dose In addition some food supplements contain 5-10µg of vitamin D3 per daily dose. Vitamin D helps the absorption and utilisation of calcium. - 15% AJR par cure renouvelable chez les enfants et adolescents, la femme enceinte, - 15% AJR par cure renouvelable chez les sujets âgés - 1.000 mg pro Tag--Erwachsene - 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. - Das Kauen von 2 Pellets Kaugummi 3*täglich liefert 1/6 RDA an kalzium - Fruit drinks with calcium content of 50mg/100g, 125mg/serving 250mg/daily serving - Mineral waters with calcium content of 36-60mg/100g, 90-150mg/serving, 180-300mg/daily serving 500mg/l of alkaline and earth-alkaline salts has also been added to mineral water. - 500-1000 mg Calcium als Calciumcitrat, 10 µg Vitamin D, 8-16 mg Zink - Wheat germ pasta + calcium product with calcium content of 130mg/100g, 104mg/serving (=80g) Cereal fibre and the manufacturing process of pasta may weaken the absorption of calcium in the body. The product was reported to contain 3.4g/100g of fibre. Flax + apricot + calcium porridge flakes with calcium content of 430mg/100g, 150mg/single serving bag (=35g) Cereal fibre may weaken the absorption of calcium in the body. The product was reported to contain 13g/100g of fibre. - Fruit and berry juices with calcium content of 120mg/100g, 24mg/serving and vitamin C content of 30mg/100g, 60mg/serving Calcium has been added to the product as calcium gluconate compound. - yes 			

- 800 mg per day
- Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 200 miligrams dairy calcium Daily amount to be consumed to produce claimed effect: 800 miligram(s) Are there factors that could interfere with bioavailability: No Length of time after consumption for claimed effect to become apparent: It is apparent immediately Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No Other conditions for use: Minimum of 800-1000mg/day
- Matured cheeses with calcium content of 800-1080 mg/100g, 80-108mg/serving
- Calcium milk drink with 180mg/100g of calcium, 360mg/serving and 0.5microg/100g of vitamin D, 1.0 microg/serving
- Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 150mg of 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 Are there factors that could interfere with bioavailability: Don't Know Length of time after consumption for claimed effect to become apparent: depends on the individual's nutritional status Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Don't Know Other conditions for use: Product should be consumed in the context of a healthy diet and lifestyle
- Fruit milk drink with calcium content of 120mg/100g, 240mg/serving
- Schulkinder, Erwachsene 80 - 800 Milligramm (mg)
- 120 Milligramm (mg) Ca/d
- Chocolate milk drinks with 100mg/100g of calcium, 363mg/serving and 0.5 microg/100g of vitamin D, 1.65 microg/serving Flavoured milks contain 94-95% of milk.
- Processed cheese slices with calcium content 640-760mg/100g, 128-152mg/serving
- Yoghurts with calcium content of 100-150mg/100g, 125-240mg/serving
- Kaltsiumi päevane soovitatav kogus 800 mg. Väidet kasutava toidukäitleja jogurt sisaldab sellest 100 g kohta 20%.
- only with at least 250 mg Calcium
- Mælkeprodukterne skal have et naturligt indhold af calcium på mindst 10% af ADT pr. 100g
- 15% RDA per 100 g
- The product must contain at least 15% of the RDA Agency guidance for supplements is that products containing > 1500mg of calcium should carry the label advisory statement "[This amount of Calcium]* may cause mild stomach upset in sensitive individuals."
- Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC Agency guidance for supplements is that products containing >1500 mg of calcium should carry the label advisory statement "this amount of calcium may cause mild stomach upset in sensitive individuals" Applicable to both adults and children
- MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006. Applicable to both adults and children Agency guidance for supplements is that Products containing >1500mg Calcium should carry the label statement '[This amount of Calcium] may cause mild stomach upset in sensitive individuals.' Applicable to both children and adults only with at least 250 mg Calcium
- Juice with calcium content of 120mg/100g, 240mg/serving

- Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 120 mg calcium Weight of average daily food serving: 360 miligram(s) Daily amount to be consumed to produce claimed effect: 360 miligram(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: Studies have indicated that regular consumption of calcium over a period of time (months/years) will help build strong and healthy bones and teeth. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No Other conditions for use: The product must contain 15% RDA Calcium
- MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG
- Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 800 miligram(s) calcium Daily amount to be consumed to produce claimed effect: 800 miligram(s) Length of time after consumption for claimed effect to become apparent: up to 12 weeks Other conditions for use: must be at least a "source of minerals" as per annex to Regulation 1924/2006
- Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 120 miligrams calcium Weight of average daily food serving: 666 miligram(s) Daily amount to be consumed to produce claimed effect: 666 miligram(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: Studies have indicated that regular consumption of calcium over a period of time (months/years) will help build strong and healthy bones and teeth. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No Other conditions for use: The product must contain 15% RDA Calcium
- Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 160 miligrams calcium Weight of average daily food serving: 1.33 gram(s) Daily amount to be consumed to produce claimed effect: 1.33 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: Studies have indicated that regular consumption of calcium over a period of time (months/years) will help build strong and healthy bones and teeth. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No Other conditions for use: The product must contain 20% RDA calcium
- Buttermilks, milks and milk drinks with 120-180mg/100g of calcium, 240-360mg/serving and 0.5microg/100g of vitamin D, 1.0microg/serving
- Number of nutrients/other substances that are essential to claimed effect: 5 Names of nutrient/other substances and Quantity in Average daily serving: 160 micorgrams Vitamin A, 12 miligrams Vitamin C, 1 micogram Vitamin D, 160 miligrams Calcium, 160 miligrams Phosphorus 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 Other conditions for use: Product should be consumed in the context of a healthy diet and lifestyle.
- Daily amount to be consumed to produce claimed effect: 800 miligram(s) Are there factors that could interfere with bioavailability: Yes Please give reason: Dietary availability from different sources is variable. Components which may inhibit absorption include phytates, oxalates and some minerals such as iron and zinc. Length of time after consumption for claimed effect to become apparent: habitual intake is necessary Is there a limit to the amount

of food which should be consumed in order to avoid adverse health effects: No			
	Food or Food constituent	Health Relationship	Proposed wording
225	Calcium	Blood pressure	Calcium helps to keep a healthy blood pressure.
	<p>Conditions of use</p> <ul style="list-style-type: none"> – Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: NA Daily amount to be consumed to produce claimed effect: 800 miligram(s) Are there factors that could interfere with bioavailability: Yes Please give reason: The bioavailability of calcium from different dietary sources is variable. Bioavailability may be affected by dietary components which inhibit absorption such as phytates, oxalates and certain minerals. Length of time after consumption for claimed effect to become apparent: Habitual intake ab 150 mg/l Calcium (siehe EG-Mineralwasser-Richtlinie) – Erwachsene 800 Gramm (g) mind. 120 mg / 100g // 100 ml – 500-1000 mg Calcium als Calciumcitrat, 10 µg Vitamin D, 8-16 mg Zink – Low-fat milk products with calcium content of 150-200mg/100g, 200-300mg/ serving 		
226	Food or Food constituent	Health Relationship	Proposed wording
	Calcium	Muscle function	Calcium is needed for muscle function
<p>Conditions of use</p> <ul style="list-style-type: none"> – ab 150 mg/l Calcium (siehe EG-Mineralwasser-Richtlinie) – MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing >1500mg Calcium should carry the label statement '[This amount of Calcium] may cause mild stomach upset in sensitive individuals.' Applicable to both children and adults 			
227	Food or Food constituent	Health Relationship	Proposed wording
	Calcium	Nerve transmission/ function	Calcium is needed for normal nerve function.
<p>Conditions of use</p> <ul style="list-style-type: none"> – ab 150 mg/l Calcium (siehe EG-Mineralwasser-Richtlinie) – Schulkinder, Erwachsene 80 – 800 Milligramm (mg), max 1200 Milligramm (mg) – MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing >1500mg Calcium should carry the label statement '[This amount of Calcium] may cause mild stomach upset in sensitive individuals.' Applicable to both children and adults 			
230	Food or Food constituent	Health Relationship	Proposed wording
	Calcium	Required for general body health: Bones and teeth; Nerves and muscles; Coagulation.	Helps maintain a healthy body Calcium is necessary for: the normal structure of bones and teeth; normal nerve and muscle function; normal coagulation
<p>Conditions of use</p>			

	<ul style="list-style-type: none"> - The product must contain at least 15 % of the RDA - 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 Number of nutrients/other substances that are essential to claimed effect: 5 Names of nutrient/other substances and Quantity in Average daily serving: 1.44 micrograms Vitamin A, 10.80 miligrams Vitamin C, .90 micrograms Vitamin D, 144 milligrams Calcium, 144 miligrams Phosphorus 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 be consumed in the context of a healthy diet and lifestyle - >15% recommended daily dose in 100 g of the product or in one portion (dairy product) - Product must contain at least 15% RDA. Agency guidance for supplements is that products containing 1500 mg of calcium should carry the label advisory statement "Supplements containing "this amount of calcium may cause mild stomach upset in sensitive individuals" Applicable to both adults and children 		
231	Food or Food constituent	Health Relationship	Proposed wording
	Calcium	Structure of teeth	<p>Calcium is needed for the development of teeth.</p> <p>Calcium is necessary for healthy teeth.</p> <p>Calcium is necessary for normal tooth development.</p>
	<p>Conditions of use</p> <ul style="list-style-type: none"> - MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG - Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC Supplements containing >1500mg calcium should carry the label advisory statement "this amount of calcium may cause mild stomach upset in sensitive individuals" Applicable to both adults and children - Does claim rely on the presence/absence in a reduced quantity/absence of a nutrient or other substance: NA Daily amount to be consumed to produce claimed effect: 800 miligram(s) Are there factors that could interfere with bioavailability: Yes Please give reason: The bioavailability of calcium from different dietary sources is variable.Bioavailability may be affected by dietary components which inhibit absorption such as phytates, oxalates and certain minerals. Length of time after consumption for claimed effect to become apparent: Habitual intake - 500-1000 mg Calcium als Calciumcitrat, 10 µg Vitamin D, 8-16 mg Zink 		
234	Food or Food constituent	Health Relationship	Proposed wording
	Calcium	Calcium is also required for the activation of numerous enzymes involved in energy metabolism.	Energy metabolism.
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Schulkinder, Erwachsene 80 - 800 Milligramm (mg), max 1200 Milligramm (mg) - Claim to be only used for Foods for sport people under the Dir. 89/398/EEC. The DRA for 		

	calcium is 1000 mg (M,F). Agency guidance for supplements is that products containing > 1500 mg of calcium should carry the label advisory statement "this amount of calcium may cause mild stomach upset in sensitive individuals"		
235	Food or Food constituent	Health Relationship	Proposed wording
	Calcium	Nerve and muscle function	Calcium regulates the functioning of nerves and muscles
Conditions of use <ul style="list-style-type: none"> – Schulkinder, Erwachsene 80 - 800 Milligramm (mg), max 1200 Milligramm (mg) – The product must contain at least 15% of the RDA. Agency guidance for supplements is that products containing >1500 mg of calcium should carry the label advisory statement "[This amount of Calcium]* may cause mild stomach upset in sensitive individuals." 			
236	Food or Food constituent	Health Relationship	Proposed wording
	Calcium	Blood coagulation	Calcium is needed for normal blood clotting.
Conditions of use <ul style="list-style-type: none"> – ab 150 mg/l Calcium (siehe EG-Mineralwasser-Richtlinie) – Schulkinder, Erwachsene 80 – 800 Milligramm (mg) max 1200 Milligramm (mg) – MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing >1500mg Calcium should carry the label statement '[This amount of Calcium] may cause mild stomach upset in sensitive individuals.' Applicable to both children and adults 			
354	Food or Food constituent	Health Relationship	Proposed wording
	Dairy calcium	Bone Health Bone structure, mineralisation & density	Dairy calcium is essential for bone health. Dairy calcium is needed to maintain and build strong bones. Dairy calcium is essential for maintaining and building bone density.
Conditions of use <ul style="list-style-type: none"> – 800-1000mg/day Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006. 			
355	Food or Food constituent	Health Relationship	Proposed wording
	Calcium	Normal functioning of digestion enzymes	Calcium supports the normal function of the enzymes required for digestion
Conditions of use <ul style="list-style-type: none"> – The product must contain at least 15% of the RDA Agency guidance for supplements is that products containing > 1500mg of calcium should carry the label advisory statement "[This amount of Calcium]* may cause mild stomach upset in sensitive individuals." 			
	Food or Food constituent	Health Relationship	Proposed wording

385	Calcium (as a citrate salt)	Healthy heart	<p>Calcium promotes a healthy heart.</p> <p>Calcium maintains a healthy heart.</p> <p>Calcium helps build a healthy heart.</p> <p>Calcium helps promote a healthy hear</p>
	<p>Conditions of use</p> <ul style="list-style-type: none"> - ab 150 mg/l Calcium (siehe EG-Mineralwasser-Richtlinie) - Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 120 miligrams calcium Weight of average daily food serving: 360 miligram(s) Daily amount to be consumed to produce claimed effect: 360 miligram(s) Number of food portions this equates to in everyday food portions: 1 Length of time after consumption for claimed effect to become apparent: Randomised trials have shown that effects are apparent after a number of weeks/months of regular consumption. Other conditions for use: The product must contain 15% RDA Calcium. - Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 120 miligrams calcium Weight of average daily food serving: 666 miligram(s) Daily amount to be consumed to produce claimed effect: 666 miligram(s) Number of food portions this equates to in everyday food portions: 1 Length of time after consumption for claimed effect to become apparent: Randomised trials have shown that effects are apparent after a number of weeks/months of regular consumption. Other conditions for use: The product must contain 15% RDA Calcium - Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 160 mg calcium Weight of average daily food serving: 1.33 gram(s) Daily amount to be consumed to produce claimed effect: 1.33 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: Randomised trials have shown that effects are apparent after a number of weeks/months of regular consumption. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No Other conditions for use: The product must contain 20% RDA Calcium 		
1419	Food or Food constituent	Health Relationship	Proposed wording
	Calcium	Cardiovascular system	Diet which includes several daily servings of low-fat milk products (about 1200 mg of calcium/day) helps to control blood pressure.
<p>Conditions of use</p> <ul style="list-style-type: none"> - Low-fat milk products with calcium content of 150-200mg/100g, 200-300mg/ serving 			
3099	Food or Food constituent	Health Relationship	Proposed wording
	Calcium phosphoryl oligosaccharide	Dental health	<ul style="list-style-type: none"> - remineralizes/restores tooth enamel after meals; - increases tooth surface hardness;

		- helps strengthen teeth
	Conditions of use <ul style="list-style-type: none">– Incorporated in toothfriendly confectionery such as chewing gum candies and chocolate at levels of about 2 – 2.5%	