SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to fluoride and maintenance of tooth mineralisation (ID 275, 276) and maintenance of bone (ID 371) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

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 fluoride and the following claimed effects: maintenance of tooth mineralisation and maintenance of bone. 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 fluoride, which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that fluoride is sufficiently characterised.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of fluoride and maintenance of tooth mineralisation.

In order to bear the claim a food should be at least a source of fluoride 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 dietary intake of fluoride and maintenance of normal bone.

KEY WORDS

Fluoride, tooth, mineralisation, bone, health claims.

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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 (EC) No 1924/2006[3] 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 fluoride which is a well-recognised nutrient and is measurable in foods by established methods.

Fluoride occurs naturally in water and some foods and is authorised for addition to selected foods and dental products (Annex I of Regulation (EC) No 1925/2006[4] and Annex I of Directive 2002/46/EC[5]). This evaluation applies to fluoride naturally present in foods, including drinking water, and to those forms authorised for addition to foods (Annex II of the Regulation (EC) No 1925/2006 and Annex II of Directive 2002/46/EC).

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

2. Relevance of the claimed effect to human health

2.1. Maintenance of tooth mineralisation (ID 275, 276)

The claimed effects are "tooth and enamel strength" and "tooth remineralisation". 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 refer to the promotion of a beneficial balance between de- and remineralisation of tooth enamel and dentin.

The Panel considers that maintenance of tooth mineralisation is beneficial to human health.

2.2. Maintenance of bone (ID 371)

The claimed effect is "bone". The Panel assumes that the target population is the general population.

In the context of the proposed wording, the Panel notes that the claimed effect refers to maintenance of normal bone.

The Panel considers that maintenance of normal bone is 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.

3. Scientific substantiation of the claimed effect

3.1. Maintenance of tooth mineralisation (ID 275, 276)

Fluoride is a highly electronegative ion, which may replace hydroxyl ions in the hydroxyapatite crystal lattice of tooth tissues (Robinson et al., 2000; ten Cate et al., 2008). Tooth hydroxyapatite crystals are resistant to dissolution at neutral pH, but their solubility drastically increases as pH drops (ten Cate et al., 2008). This drop in pH may lead to a net loss of tooth minerals. Fluoride substituted apatite is less soluble, and hence more resistant to acid exposure (Aoba, 2004).

Maintenance of tooth mineralisation is affected by the availability of ionic calcium, phosphate and fluoride at the tooth crystal interface. As long as a state of ionic supersaturation or equilibrium is maintained tooth mineral is not lost and may even be gained. The evidence provided by consensus opinions/reports from authoritative bodies, reviews, and scientific original papers shows that fluoride is beneficial for tooth health in the entire population by counteracting hydroxyapatite demineralisation and supporting remineralisation, i.e. maintenance of tooth mineralisation (Dean, 1942; ten Cate et al., 2008; Benson et al., 2009; Gillespie, 2009; Griffin et al., 2007; Hattab et al., 1989; Hjortsjö et al., 2009; NIH, 2001; ten Cate, 2004; Yeung et al., 2005).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of fluoride and maintenance of tooth mineralisation.

3.2. Maintenance of bone (ID 371)

The normal mineralisation of bone mainly involves the deposition of calcium and phosphate as essential structural components of the bone mineral. Other minerals can be also incorporated to the apatite crystals, but no structural function in bone has been defined for them. No evidence has been provided in any of the references cited for the substantiation of this claim for a role of fluoride in the deposition of calcium or phosphorus in bone.

Fluoride is incorporated into bone and can increase bone mineral density in humans. However, there is evidence for a biphasic effect on bone strength and risk of bone fracture in both animals and humans, and the precise dose response relationship taking into account body burden and time of exposure cannot be defined. Inadequate intakes or status of fluoride contributing to impaired bone health or bone strength cannot be identified. Recommendations for fluoride intake in different population groups are based on dental health outcomes (EFSA, 2005).

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of fluoride and maintenance of normal bone.

4. Panel's comments on the proposed wording

4.1. Maintenance of tooth mineralisation (ID 275, 276)

The Panel considers that the following wording reflects the scientific evidence: "Fluoride contributes to maintain tooth mineralisation".

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 fluoride 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. Tolerable Upper Intake Levels have been established for

fluoride (EFSA, 2005). Excess intake may harm tooth formation during childhood. Tolerable Upper Intake Levels for fluoride at different ages have been defined in the EU.

CONCLUSIONS

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

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

Maintenance of tooth mineralisation (ID 275, 276)

- The claimed effects are "tooth and enamel strength" and "tooth remineralisation". The target population is assumed to be the general population. Maintenance of tooth mineralisation is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of fluoride and maintenance of tooth mineralisation.
- The following wording reflects the scientific evidence: "Fluoride contributes to maintain tooth mineralisation".

Maintenance of bone (ID 371)

- The claimed effect is "bone". The target population is assumed to be the general population. Maintenance of normal bone is beneficial to human health.
- A cause and effect relationship has not been established between the dietary intake of fluoride and maintenance of normal bone.

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 fluoride 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. Excess intake may harm tooth formation during childhood.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1062, EFSA-Q-2008-1063, EFSA-Q-2008-1158). The scientific substantiation is based on the information provided by the Members 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/EFSA/efsa_locale-1178620753812_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 foods[6] (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 FOOD[7]

Foods are commonly involved in many different functions[8] 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 DISCAIMER

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

ID	Food or Food constituent	Health Relationship	Proposed wording
275	Fluoride	Tooth and enamel strength, remineralisation	- Fluoride strengthens the teeth/ enamel; - Fluoride helps protect the teeth; - Fluoride helps the teeth recover after meals.
	Conditions of use • MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 • MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG • Schulkinder, Erwachsene 0,5 - 2 Milligramm (mg) max 4 Milligramm (mg) • ab 1 mg/l Fluorid (siehe EG-Mineralwasser-Richtlinie)		
276	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Fluoride	Teeth	- Fluoride contributes to the maintenance of healthy teeth
	Conditions of use • MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults		
371	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Fluoride	Bone	- Fluoride supports the mineralisation of bones.
	Conditions of use • No conditions of use provided		