SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to selenium and maintenance of normal hair (ID 281), maintenance of normal nails (ID 281), protection against heavy metals (ID 383), maintenance of normal joints (ID 409), maintenance of normal thyroid function (ID 410, 1292), protection of DNA, proteins and lipids from oxidative damage (ID 410, 1292), and maintenance of the normal function of the immune system (ID 1750) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to selenium and maintenance of normal hair, maintenance of normal nails, protection against heavy metals, maintenance of normal joints, maintenance of normal thyroid function, protection of DNA, proteins and lipids from oxidative damage, and maintenance of the normal function of the immune system. 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 selenium, which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that selenium is sufficiently characterised.

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[1] On request from the European Commission, Question No EFSA-Q-2008-1068, adopted on 11 February 2010 and Question No EFSA-Q-2008-1170, EFSA-Q-2008-1196, EFSA-Q-2008-1197, EFSA-Q-2008-2030, EFSA-Q-2008-2483, adopted on 9 July 2010.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

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Maintenance of normal hair

The claimed effect is "hair and nail formation". The target population is assumed to be the general population. The Panel considers that maintenance of normal hair is a beneficial physiological effect.

Deficiency in selenium has been shown to result in various disorders including impairment of hair.

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

Maintenance of normal nails

The claimed effect is "hair and nail formation". The target population is assumed to be the general population. The Panel considers that maintenance of normal nails is a beneficial physiological effect.

Deficiency in selenium has been shown to result in various disorders including impairment of nails.

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

Protection against heavy metals

The claimed effect is "detoxification". The target population is assumed to be the general population. The Panel considers that protection against heavy metals is a beneficial physiological effect.

No conclusions can be drawn from the only reference provided for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the dietary intake of selenium and protection against heavy metals.

Maintenance of normal joints

The claimed effect is "joint function". The target population is assumed to be the general population. The Panel considers that maintenance of normal joints is a beneficial physiological effect.

No conclusions can be drawn from the references provided for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the dietary intake of selenium and maintenance of normal joints.

Maintenance of normal thyroid function

The claimed effects are "key function within metabolism (e.g. GSH-peroxidase)", "antioxidant to prevent oxidative stress", "proper thyroid function" and "maintenance of cellular redox status. The target population is assumed to be the general population.

A claim on selenium and normal thyroid function has already been assessed with a favourable outcome.

Protection of DNA, proteins and lipids from oxidative damage

The claimed effects are "key function within metabolism (e.g. GSH-peroxidase)", "antioxidant to prevent oxidative stress", "proper thyroid function" and "maintenance of cellular redox status". The target population is assumed to be the general population.

A claim on selenium and protection of DNA, proteins and lipids from oxidative damage has already been assessed with a favourable outcome.

Maintenance of the normal function of the immune system

The claimed effect is "natural defences/immune system". The target population is assumed to be the general population.

A claim on selenium and normal function of the immune system has already been assessed with a favourable outcome.

Conditions and possible restrictions of use

The Panel considers that in order to bear the claims a food should be at least a source of selenium as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

KEY WORDS

Selenium, minerals, hair, nails, heavy metals, joints, thyroid, immune system, health claims.

TABLE OF CONTENTS

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

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

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

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is selenium, which is a well recognised nutrient and is measurable in foods by established methods.

Selenium occurs naturally in foods and is authorised for addition to foods and for use in food supplements (Annex I of the Regulation (EC) No 1925/2006[6] and Annex I of Directive 2002/46/EC[7]). This evaluation applies to selenium naturally present in foods and to 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, selenium, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Maintenance of normal hair (ID 281)

The claimed effect is "hair and nail formation". The Panel assumes that the target population is the general population.

The Panel considers that maintenance of normal hair is a beneficial physiological effect.

2.2. Maintenance of normal nails (ID 281)

The claimed effect is "hair and nail formation". The Panel assumes that the target population is the general population.

[4] 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.
[5] Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims: http://www.efsa.europa.eu/en/ndameetings/docs/nda100601-ax01.pdf
[6] 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.
[7] 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.

The Panel considers that maintenance of normal nails is a beneficial physiological effect.

2.3. Protection against heavy metals (ID 383)

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

In the context of the wording provided, the Panel assumes that the claimed effect is related to the protection against heavy metals.

The Panel considers that protection against heavy metals is a beneficial physiological effect.

2.4. Maintenance of normal joints (ID 409)

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

The Panel considers that maintenance of normal joints is a beneficial physiological effect.

2.5. Maintenance of normal thyroid function (ID 410, 1292)

The claimed effects are "key function within metabolism (e.g. GSH-peroxidase)", "antioxidant to prevent oxidative stress", "proper thyroid function" and "maintenance of cellular redox status". The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effects are related to thyroid function.

A claim on selenium and normal thyroid function has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009).

2.6. Protection of DNA, proteins and lipids from oxidative damage (ID 410, 1292)

The claimed effects are "key function within metabolism (e.g. GSH-peroxidase)", "antioxidant to prevent oxidative stress", "proper thyroid function" and "maintenance of cellular redox status". The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effects are related to the protection of DNA, proteins and lipids from oxidative damage.

A claim on selenium and protection of DNA, proteins and lipids from oxidative damage has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009).

2.7. Maintenance of the normal function of the immune system (ID 1750)

The claimed effect is "natural defences/immune system". The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect is related to the normal function of the immune system.

A claim on selenium and normal function of the immune system has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009).

3. Scientific substantiation of the claimed effect

Selenium is an essential trace element. Twenty-five selenoprotein genes have been identified in the human genome (Kryukov et al., 2003). Selenoproteins have a number of functions, comprising various catalytic roles (glutathione peroxidases, thioredoxin reductases, and iodothyronine deiodinases), structural roles, and storage and transport activities. Selenium is present in foods mainly as selenomethionine and selenocysteine. It is absorbed efficiently by the intestine over a wide range of concentrations and across a variety of different molecular forms (Bates, 2005).

3.1. Maintenance of normal hair (ID 281)

Deficiency in selenium has been shown to result in various disorders including impairment of hair (Biesalski et al., 1995; Sunde, 2006). Clinical manifestations such as white nail beds, pseudoalbinism, alopecia and thin hair have been observed in particular in patients receiving total parenteral nutrition lacking selenium. Administration of selenium was able to restore these deficiency symptoms (Abrams et al., 1992; Kanekura et al., 2005; Masumoto et al., 2007; Vinton et al., 1987).

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

3.2. Maintenance of normal nails (ID 281)

Deficiency in selenium has been shown to result in various disorders including impairment of nails (Biesalski et al., 1995; Sunde, 2006). Clinical manifestations such as white nail beds, pseudoalbinism, alopecia and thin hair have been observed in particular in patients receiving total parenteral nutrition lacking selenium. Administration of selenium was able to restore these deficiency symptoms (Abrams et al., 1992; Kanekura et al., 2005; Masumoto et al., 2007; Vinton et al., 1987).

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

3.3. Protection against heavy metals (ID 383)

One reference was provided for the scientific substantiation of the claim which was a textbook in which the claimed effect was mentioned. No further evidence was provided in support of the claim. The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of selenium and protection against heavy metals.

3.4. Maintenance of normal joints (ID 409)

A total of 15 references were provided for the scientific substantiation of the claim. Ten human studies assessed plasma selenium concentrations in patients with rheumatoid arthritis, (juvenile) chronic polyarthritis, psoriatic arthritis, or in patients with elevated C-reactive protein, lung cancer or

adult T-cell leukaemia. Five human intervention studies have been provided which were carried out in patients with rheumatoid arthritis or chronic polyarthritis. The Panel considers that the evidence provided does not establish that patients with arthritis of different origin are representative of the general population with regard to the status of joint tissue, or that results obtained in studies on subjects with arthritis of different origin relating to the treatment of symptoms of these diseases can be extrapolated to the maintenance of normal joints in the general population.

The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

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

4. Panel's comments on the proposed wordings

4.1. Maintenance of normal hair (ID 281)

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

4.2. Maintenance of normal nails (ID 281)

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

5. Conditions and possible restrictions of use

The Panel considers that in order to bear the claims a food should be at least a source of selenium as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population. Tolerable Upper Intake Levels (ULs) have been established for adults, pregnant and lactating woman, children and adolescents (SCF, 2000).

CONCLUSIONS

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

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

Maintenance of normal hair (ID 281)

- The claimed effect is "hair and nail formation". The target population is assumed to be the general population. Maintenance of normal hair is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of selenium and maintenance of normal hair.
- The evidence provided does not establish that inadequate intake of selenium leading to impaired maintenance of normal hair occurs in the general EU population.
- The following wording reflects the scientific evidence: "Selenium contributes to the maintenance of normal hair".

Maintenance of normal nails (ID 281)

- The claimed effect is "hair and nail formation". The target population is assumed to be the general population. Maintenance of normal nails is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of selenium and maintenance of normal nails.
- The evidence provided does not establish that inadequate intake of selenium leading to impaired maintenance of normal nails occurs in the general EU population.
- The following wording reflects the scientific evidence: "Selenium contributes to the maintenance of normal nails".

Protection against heavy metals (ID 383)

- The claimed effect is "detoxification". The target population is assumed to be the general population. Protection against heavy metals is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of selenium and protection against heavy metals.

Maintenance of normal joints (ID 409)

- The claimed effect is "joint function". The target population is assumed to be the general population. Maintenance of normal joints is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of selenium and maintenance of normal joints.

Maintenance of normal thyroid function (ID 410, 1292)

- The claimed effects are "key function within metabolism (e.g. GSH-peroxidase)", "antioxidant to prevent oxidative stress", "proper thyroid function", and "maintenance of cellular redox status. The target population is assumed to be the general population.
- A claim on selenium and normal thyroid function has already been assessed with a favourable outcome.

Protection of DNA, proteins and lipids from oxidative damage (ID 410, 1292)

- The claimed effects are "key function within metabolism (e.g. GSH-peroxidase)", "antioxidant to prevent oxidative stress", "proper thyroid function", and "maintenance of cellular redox status". The target population is assumed to be the general population.
- A claim on selenium and protection of DNA, proteins and lipids from oxidative damage has already been assessed with a favourable outcome.

Maintenance of the normal function of the immune system (ID 1750)

- The claimed effect is "natural defences/immune system". The target population is assumed to be the general population.
- A claim on selenium and normal function of the immune system has already been assessed with a favourable outcome.

Conditions and possible restrictions of use

- In order to bear the claims a food should be at least a source of selenium as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1068, EFSA-Q-2008-1170, EFSA-Q-2008-1196, EFSA-Q-2008-1197, EFSA-Q-2008-2030, EFSA-Q-2008-2483). 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/panels/nda/claims/article13.htm

REFERENCES

Abrams CK, Siram SM, Galsim C, Johnson-Hamilton H, Munford FL and Mezghebe H, 1992. Selenium deficiency in long-term total parenteral nutrition. Nutrition in Clinical Practice, 7, 175-178.

Bates CJ, 2005. Selenium. In: Encyclopedia of Human Nutrition. Eds Caballero B, Allen L, Prentice A. Elsevier, Oxford, 118-125.

Biesalski HK, Fürst P, Kasper H, Kluthe R, Pölert W, Puchstein C, and Stählin HB, 1995. Ernährungsmedizin. Georg Thieme Verlag, Stuttgart.

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009. Scientific Opinion on the substantiation of health claims related to selenium and protection of DNA, proteins and lipids from oxidative damage (ID 277, 283, 286, 1289, 1290, 1291, 1293, 1751), function of the immune system (ID 278), thyroid function (ID 279, 282, 286, 1289, 1290, 1291, 1293), function of the heart and blood vessels (ID 280), prostate function (ID 284), cognitive function (ID 285) and spermatogenesis (ID 396) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from the European Commission. EFSA Journal, 7(9):1220, 24 pp.

Kanekura T, Yotsumoto S, Maeno N, Kamenosono A, Saruwatari H, Uchino Y, Mera Y, Kanzaki T, 2005. Selenium deficiency: report of a case. Clinical and Experimental Dermatology, 30, 346-348.

Kryukov GV, Castellano S, Novoselov SV, Lobanov AV, Zehtab O, Guigó R and Gladyshev VN, 2003. Characterization of Mammalian Selenoproteomes. Science, 300, 1439-1443.

Masumoto K, Nagata K, Higashi M, Nakatsuji T, Uesugi T, Takahashi Y, Nishimoto Y, Kitajima J, Hikino S, Hara T, Nakashima K, Nakashima K, Oishi R and Taguchi T, 2007. Clinical features of selenium deficiency in infants receiving long-term nutritional support. Nutrition, 23, 782-787.

SCF (Scientific Committee on Food), 2000. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Selenium.

Sunde RA, 2006. Selenium. In: Present knowledge in nutrition. Eds Bowman BA and Russell RM. International Life Sciences Institute (ILSI), Washington, DC.

Vinton NE, Dahlstrom KA, Strobel CT, Ament ME, 1987. Macrocytosis and pseudoalbinism: manifestations of selenium deficiency. Journal of Pediatrics, 111, 711-717.

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[8] (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[9]

Foods are commonly involved in many different functions[10] 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.

[8] OJ L12, 18/01/2007
[9] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[10] 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 selenium, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
281	Selenium	Hair and Nail formation	- Selenium essential for hair and nail formation. - Selenium required for hair and nail formation.
	Conditions of use - MINIMUM 15% RDA		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
383	sélénium	detoxification	participe à la protection contre les métaux lourds
	Conditions of use - 50 µg/j		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
409	Selen Clarification provided selenium	Gelenkfunktion Clarification provided joint function	Selen ist wichtig für die Gelenkfunktion Clarification provided selenium is important for joint function
	Conditions of use - none provided		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
410	Selen Clarification provided selenium	Stoffwechsel Clarification provided Key function within metabolism (e.g. GSH-peroxidase)	Selen ist wichtig für den Stoffwechsel. Clarification provided Selenium has an important role in cell metabolism / it cares for a proper function of the thyroid gland.
	Conditions of use - Jugendliche, Erwachsene: 20 bis 50 µg, UL 100 µg - Jugendliche, Erwachsene: 20 µg		
	Comments from Member States Example of wording from industry: Selenium has an important role in cell metabolism / is essential for the healthy functioning of the thyroid gland.		

ID	Food or Food constituent	Health Relationship	Proposed wording
1292	Milk and dairy products	- Antioxidant to prevent oxidative stress - Proper thyroid function - Maintenance of cellular redox status	Selenium is an essential trace element involved in the development and maintenance of immunocompetence, thyroid function and as an antioxidant to prevent oxidative stress in living tissues. Selenium-Enriched* Sel-Plex Inside* Contains x micrograms Se/100 g (*by feeding animals the approved selenium yeast, Sel-Plex®)
	Conditions of use - selenium to be present at a significant amount linked to the newly agreed reference intake value		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1750	Selenomethionine enriched Saccharomyces cerevisiae ATY-SC-107	Natural defenses / Immune system <u>Clarification provided</u> increases the performance of immune system	-Selenomethionine is necessary for the function of the immune system.
	Conditions of use - 55 µg Se/day		