SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to vitamin C and reduction of tiredness and fatigue (ID 139, 2622), contribution to normal psychological functions (ID 140), regeneration of the reduced form of vitamin E (ID 202), contribution to normal energy-yielding metabolism (ID 2334, 3196), maintenance of the normal function of the immune system (ID 4321) and protection of DNA, proteins and lipids from oxidative damage (ID 3331) 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 vitamin C and reduction of tiredness and fatigue, contribution to normal psychological functions, regeneration of the reduced form of vitamin E, contribution to normal energy-yielding metabolism, maintenance of the normal function of the immune system and protection of DNA, proteins and lipids from oxidative damage. 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.

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1 On request from the European Commission, Question No EFSA-Q-2008-926, EFSA-Q-2008-927, EFSA-Q-2008-989, EFSA-Q-2008-3067, EFSA-Q-2008-3355, EFSA-Q-2008-3928, EFSA-Q-2008-4062, EFSA-Q-2010-00274 adopted on 10 September 2010.

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3 Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: 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. The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain, and Peter Willatts.

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The food constituent that is the subject of the health claims is vitamin C (L-ascorbic acid, ascorbate). The Panel considers that vitamin C is sufficiently characterised.

Reduction of tiredness and fatigue

The claimed effect is "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status". The target population is assumed to be the general population. The Panel considers that the reduction of tiredness and fatigue is a beneficial physiological effect.

The symptoms of vitamin C deficiency include weakness and fatigue.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C and reduction of tiredness and fatigue.

Contribution to normal psychological functions

The claimed effect is "the role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)". The target population is assumed to be the general population. The Panel considers that contribution to normal psychological functions, which encompass cognitive and affective domains, is a beneficial physiological effect.

Advanced vitamin C deficiency results in scurvy. The symptoms of scurvy include listlessness and general malaise, sometimes associated with personality changes and psychomotor performance. Depression is one of the symptoms associated with scurvy.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C and contribution to normal psychological functions.

Regeneration of the reduced form of vitamin E

The claimed effect is "regeneration of vitamin E, have synergistic effects". The target population is assumed to be the general population. In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers to the regeneration of the reduced form of vitamin E. The Panel considers that the regeneration of the reduced form of vitamin E is a beneficial physiological effect.

Vitamin C as a water-soluble antioxidant can regenerate reduced alpha-tocopherol (vitamin E) as a lipid-soluble antioxidant added to liposomes *in vitro*.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C and the regeneration of the reduced form of vitamin E.

Contribution to normal energy-yielding metabolism

The claimed effect is "invigoration of the body" and "physical health". The target population is assumed to be the general population. In the context of the proposed wording and clarifications provided by Member States, the Panel assumes that the claimed effect refers to energy-yielding metabolism.

A claim on vitamin C and energy-yielding metabolism has already been assessed with a favourable outcome.

Maintenance of the normal function of the immune system

The claimed effect is "is a rich source of vitamin C that has immunostimulating activities". The target population is assumed to be the general population. In the context of the proposed wording, the Panel assumes that the claimed effect refers to the normal function of the immune system.

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

Protection of DNA, proteins and lipids from oxidative damage

The claimed effect is "anti oxydant, par sa teneur en vitamine C". The target population is assumed to be the general population. The Panel assumes that the claimed effect refers to the protection of DNA, proteins and lipids from oxidative damage.

A claim on vitamin C and protection of DNA, proteins and lipids from oxidative damage 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 vitamin C 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

Vitamin C, tiredness, fatigue, immune system, energy, oxidative damage, mental, psychological, regeneration, health claims.

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[4] submitted by Member States contains main entry claims with corresponding conditions of use and literature for 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 vitamin C (L-ascorbic acid, ascorbate), which is a well recognised nutrient and is measurable in foods by established methods.

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

2. Relevance of the claimed effect to human health

2.1. Reduction of tiredness and fatigue (ID 139, 2622)

The claimed effect is "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status". The Panel assumes that the target population is the general population.

In the context of the proposed wording and clarifications provided by Member States, the Panel assumes that the claimed effect refers to the reduction of tiredness and fatigue.

The Panel considers that reduction of tiredness and fatigue is a beneficial physiological effect.

[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.

2.2. Contribution to normal psychological functions (ID 140)

The claimed effect is "the role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)". The Panel assumes that the target population is the general population.

The Panel considers that contribution to normal psychological functions, which encompass cognitive and affective domains, is a beneficial physiological effect.

2.3. Regeneration of the reduced form of vitamin E (ID 202)

The claimed effect is "regeneration of vitamin E, have synergistic effects". 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 refers to the regeneration of the reduced form of vitamin E.

The Panel considers that the regeneration of the reduced form of vitamin E is a beneficial physiological effect.

2.4. Contribution to normal energy-yielding metabolism (ID 2334, 3196)

The claimed effect is "invigoration of the body" and "physical health". The Panel assumes that the target population is the general population.

In the context of the proposed wording and clarifications provided by Member States, the Panel assumes that the claimed effect refers to energy-yielding metabolism.

A claim on vitamin C and energy-yielding metabolism has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009).

2.5. Maintenance of the normal function of the immune system (ID 4321)

The claimed effect is "is a rich source of vitamin C that has immunostimulating activities". The Panel assumes that the target population is the general population.

In the context of the proposed wording, the Panel assumes that the claimed effect refers to the maintenance of the normal function of the immune system.

A claim on vitamin C and the function of the immune system 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 3331)

The claimed effect is "anti oxydant, par sa teneur en vitamine C". The Panel assumes that the target population is the general population.

The Panel assumes that the claimed effect refers to the protection of DNA, proteins and lipids from oxidative damage.

A claim on vitamin C and the 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).

3. Scientific substantiation of the claimed effect

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is consensus on the role of vitamin C in the body (Bender, 2003; Garrow et al., 2000; IoM, 2000; NNR, 2004; Sadler et al., 1999; Levine et al., 2006; EVM, 2002). Vitamin C is an electron donor, or reducing agent, and its functions are attributable to this action (Levine et al., 2006). Vitamin C acts as a free radical scavenger in the body and as electron donor (and cofactor) for eight human enzymes, three of which participate in the biosynthesis (and cross-linking) of collagen and other components of the connective tissue, two of which are required in the biosynthesis of carnitine, one of which is required in tyrosine metabolism and two of which are required in the biosynthesis of the catecholamines adrenaline and noradrenaline (which act as neurotransmitters) and in the amidation of peptide hormones.

3.1. Reduction of tiredness and fatigue (ID 139, 2622)

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that weakness and fatigue are among the symptoms of vitamin C deficiency (IoM, 2000; Lukaski, 2004). These symptoms respond to vitamin C supplementation (Levine et al., 1996).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C and reduction of tiredness and fatigue.

3.2. Contribution to normal psychological functions (ID 140)

Advanced vitamin C deficiency results in scurvy. The symptoms of scurvy include listlessness and general malaise, sometimes associated with personality changes and psychomotor performance (Bender, 2009). Depression is one of the symptoms associated with scurvy (IoM, 2000).

Among its biological functions, vitamin C modulates neurotransmitter receptors, the function of glutamatergic and dopaminergic neurons, and the formation of glial cells and myelin. Vitamin C, as a co-factor for dopamine-β-hydroxylase, also contributes to catecholamines, norepinephrine (noradrenaline) and epinephrine (adrenaline) biosynthesis (IoM, 2000).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C and contribution to normal psychological functions.

3.3. Regeneration of the reduced form of vitamin E (ID 202)

Vitamin C is an electron donor, or reducing agent, and its functions are attributable to this action. According to a report on the interaction between ascorbate and alpha-tocopherol (Niki, 1987), vitamin C as a water-soluble antioxidant can regenerate reduced alpha-tocopherol (vitamin E) as a lipid-soluble antioxidant added to liposomes *in vitro* (Levine et al., 2006).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C and the regeneration of the reduced form of vitamin E.

4. Panel's comments on the proposed wording

4.1. Reduction of tiredness and fatigue (ID 139, 2622)

The Panel considers that the following wording reflects the scientific evidence: "Vitamin C can contribute to the reduction of tiredness and fatigue".

4.2. Contribution to normal psychological functions (ID 140)

The Panel considers that the following wording reflects the scientific evidence: "Vitamin C contributes to normal psychological functions".

4.3. Regeneration of the reduced form of vitamin E (ID 202)

The Panel considers that the following wording reflects the scientific evidence: "Vitamin C contributes to the regeneration of the reduced form of vitamin E".

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 vitamin C 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.

CONCLUSIONS

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

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

Reduction of tiredness and fatigue (ID 139, 2622)

- The claimed effect is "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status". The target population is assumed to be the general population. Reduction of tiredness and fatigue is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of vitamin C and reduction of tiredness and fatigue.
- The following wording reflects the scientific evidence: "Vitamin C can contribute to the reduction of tiredness and fatigue".

Contribution to normal psychological functions (ID 140)

- The claimed effect is "the role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)". The target population is assumed to be the general population. Contribution to normal psychological functions, which encompass cognitive and affective domains, is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of vitamin C and contribution to normal psychological functions.

- The following wording reflects the scientific evidence: "Vitamin C contributes to normal psychological functions".

Regeneration of the reduced form of vitamin E (ID 202)

- The claimed effect is "regeneration of vitamin E, have synergistic effects". The target population is assumed to be the general population. The regeneration of the reduced form of vitamin E is a beneficial physiological effect.

- A cause and effect relationship has been established between the dietary intake of vitamin C and the regeneration of the reduced form of vitamin E.

- The following wording reflects the scientific evidence: "Vitamin C contributes to the regeneration of the reduced form of vitamin E".

Contribution to normal energy-yielding metabolism (ID 2334, 3196)

- The claimed effect is "invigoration of the body" and "physical health". The target population is assumed to be the general population. In the context of the proposed wording and clarifications provided by Member States, the Panel assumes that the claimed effect refers to energy-yielding metabolism.

- A claim on vitamin C and energy-yielding metabolism has already been assessed with a favourable outcome.

Maintenance of the normal function of the immune system (ID 4321)

- The claimed effect is "is a rich source of vitamin C that has immunostimulating activities". The target population is assumed to be the general population. In the context of the proposed wording the Panel assumes that the claimed effect refers to the maintenance of the normal function of the immune system.

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

Protection of DNA, proteins and lipids from oxidative damage (ID 3331)

- The claimed effect is "anti oxydant, par sa teneur en vitamine C". The target population is assumed to be the general population. The Panel assumes that the claimed effect refers to the protection of DNA, proteins and lipids from oxidative damage.

- A claim on vitamin C and the protection of DNA, proteins and lipids from oxidative damage 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 vitamin C 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-2008-926, EFSA-Q-2008-927, EFSA-Q-2008-989, EFSA-Q-2008-3067, EFSA-Q-2008-3355, EFSA-Q-2008-

3928, EFSA-Q-2008-4062, EFSA-Q-2010-00274). 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 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 vitamin C, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
139	Vitamin C	Vitamin/mineral supplementation to reduce fatigue and tirednes in situations of inadequate micronutrient status Clarifications provided Reduce fatigue and tiredness, particularly in situations of inadequate micronutrient status, due to role in energy metabolism	Supplementation with B-vitamins, iron, magnesium as well as vitamin C can reduce fatigue and tiredness in situations of inadequate micro-nutrient status
	Conditions of use - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
140	Vitamin C	The role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)	Water-soluble vitamins, calcium, magnesium and zinc are essential for mental function and performance In situations of inadequate micronutrient status, supplementation with water-soluble vitamins, minerals and zinc can sustain mental performance. Necessary for the healthy functioning of the brain and the nervous system Beneficial effect on brain activity Helps maintain activity, memory, perception of the environment Promotes mental concentration Stimulates mental capacities Improves the psychoemotional state
	Conditions of use - Only for products with at least 100 % RDA of vitamins. Agency guidance for supplements is that products containing >1000 mg of Vitamin C should carry the label advisory statement "[This amount of Vitamin C] may cause mild stomach upset in sensitive individuals" - Population cible : Enfants de 6 à 14 ans : 100% AJR		

ID	Food or Food constituent	Health Relationship	Proposed wording
202	Vitamin C	Regeneration of vitamin E, have synergistic effects Clarification provided Vitamin C is necessary for the regeneration of the antioxidant form of vitamin E	Regeneration of vitamin E
	Conditions of use - 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. - Agency guidance for supplements is that products containing >1000mg vitamin C should carry the label advisory statement "this amount of vitamin C may cause mild stomach upset in sensitive individuals"		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2334	Rosa canica - common name : Cynorrhodon, Eglantier	Invigoration of the body Clarifications provided high level of vitamin C that contribute to the energy metabolism	"Used to feel more energetic" "Helps to find more energy" "Contributes to find more energy" "Used for mental and physical fatigue" "Helps to enhance mental and physical capacities" "Contributes to enhance mental and physical capacities" "Helps to strengthen the body" "Contributes to strengthen the body" "Supports energetic alertness" "Tonic effect" "Makes you feel more energetic" "Has stimulating and tonic properties that contribute to the resistance against mental and physical fatigue".
	Conditions of use - Traditional use of the pseudo-fructus / 2-2,5g of pseudo-fructus as an infusion / Equivalent quantity in extract - Rose hipe is traditionaly used in infusion: 2-2,5 g or an extract equivalent to these 2-2,5 g - Fruits		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**

2622	Cynorrhodon	Anti-asthénique source de vitamine C	Entretien l'énergie et le tonus Renforce la vitalité.
	Conditions of use - Fruit, 45mg vitamine C/jour		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3196	Acerola (Malpighia glabra L.)	Physical health Clarifications provided Increase energy levels which is needed for the energy metabolism and the transformation of food into energy.	Helps to support the body's vitality. Helps to make you feel more energetic. Enhancement of vitality/energy. Supports vitality. Helps in case of fatigue.
	Conditions of use - Fruit / At least an acerola daily amount equivalent to 25 mg vitamin C.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3331	cynorrhodon	anti oxydant, par sa teneur en vitamine C	anti oxydant, par sa teneur en vitamine C
	Conditions of use - 1 cuillère café de macération de la plante par jour		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4321	Dog rose (Rosa canina) fruit	is a rich source of vitamin C that has immunostimulating activities	helps support the body's immune system/Boosts the immune system
	Conditions of use - Fruit- 45 mg of vitamin C/day		

GLOSSARY AND ABBREVIATIONS

DNA Deoxyribonucleic Acid