

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to vitamin E and protection of DNA, proteins and lipids from oxidative damage (ID 160, 162, 1947), maintenance of the normal function of the immune system (ID 161, 163), maintenance of normal bone (ID 164), maintenance of normal teeth (ID 164), maintenance of normal hair (ID 164), maintenance of normal skin (ID 164), maintenance of normal nails (ID 164), maintenance of normal cardiac function (ID 166), maintenance of normal vision by protection of the lens of the eye (ID 167), contribution to normal cognitive function (ID 182, 183), regeneration of the reduced form of vitamin C (ID 203), maintenance of normal blood circulation (ID 216) and maintenance of normal a scalp (ID 2873) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

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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 E and protection of DNA, proteins and lipids from oxidative damage, maintenance of the normal function of the immune system, maintenance of normal bone, maintenance of normal teeth, maintenance of normal hair, maintenance of normal skin, maintenance of normal nails, maintenance of normal cardiac function, maintenance of normal vision by protection of the lens of the eye, contribution to normal cognitive function, regeneration of the reduced form of vitamin C, maintenance of normal blood circulation and maintenance of a normal scalp. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is vitamin E. The Panel considers that vitamin E is sufficiently characterised.

Protection of DNA, proteins and lipids from oxidative damage

The claimed effects are “protection of body cells from oxidative damage by being a free radical scavenger” and “antioxidants and aging”. The target population is assumed to be the general population. The Panel considers that protection of DNA, protein and lipids from oxidative damage may be a beneficial physiological effect.

Vitamin E functions physiologically as a chain-breaking antioxidant that prevents the propagation of lipid peroxidation.

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 E and protection of DNA, protein and lipids from oxidative damage.

Maintenance of the normal function of the immune system

The claimed effects are “normal immune system function” and “is important for the immune system”. The target population is assumed to be the general population. The Panel considers that maintenance of the normal function of the immune system is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the studies presented did not demonstrate immune defects in vitamin E deficient individuals, and that a restoration of a depressed immune system by vitamin E has not been shown.

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 vitamin E and maintenance of the normal function of the immune system.

Maintenance of normal bone

The claimed effect is “bone/teeth/hair/skin and nails health”. The target population is assumed to be the general population. The Panel considers that maintenance of normal bone is a beneficial physiological effect.

No references were provided from which conclusions could be drawn 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 vitamin E and maintenance of normal bone.

Maintenance of normal teeth

The claimed effect is “bone/teeth/hair/skin and nails health”. The target population is assumed to be the general population. The Panel considers that maintenance of normal teeth is a beneficial physiological effect.

No references were provided from which conclusions could be drawn 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 vitamin E and maintenance of normal teeth.

Maintenance of normal hair

The claimed effect is “bone/teeth/hair/skin and nails health”. The target population is assumed to be the general population. The Panel considers that maintenance of normal hair is a beneficial physiological effect.

No references were provided from which conclusions could be drawn 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 vitamin E and maintenance of normal hair.

Maintenance of normal skin

The claimed effect is “bone/teeth/hair/skin and nails health”. The target population is assumed to be the general population. The Panel considers that maintenance of normal skin is a beneficial physiological effect.

No references were provided from which conclusions could be drawn 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 vitamin E and maintenance of normal skin.

Maintenance of normal nails

The claimed effect is “bone/teeth/hair/skin and nails health”. The target population is assumed to be the general population. The Panel considers that maintenance of normal nails is a beneficial physiological effect.

No references were provided from which conclusions could be drawn 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 vitamin E and maintenance of normal nails.

Maintenance of normal cardiac function

The claimed effect is “can neutralise free radicals and help maintain a healthy heart”. The target population is assumed to be the general population. The Panel considers that maintenance of normal cardiac function is a beneficial physiological effect.

The results of intervention studies with vitamin E do not support the majority of the findings from epidemiological studies that vitamin E might be important in maintaining normal cardiac function.

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 vitamin E and maintenance of normal cardiac function.

Maintenance of normal vision by protection of the lens of the eye

The claimed effect is “eye health; vitamin E, C are found in the lens of the eye; acts jointly with vitamin C”. The target population is assumed to be the general population. The Panel considers that maintenance of normal vision by protection of the lens of the eye is a beneficial physiological effect.

No references were provided from which conclusions could be drawn 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 vitamin E and maintenance of normal vision by protection of the lens of the eye.

Contribution to normal cognitive function

The claimed effects are “antioxidant activity and cognitive function” and “mental state and performance”. The target population is assumed to be the general population. The Panel considers that contribution to normal cognitive function is a beneficial physiological effect.

No references were provided from which conclusions could be drawn 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 vitamin E and contribution to normal cognitive function.

Regeneration of the reduced form of vitamin C

The claimed effect is “regeneration of vitamin C, vitamin C and vitamin E have synergistic effects”. The target population is assumed to be the general population. The Panel considers that regeneration of the reduced form of vitamin C is a beneficial physiological effect.

No references were provided from which conclusions could be drawn 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 vitamin E and regeneration of the reduced form of vitamin C.

Maintenance of normal blood circulation

The claimed effect is “blood circulation”. The target population is assumed to be the general population. Maintenance of normal blood circulation is a beneficial physiological effect.

No references were provided from which conclusions could be drawn 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 vitamin E and maintenance of normal blood circulation.

Maintenance of a normal scalp

The claimed effect is “health of the scalp”. The target population is assumed to be the general population. The Panel considers that maintenance of a normal scalp is a beneficial physiological effect.

No references were provided from which conclusions could be drawn 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 vitamin E and maintenance of a normal scalp.

Conditions and possible restrictions of use

The Panel considers that in order to bear the claim a food should be at least a source of vitamin E 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 E, antioxidant, immune system, bone, teeth, hair, skin, nails, cardiac function, vision, lens, cognitive function, regeneration, blood circulation, scalp, health claims.

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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 1924/2006⁴ 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 out⁵. 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 E, which is a well recognised nutrient and is measurable in foods by established methods.

Vitamin E is authorised for addition to foods (Annex I of the Regulation (EC) No 1925/2006⁶ and Annex I of Directive 2002/46/EC⁷). This evaluation applies to vitamin E naturally present in foods and those forms authorised for addition to foods (Annex II of Regulation (EC) No 1925/2006 and Annex II of Directive 2002/46/EC).

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

2. Relevance of the claimed effect to human health

2.1. Protection of DNA, proteins and lipids from oxidative damage (ID 160, 162, 1947)

The claimed effects are “protection of body cells from oxidative damage by being a free radical scavenger”, “antioxidants and aging”, and “antioxidant”. The Panel assumes that the target population is the general population.

Reactive oxygen species (ROS) including several kinds of radicals are generated in biochemical processes (e.g. respiratory chain) and as a consequence of exposure to exogenous factors (e.g. radiation, pollutants). These reactive intermediates can damage molecules such as DNA, proteins and lipids if they are not intercepted by the antioxidant network, which includes free radical scavengers such as antioxidant nutrients.

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.

No definition has been provided of what constitutes “aging”, and therefore the Panel cannot evaluate the “anti-aging effects” implied in claim ID 162. Also, it should be noted that there is a difference between the ageing process itself and the increasing risk for specific age-related diseases where oxidative and/or free radical-mediated damage may play a role.

The Panel considers that protection of DNA, proteins and lipids from oxidative damage may be a beneficial physiological effect.

2.2. Maintenance of the normal function of the immune system (ID 161, 163)

The claimed effects are “normal immune system function” and “is important for the immune system”. The Panel assumes that the target population is the general population.

The Panel considers that maintenance of the normal function of the immune system is a beneficial physiological effect.

2.3. Maintenance of normal bone (ID 164)

The claimed effect is “bone/teeth/hair/skin and nails health”. The Panel assumes that the target population is the general population.

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

2.4. Maintenance of normal teeth (ID 164)

The claimed effect is “bone/teeth/hair/skin and nails health”. The Panel assumes that the target population is the general population.

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

2.5. Maintenance of normal hair (ID 164)

The claimed effect is “bone/teeth/hair/skin and nails health”. The Panel assumes that the target population is the general population.

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

2.6. Maintenance of normal skin (ID 164)

The claimed effect is “bone/teeth/hair/skin and nails health”. The Panel assumes that the target population is the general population.

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

2.7. Maintenance of normal nails (ID 164)

The claimed effect is “bone/teeth/hair/skin and nails health”. The Panel assumes that the target population is the general population.

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

2.8. Maintenance of normal cardiac function (ID 166)

The claimed effect is “can neutralise free radicals and help maintain a healthy heart”. The Panel assumes that the target population is the general population. The Panel assumes that the claimed effect refers to the maintenance of normal cardiac function.

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

2.9. Maintenance of normal vision by protection of the lens of the eye (ID 167)

The claimed effect is “eye health; vitamin E, C are found in the lens of the eye; acts jointly with vitamin C”. 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 protection of the lens of the eye.

The Panel considers that maintenance of normal vision by protection of the lens of the eye is a beneficial physiological effect.

2.10. Contribution to normal cognitive function (ID 182, 183)

The claimed effects are “antioxidant activity and cognitive function”, and “mental state and performance”. The Panel assumes that the target population is the general population.

Cognitive function includes memory, attention (concentration), learning, intelligence and problem solving. These are well defined constructs and can be measured by validated psychometric cognitive tests.

The Panel considers that contribution to normal cognitive function is a beneficial physiological effect.

2.11. Regeneration of the reduced form of vitamin C (ID 203)

The claimed effect is “regeneration of vitamin C, vitamin C and vitamin E have synergistic effects”. The Panel assumes that the target population is the general population.

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

2.12. Maintenance of normal blood circulation (ID 216)

The claimed effect is “blood circulation”. The Panel assumes that the target population is the general population.

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

2.13. Maintenance of a normal scalp (ID 2873)

The claimed effect is “health of the scalp”. The Panel assumes that the target population is the general population.

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

3. Scientific substantiation of the claimed effect

The evidence provided by opinions/reports from authoritative bodies and reviews shows that there is good consensus on the role of vitamin E in the body (Berdanier et al., 2002; EVM, 2002; Gibney et al., 2002; IoM, 2000; NNR, 2004; Sadler et al., 1999; SCF, 2003; Shils et al., 2006). Vitamin E is fat-soluble and is transported in plasma lipoproteins and partitions into membranes and fat-storage sites where it has the unique role of protecting polyunsaturated fatty acids from peroxidation. Plasma α -tocopherol is regulated by the liver α -tocopherol transfer protein (α -TTP). In humans, a genetic defect in α -TTP results in severe vitamin E deficiency (Shils et al., 2006).

A major vitamin E deficiency symptom in humans is peripheral neuropathy characterised by the degeneration of the large calibre axons in the sensory neurons (IoM, 2000). Vitamin E deficiency as a result of inadequate intake of vitamin E is uncommon. Vitamin E deficiency can occur as a result of genetic abnormalities in α -TTP and as a result of various fat malabsorption syndromes. Vitamin E supplementation halts the progression of the neurological abnormalities caused by inadequate nerve tissue α -tocopherol and, in some cases, has reversed these abnormalities. Other vitamin E deficiency symptoms observed in humans include spinocerebellar ataxia, skeleton myopathy, pigmented retinopathy (IoM, 2000), loss of deep tendon reflexes, unsteady gait, restriction of upward gaze and visual field loss (Sadler et al., 1999).

3.1. Protection of DNA, proteins and lipids from oxidative damage (ID 160, 162, 1947)

Vitamin E functions physiologically as a chain-breaking antioxidant that prevents the propagation of lipid peroxidation (Shils et al., 2006; IoM 2000). Vitamin E is part of the antioxidant defence system, which is a complex network including both endogenous and dietary antioxidants, antioxidant enzymes and repair mechanisms, with mutual interactions and synergetic effects among the various components.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin E and protection of DNA, proteins and lipids from oxidative damage.

3.2. Maintenance of the normal function of the immune system (ID 161, 163)

Eighty-three references were provided in the consolidated list in relation to vitamin E and the immune system which included textbooks, systematic reviews, human studies, animal studies and *in vitro* studies.

Some randomised, double-blind, placebo-controlled clinical trials investigated the efficacy of supplementation of vitamin E and stimulation of delayed-type-hypersensitivity skin response (Meydani et al., 1990, 1997; Pallast et al., 1999). The Panel notes that this endpoint is not appropriate to draw a conclusion on the role of vitamin E and the function of the immune system.

Only one observational study reported a relationship between low plasma concentrations of vitamin E and an increased number of infections (Chavance et al., 1989), but randomised, double-blind, placebo-controlled clinical trials failed to show effects of vitamin E on the incidence of infections (Meydani et al., 2004), or even noted adverse effects of vitamin E on illness severity of respiratory infections (Graat et al., 2002).

In weighing the evidence, the Panel took into account that the studies presented did not demonstrate immune defects in vitamin E deficient individuals, and that a restoration of a depressed immune system by vitamin E has not been shown.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin E and maintenance of the normal function of the immune system.

3.3. Maintenance of normal bone (ID 164)

A total of 29 references were cited to substantiate the claimed effect. Some of these references were textbooks or opinions from scientific bodies in which the claimed effect was not stated or addressed. 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 vitamin E and maintenance of normal bone.

3.4. Maintenance of normal teeth (ID 164)

A total of 29 references were cited to substantiate the claimed effect. None of the references addressed the claimed effect. 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 vitamin E and maintenance of normal teeth.

3.5. Maintenance of normal hair (ID 164)

A total of 29 references were cited to substantiate the claimed effect. None of the references addressed the claimed effect. 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 vitamin E and maintenance of normal hair.

3.6. Maintenance of normal skin (ID 164)

A total of 29 references were cited to substantiate the claimed effect. Some of these references were textbooks or opinions from scientific bodies in which the claimed effect was not stated. The Panel notes that only one reference (Weber et al., 2003) was provided in relation to skin health. This study involved the use of benzoyl peroxide, which is a common drug for the treatment of acne vulgaris and topical supplementation of alpha-tocotrienol. The aim of this study was to show that antioxidant supplementation may mitigate the benzoyl peroxide-induced stratum corneum changes. 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 vitamin E and maintenance of normal skin.

3.7. Maintenance of normal nails (ID 164)

A total of 29 references were cited to substantiate the claimed effect. None of the references addressed the claimed effect. 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 vitamin E and maintenance of normal nails.

3.8. Maintenance of normal cardiac function (ID 166)

The literature provided in the consolidated list in relation to vitamin E and cardiac function in humans consisted of 18 references, of which three were textbooks and four were reports from authoritative bodies. Two of the references were not pertinent to the claimed effect as one study was confounded by vitamin C (Jaxa-Chamiec et al., 2005), and the other study did not address relevant endpoints (Kraemer et al., 2004). Eight of the remaining references reported on observational studies (either cross-sectional or prospective cohort studies) which reported associations between dietary vitamin E intake or plasma concentrations of vitamin E and coronary heart disease endpoints or various indicators of atherosclerosis or LDL (Low-Density Lipoprotein) oxidation (Cherubini et al., 2001; Gale et al. 2001; Knekt et al., 1994; Kushi et al., 1996; McQuillan et al., 2001; Rimm et al., 1993; Simon et al., 2001; Stampfer et al. 1993).

A meta-analysis of randomised controlled trials of vitamin E supplementation of different population groups, including seven studies on patients at risk of or with coronary heart disease, showed a statistically significant dose-dependent relationship between vitamin E supplementation and all-cause mortality (Miller et al., 2005). The Panel considers that no conclusions can be drawn from this meta-analysis for the scientific substantiation of the claimed effect as no relevant endpoint for the claimed effect has been included in the analysis.

Four published, large-scale, randomised, double-blind clinical intervention studies have tested the ability of vitamin E to prevent myocardial infarction. One of these, a secondary prevention trial (CHAOS), was associated with a statistically significant decrease in the occurrence of non-fatal and total myocardial infarctions and a non-statistically significant increase in fatal myocardial infarctions, while the other three, one carried out in a group of high risk cigarette smokers (ATBC Cancer Prevention Study) and the other two in high-risk cardiovascular patients (GISSI Prevenzione trial; HOPE Study), were neutral (IoM, 2000).

The Panel notes that the results of intervention studies with vitamin E do not support the majority of the findings from the epidemiological studies that vitamin E might be important in maintaining normal cardiac function.

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

3.9. Maintenance of normal vision by protection of the lens of the eye (ID 167)

The references provided included one textbook and four articles which reported on human epidemiological studies.

Two studies, Jacques et al. (2001) and Taylor et al. (2002), found no significant correlation between supplement intake of vitamin E and the incidence of lens opacity and reduced prevalence of cataract, respectively. The remaining two studies (Kuzniarz et al., 2001; Mares-Perlman et al., 2000), considered the use of vitamin supplements in general and cannot be used to substantiate a claim on vitamin E alone. 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 vitamin E and maintenance of normal vision by protection of the lens of the eye.

3.10. Contribution to normal cognitive function (ID 182, 183)

A total of seven references were provided to substantiate the claimed effect. Three references did not address relevant endpoints (cardiovascular efficacy, safety of high vitamin E intake). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect. The narrative review provided discussed the use of antioxidants, including vitamin E, in prevention and treatment of Alzheimer disease. This reference did not contain any primary data that could be used to substantiate the claimed effect.

Three articles reported on observational human studies.

One of these, a large (n=3,385) longitudinal cohort study of healthy men aged 71-90 years, investigated associations between the use of both vitamin E and vitamin C supplements and cognitive performance assessed two years later using the Cognitive Abilities Screening Instrument (Masaki et al., 2000). The Panel notes that findings from this study cannot be used for the scientific substantiation of the claimed effect as the study investigated the association of two vitamins rather than vitamin E alone.

The two other studies were a prospective cohort study, which evaluated the association between dietary intake of antioxidants (including vitamin E) and risk of Alzheimer disease (Engelhart et al., 2002) and a cross-sectional study, which examined associations between dietary intake of nutrients (including vitamin E) and cognitive performance in 260 elderly people, aged 65-90 years, who were free of significant cognitive impairment (Ortega et al., 1997). The Panel notes that no conclusions on a causal relationship between the dietary intake of vitamin E and cognitive function can be drawn from these studies because confounding by other dietary and lifestyle factors inherent to the observational study design cannot be excluded.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin E and contribution to normal cognitive function.

3.11. Regeneration of the reduced form of vitamin C (ID 203)

Two references were cited to substantiate the claimed effect. One was a textbook (Berman, 1991) and the other was a report on the antioxidant activity of vitamin E and vitamin C (Janisch et al., 2005). 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 vitamin E and regeneration of the reduced form of vitamin C.

3.12. Maintenance of normal blood circulation (ID 216)

One study was provided in the consolidated list in relation to vitamin E and blood circulation (Bursell et al., 1999). This study was a randomised, double-blind, placebo-controlled cross-over trial in type 1 diabetic subjects. The aim of this study was to measure retinal blood flow and renal function. The Panel considers that the evidence provided does not establish that patients with diabetes are representative of the general population with regard to retinal blood flow and renal function, or that results obtained in studies on subjects with diabetes can be extrapolated to the general population with regard to retinal blood flow and renal function owing to the abnormal eye and kidney functions of diabetic subjects.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin E and maintenance of normal blood circulation.

3.13. Maintenance of a normal scalp (ID 2873)

Two studies (one human and one *in vitro* study) were provided in the consolidated list which did not address the claimed effect. 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 vitamin E and maintenance of a normal scalp.

4. Panel's comments on the proposed wording

4.1. Protection of DNA, proteins and lipids from oxidative damage (ID 160, 162, 1947)

The Panel considers that the following wording reflects the scientific evidence: "Vitamin E contributes to the protection of cell constituents from oxidative damage".

5. Conditions and possible restrictions of use

The Panel considers that in order to bear the claim a food should be at least a source of Vitamin E 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 (UL) have been established for vitamin E in children, adolescents and adults (SCF, 2003).

CONCLUSIONS

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

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

Protection of DNA, proteins and lipids from oxidative damage (ID 160, 162, 1947)

- The claimed effects are "protection of body cells from oxidative damage by being a free radical scavenger" and "antioxidants and aging". The target population is assumed to be the general population. Protection of DNA, protein and lipids from oxidative damage may be a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of vitamin E and protection of DNA, protein and lipids from oxidative damage.
- The following wording reflects the scientific evidence: "Vitamin E contributes to the protection of cell constituents from oxidative damage".

Maintenance of the normal function of the immune system (ID 161, 163)

- The claimed effects are "normal immune system function" and "is important for the immune system". The target population is assumed to be the general population. Maintenance of the normal function of the immune system is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of vitamin E and maintenance of the normal function of the immune system.

Maintenance of normal bone (ID 164)

- The claimed effect is “bone/teeth/hair/skin and nails health”. The target population is assumed to be the general population. Maintenance of normal bone is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of vitamin E and maintenance of normal bone.

Maintenance of normal teeth (ID 164)

- The claimed effect is “bone/teeth/hair/skin and nails health”. The target population is assumed to be the general population. Maintenance of normal teeth is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of vitamin E and maintenance of normal teeth.

Maintenance of normal hair (ID 164)

- The claimed effect is “bone/teeth/hair/skin and nails health”. 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 not been established between the dietary intake of vitamin E and maintenance of normal hair.

Maintenance of normal skin (ID 164)

- The claimed effect is “bone/teeth/hair/skin and nails health”. The target population is assumed to be the general population. Maintenance of normal skin is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of vitamin E and maintenance of normal skin.

Maintenance of normal nails (ID 164)

- The claimed effect is “bone/teeth/hair/skin and nails health”. 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 not been established between the dietary intake of vitamin E and maintenance of normal nails.

Maintenance of normal cardiac function (ID 166)

- The claimed effect is “can neutralize free radicals and help maintain a healthy heart”. The target population is assumed to be the general population. Maintenance of normal cardiac function is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of vitamin E and maintenance of normal cardiac function.

Maintenance of normal vision by protection of the lens of the eye (ID 167)

- The claimed effect is “eye health; vitamin E, C are found in the lens of the eye; acts jointly with vitamin C”. The target population is assumed to be the general population.

Maintenance of normal vision by protection of the lens of the eye is a beneficial physiological effect.

- A cause and effect relationship has not been established between the dietary intake of vitamin E and maintenance of normal vision by protection of the lens of the eye.

Contribution to normal cognitive function (ID 182, 183)

- The claimed effects are “antioxidant activity and cognitive function”, and “mental state and performance”. The target population is assumed to be the general population. Contribution to normal cognitive function is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of vitamin E and contribution to normal cognitive function.

Regeneration of the reduced form of vitamin C (ID 203)

- The claimed effect is “regeneration of vitamin C, vitamin C and vitamin E have synergistic effects”. The target population is assumed to be the general population. Regeneration of the reduced form of vitamin C is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of vitamin E and regeneration of the reduced form of vitamin C.

Maintenance of normal blood circulation (ID 216)

- The claimed effect is “blood circulation”. The target population is assumed to be the general population. Maintenance of normal blood circulation is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of vitamin E and maintenance of normal blood circulation.

Maintenance of a normal scalp (ID 2873)

- The claimed effect is “health of the scalp”. The target population is assumed to be the general population. Maintenance of a normal scalp is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of vitamin E and maintenance of a normal scalp.

Conditions and possible restrictions of use

- In order to bear the claim a food should be at least a source of vitamin E 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-2008-947, EFSA-Q-2008-948, EFSA-Q-2008-949, EFSA-Q-2008-950, EFSA-Q-2008-951, EFSA-Q-2008-953, EFSA-Q-2008-954, EFSA-Q-2008-969, EFSA-Q-2008-970, EFSA-Q-2008-990, EFSA-Q-2008-1003, EFSA-Q-2008-2680, EFSA-Q-2008-3606). 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 foods⁸ (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 FOOD⁹

Foods are commonly involved in many different functions¹⁰ 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 E, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food component	Health Relationship	Proposed wording
160	Vitamin E	Protection of body tissues, cells, membranes and lipids from oxidative damage (such as the oxidation of polyunsaturated fatty acids in red blood cell membranes). Antioxidant activity.	Vitamin E is an antioxidant that protects the body's cells.
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Es werden nur die Nährstoffe beworben, die lt. Nährwertkennzeichnungs-verordnung (Anlage 1) mindestens 15 Prozent der empfohlenen Tagesdosis in 100 g oder 100 ml enthalten. - 10 mg per day - Names of nutrient/other substances and quantity in average daily serving: 1.5 miligram(s) vitamin E. Daily amount to be consumed to produce claimed effect: 1.5 miligram(s). Length of time after consumption for claimed effect to become apparent: regular consumption. - Must at least be a source of vitamin/s as per annex to Regulation 1924/2006. Applicable to both children and adults. Guidance level is 540mg/day or less from supplements (FSA). - 50 mg Tocotrienolgemisch - Claim to be only used for Foods for sport people under the Dir. 89/398/EEC. The DRA for vit E is 15 mg alpha-TE. CEDAP recommendations for sports people: vit E is 60 mg alpha-TE. 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. - Juices with vitamin E content of 2.5mg/100g, 5mg/serving. - Minimum 15% RDA (1,5 mg) dziennie. - Fruit juice with 2mg/100g, 5mg/serving and 10mg/daily serving. - Wheat germs with vitamin E content of 14mg/100g, 0.8mg/tbs (=6g). - 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. applicable to children and adults. - At least 15% RDA per 100 g or 100 ml or per portion as per 90/496/EEC. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
161	Vitamin E	Normal immune system function.	Vitamin E contributes to a normal immune system function; vitamin E helps to strenghten the body's defences; vitamin E helps to support cell-mediated immunity in older people.
	<p>Conditions of use:</p>		

	<ul style="list-style-type: none"> - 50 mg Tocotrienolgemisch - 100-200 IU pro Tag bzw. 70-135 mg - Must at least be a source of vitamin/s as per annex to Regulation 1924/2006 (amount to evaluate by EFSA). - Must at least be a source of vitamin/s as per annex to Regulation 1924/2006. 100-200 IU per day = approx 70-135 mg Guidance level is 540mg/day or less from supplements (FSA). 		
ID	Food or Food constituent	Health Relationship	Proposed wording
162	Vitamin E	Antioxidants and aging.	Antioxidant vitamins and minerals act against age-accelerating free radicals.
	Conditions of use <ul style="list-style-type: none"> - 20% of RDA, 90/496/EEC, per serving. - Tagesbedarf gemäß NwKVO 10 mg pro Tag - <200mg - 11-15 mg / d von Tocopherol-Äquivalenten—Erwachsene - 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. - A, C, E Tagesbedarf gemäß NwKVO—Selen –max. 100µg - D-Tocopherol –10 mg (Vitamin E 10 mg) 		
ID	Food or Food constituent	Health Relationship	Proposed wording
163	Vitamin E	The role of vitamins and minerals in immunity.	Vitamin C, E, A, D, B6, B12 folic acid, Selenium, Zinc, Copper and Iron are important for the immune system/natural defences.
	Conditions of use <ul style="list-style-type: none"> - 100% of RDA. - 100-200 IU per day = approx 70-135mg. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
164	Vitamin E	Bone/teeth/hair/skin and nail health.	Necessary for healthy teeth, bones, hair, skin and nails.
	Conditions of use <ul style="list-style-type: none"> - 50 mg Tocotrienolgemisch - 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
166	Vitamin E	Heart health.	Can neutralise free radicals and help maintain a healthy heart.
	Conditions of use		

	<ul style="list-style-type: none"> - 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. - Food supplement with 400mg of alpha-TE vitamin E in the daily dose. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
167	Vitamin E	Eye health; vitamin E, C are found in the lens of the eye; acts jointly with vitamin C.	Protects the lens.
	Conditions of use <ul style="list-style-type: none"> - 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. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
182	Vitamin E	Antioxidant activity and cognitive function.	Due to Vitamin E favourable effects on free radicals it could support reducing the age related cognitive decline.
	Conditions of use <ul style="list-style-type: none"> - See above <u>Clarification provided</u> <ul style="list-style-type: none"> - Significant quantity (15% RDA) according to dir. 9/496/EEC or significant quantity (RDA 15%) in the daily does of food supplements. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
183	Vitamin E	Mental state and performance.	Helps memory and perception retention, especially in the elderly.
	Conditions of use <ul style="list-style-type: none"> - Food supplement with 400mg of alpha-TE alpha-tocopherol in the daily dose. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
203	Vitamin E	Regeneration of vitamin C, vitamin C and vitamin E have synergistic effects. <u>Clarification provided</u> Vitamin E is necessary for the regeneration of the antioxidant form of vitamin C	Regeneration of vitamin C
	Conditions of use <ul style="list-style-type: none"> - 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. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
216	Vitamin E	Gefäße / Durchblutung.	[In German] Wichtig für

		<u>Clarification provided</u> Blood circulation.	Blutfließeigenschaften. <u>Clarification provided</u> Important for blood flow parameters.
Conditions of use - No conditions of use provided			
ID	Food or Food constituent	Health Relationship	Proposed wording
1947	Tocophérols	Antioxydant.	L'association des formes naturelles alfa et gamma améliore la neutralisation de certains radicaux libres très agressifs.
Conditions of use - 30mg/j			
No clarification provided by Member States			
ID	Food or Food constituent	Health Relationship	Proposed wording
2873	Vitamin E acetate (D,L-alpha tocopherol acetate)	Health of the scalp.	Support the microcirculation and the oxygenation of the scalp.
Conditions of use - 10 mg of vitamin E acetate per day.			

GLOSSARY AND ABBREVIATIONS

α -TTP	α -tocopherol transfer protein
ATBC	Alpha-Tocopherol Beta-Carotene Cancer Prevention
CHAOS	Cambridge Heart Antioxidant Study
DNA	Deoxyribonucleic acid
GISSI	Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto Miocardico
HOPE	Heart Outcomes Prevention Evaluation
IU	International unit
LDL	Low-density lipoprotein
ROS	Reactive oxygen species
UL	Tolerable upper intake levels