

## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to vitamin C and protection of DNA, proteins and lipids from oxidative damage (ID 129, 138, 143, 148), antioxidant function of lutein (ID 146), maintenance of vision (ID 141, 142), collagen formation (ID 130, 131, 136, 137, 149), function of the nervous system (ID 133), function of the immune system (ID 134), function of the immune system during and after extreme physical exercise (ID 144), non-haem iron absorption (ID 132, 147), energy-yielding metabolism (ID 135), and relief in case of irritation in the upper respiratory tract (ID 1714, 1715) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>**

#### **EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2</sup>**

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 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to vitamin C and the following claimed effects: protection of DNA, proteins and lipids from oxidative damage, antioxidant function of lutein, maintenance of vision, collagen formation, function of the nervous system, function of the immune system, function of the immune system during and after extreme physical exercise, non-haem iron absorption, energy-yielding metabolism, and relief in case

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-916, EFSA-Q-2008-917, EFSA-Q-2008-918, EFSA-Q-2008-919, EFSA-Q-2008-920, EFSA-Q-2008-921, EFSA-Q-2008-922, EFSA-Q-2008-923, EFSA-Q-2008-924, EFSA-Q-2008-925, EFSA-Q-2008-928, EFSA-Q-2008-929, EFSA-Q-2008-930, EFSA-Q-2008-931, EFSA-Q-2008-933, EFSA-Q-2008-934, EFSA-Q-2008-935, EFSA-Q-2008-936, EFSA-Q-2008-2450, EFSA-Q-2008-2451 adopted on 02 July 2009.

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<sup>3</sup> After publication of this opinion, the following changes have been made in the conclusion section of the opinion on page 11: "Protection of biologically relevant molecules such as DNA, proteins and lipids from oxidative damage (ID 129, 138, 143, 144, 148)" has been replaced with "Protection of DNA, proteins and lipids from oxidative damage (ID 129, 138, 143, 148)" in order to reflect the conclusions of the NDA Panel as outlined in the main text of the opinion.

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of irritation in the upper respiratory tract pursuant to Article 13(1) of Regulation (EC) No 1924/2006. 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 C, which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that vitamin C is sufficiently characterised.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C and the protection of DNA, proteins and lipids from oxidative damage, normal collagen formation, normal function of the nervous system, normal function of the immune system, maintenance of normal function of the immune system during and after extreme physical exercise, non-haem iron absorption and normal energy-yielding metabolism.

The Panel considers that, in order to bear a claim, a food should be at least a source of vitamin C as per Annex to Regulation 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

The Panel considers that, in order to bear the claim related to the maintenance of normal function of the immune system during and after intense physical exercise, a food should contain at least 200 mg vitamin C to be consumed daily in addition to the usual diet. Such amounts can be easily consumed as part of a balanced diet. The target population is subjects performing intense physical exercise.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin C and the promotion of the antioxidant function of lutein, and the relief in case of irritation in the upper respiratory tract.

The evidence provided is insufficient to establish a cause and effect relationship between the dietary intake of vitamin C intake and the maintenance of normal vision.

#### **KEY WORDS**

Vitamin C, collagen formation, immune function, oxidative damage, energy metabolism, non-haem iron absorption, physical exercise, health claims.

## TABLE OF CONTENTS

Summary .....	1
Table of contents .....	3
Background as provided by the European Commission.....	4
Terms of reference as provided by the European Commission.....	4
EFSA Disclaimer.....	4
Acknowledgements .....	4
Information as provided in the consolidated list .....	5
Assessment .....	5
1. Characterisation of the food/constituent.....	5
2. Relevance of the claimed effect to human health .....	5
2.1. Protection of DNA, proteins and lipids from oxidative damage (ID 129, 138, 143, 148) .....	5
2.2. Antioxidant function of lutein (ID 146).....	5
2.3. Maintenance of vision (ID 141, 142) .....	6
2.4. Collagen formation (ID 130, 131, 136, 137, 149).....	6
2.5. Function of the nervous system (ID 133).....	6
2.6. Function of the immune system (ID 134) .....	6
2.7. Function of the immune system during and after extreme physical exercise (ID 144) .....	6
2.8. Non-haem iron absorption (ID 132, 147).....	6
2.9. Energy-yielding metabolism (ID 135) .....	7
2.10. Relief in case of irritation in the upper respiratory tract (ID 1714, 1715) .....	7
3. Scientific substantiation of the claimed effect.....	7
3.1. Protection of DNA, proteins and lipids from oxidative damage (ID 129, 138, 143, 148) .....	7
3.2. Antioxidant function of lutein (ID 146).....	8
3.3. Maintenance of vision (ID 141, 142) .....	8
3.4. Collagen formation (ID 130, 131, 136, 137, 149).....	8
3.5. Function of the nervous system (ID 133).....	9
3.6. Function of the immune system (ID 134) .....	9
3.7. Function of the immune system during and after extreme physical exercise (ID 144) .....	9
3.8. Non-haem iron absorption (ID 132, 147).....	9
3.9. Energy-yielding metabolism (ID 135) .....	10
3.10. Relief in case of irritation in the upper respiratory tract (ID 1714, 1715) .....	10
4. Panel's comments on the proposed wording .....	10
4.1. Protection of DNA, proteins and lipids from oxidative damage (ID 129, 138, 143, 148) ....	10
4.2. Collagen formation (ID 130, 131, 136, 137, 149).....	10
4.3. Function of the nervous system (ID 133).....	10
4.4. Non-haem iron absorption (ID 132, 147).....	10
4.5. Function of the immune system (ID 134) .....	10
4.6. Function of the immune system during and after extreme physical exercise (ID 144) .....	11
4.7. Energy-yielding metabolism (ID 135) .....	11
5. Conditions and restrictions of use.....	11
5.1. Protection of DNA, proteins and lipids from oxidative damage (ID 129, 138, 143, 148), collagen formation (ID 130, 131, 136, 137, 149), function of the nervous system (ID 133), non-haem iron absorption (ID 132), function of the immune system (ID 134), and energy-yielding metabolism (ID 135).....	11
5.2. Function of the immune system during and after extreme physical exercise (ID 144) .....	11
Conclusions .....	11
Documentation provided to EFSA .....	13
References .....	14
Appendices .....	16

**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

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The members of the Claims Sub-Working Group on Cardiovascular Health/Oxidative Stress: Antti Aro, Marianne Geleijnse, Marina Heinonen, Ambroise Martin, Wilhelm Stahl and Henk van den Berg.

## INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006<sup>4</sup> submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims. The information provided in the consolidated list for the health claims subject to this opinion is tabulated in Appendix C.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is vitamin C (L-ascorbic acid, ascorbate), which is a well recognised nutrient and it is measurable in foods by established methods.

Vitamin C occurs naturally in foods. Ascorbic acid and its salts (ascorbates) are the forms authorised for addition to foods and for use in food supplements (Annex II of the Regulation (EC) No 1925/2006<sup>5</sup> and Annex II of Directive 2002/46/EC<sup>6</sup>). 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 claim, is sufficiently characterised.

### 2. Relevance of the claimed effect to human health

#### 2.1. Protection of DNA, proteins and lipids from oxidative damage (ID 129, 138, 143, 148)

The claimed effects are “protection of body cells from oxidative damage”, “antioxidant activity/antioxidant”, “antioxidants and aging”, “cell protection from free radical damage” and “antioxidant properties”. The Panel assumes that the target population is the general population.

No definition has been provided of what constitutes “aging”, and therefore the Panel cannot evaluate the “anti-aging effects” implied in claim ID 138. Also, it should be noted the 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.

In the context of the proposed wordings, the Panel notes that the claimed effects relate to the protection of body cells from oxidative damage caused by free radicals.

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 damage biologically relevant molecules such as DNA, proteins and lipids if they are not intercepted by the antioxidant network which includes free radical scavengers like antioxidant nutrients.

The Panel considers that protection of DNA, proteins and lipids from oxidative damage is beneficial to human health.

#### 2.2. Antioxidant function of lutein (ID 146)

The claimed effect is “promotes the antioxidant function of lutein”. The Panel assumes that the target population is the general population.

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57.

The Panel notes that no evidence is provided to establish that having antioxidant activity per se is beneficial to human health.

The Panel considers that the benefit to human health of the promotion of the antioxidant function of lutein is unknown.

### **2.3. Maintenance of vision (ID 141, 142)**

The claimed effects are “eye health, free-radical scavenger” and “eye health”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that the claimed effects relates to the maintenance of normal vision.

The Panel considers that maintenance of normal vision is beneficial to human health.

### **2.4. Collagen formation (ID 130, 131, 136, 137, 149)**

The claimed effects are “structure and function of blood vessels”, “healthy gums”, “healthy skin” and “cofactor for several enzymes involved in the biosynthesis of collagen”.

Collagen is a structural component of several tissues in the body including bones, cartilage, gums, skin, tendons and blood vessels.

The Panel considers that normal collagen formation is beneficial to human health.

### **2.5. Function of the nervous system (ID 133)**

The claimed effect is “neurological system function”. The Panel assumes that the target population is the general population.

The Panel considers that normal function of the nervous system is beneficial to human health.

### **2.6. Function of the immune system (ID 134)**

The claimed effect is “immune system function”. The Panel assumes that the target population is the general population.

The Panel considers that a normal function of the immune system is beneficial to human health.

### **2.7. Function of the immune system during and after extreme physical exercise (ID 144)**

The claimed effect is “oxidative stress, acts as antioxidant and helps protect the body tissues against potentially damaging effects of free radicals”. The protection of DNA, proteins and lipids from oxidative damage is considered in sections 2.1. and 2.3. of this opinion.

In the context of the proposed wording, the Panel notes that the claimed effect relates to the maintenance of the normal function of the immune system which may be depressed during and after extreme exercise. The Panel assumes that the target population is subjects performing physical exercise.

The Panel considers that the maintenance of a normal function of the immune system during and after extreme physical exercise is beneficial to human health.

### **2.8. Non-haem iron absorption (ID 132, 147)**

The claimed effect is “iron absorption”. The Panel assumes that the target population is the general population.

The Panel considers that improving non-haem iron absorption may be beneficial to human health.

## **2.9. Energy-yielding metabolism (ID 135)**

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

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

## **2.10. Relief in case of irritation in the upper respiratory tract (ID 1714, 1715)**

The claimed health relationship is “respiratory health” and “soothing/relief in case of tickle” in the upper respiratory tract. The Panel assumes that the target population is the general population.

Respiratory health is too broad for a scientific evaluation. However, “relief in case of tickle” in the throat could be assessed if adequate validated tests were available.

The Panel considers that relief in case of irritation in the upper respiratory tract might be beneficial to health.

## **3. Scientific substantiation of the claimed effect**

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus on the role of vitamin C in the body (Bender, 2003; Garrow et al., 2000; IoM, 2000; NNR, 2004; Sadler et al., 1999; Shils et al., 2006; EVM, 2002). Vitamin C is an electron donor, or reducing agent, and its functions are attributable to this action (Shils et al., 2006). On the one hand, vitamin C acts as a major 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 them are required in the biosynthesis of carnitine, one in tyrosine metabolism and two in the biosynthesis of the catecholamines adrenaline and noradrenaline (which act as neurotransmitters) and in the amidation of peptide hormones.

### **3.1. Protection of DNA, proteins and lipids from oxidative damage (ID 129, 138, 143, 148)**

One human intervention study (Engelhart et al., 2002) and one narrative review (Grundman and Delaney, 2002) on the relationship between dietary intake of antioxidants and risk of Alzheimer disease and one cross-sectional study (Ortega et al., 1997) on the association between nutrient intake and cognitive function in the elderly were also presented to support this claim. The Panel considers that these publications are not pertinent to evaluate the claimed effect.

Evidence for in vivo antioxidant functions of ascorbate include the scavenging of reactive oxidants in activated leukocytes, lung and gastric mucosa, and diminished lipid peroxidation as measured by urinary isoprostane excretion (IoM, 2000). According to a recent systematic Cochrane review, the current evidence does not support the use of antioxidant supplements in the general population or in patients with certain diseases (Bjelakovic et al., 2008).

Vitamin C functions physiologically as a water-soluble antioxidant and plays a major role as a free radical scavenger (Sadler et al., 1999; IoM, 2000). Vitamin C is part of the antioxidant defence system, which is a complex network including endogenous antioxidants 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 C and the protection of DNA, proteins and lipids from oxidative damage.

### **3.2. Antioxidant function of lutein (ID 146)**

One reference was cited to substantiate the claimed effect which is a human intervention study investigating the effects of vitamin C co-supplementation on crystalline lutein supplement absorption (Tanumihardjo et al., 2005).

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin C and the promotion of the antioxidant function of lutein.

### **3.3. Maintenance of vision (ID 141, 142)**

The references cited in relation to vitamin C and eye health in humans consist of observational studies (either cross-sectional or prospective cohort studies) reporting associations between vitamin C intake, plasma concentrations of vitamin C or use of vitamin C supplements and lower risk of age-related lens opacities (either nuclear or cortical cataract). Animal, ex vivo and in vitro studies reporting vitamin C concentrations in tears, lens damage in vitamin C deficiency or after UV radiation exposure, and one narrative review on the role of antioxidant compounds in general in cataract prevention were also provided.

All the human studies presented to support this claim have been subject to extensive reviews (Chiu and Taylor, 2007; Meyer and Sekundo, 2005). Eight out of 15 studies found that increased vitamin C intake, supplement use, or blood concentrations were related to diminished risk for nuclear cataract. Long-term duration of supplementation (>10 years) was most frequently associated with the reduction of risk, and the presence of diabetes mellitus could affect this association. Only three out of ten studies found that increased vitamin C intake, supplement use, or blood concentrations were related to diminished risk for cortical cataract. One study found that increased vitamin C supplement use was related to increased risk for cortical cataract in non-diabetic subjects and decreased the risk for cortical cataract in diabetics. The remaining six studies showed no effect, including the AREDS intervention. Only three out of eight studies found that increased vitamin C intake or elevated blood concentrations were related to diminished risk for posterior subcapsular cataract (PSC). The remaining five studies showed no effect, including the AREDS intervention. Two out of four studies found that increased vitamin C supplement use or blood concentrations were related to diminished risk for mixed cataract, including the REACT intervention. Finally, only two out of six studies found that vitamin C supplement use is related to diminished risk for cataract extraction. The four remaining studies showed no effect, including the AREDS intervention (Chiu and Taylor, 2007; Meyer and Sekundo, 2005).

The Panel notes that, despite the fact that vitamin C supplement use and elevated blood concentrations of vitamin C have been inversely associated with at least one type of cataract in many (but not all) epidemiological studies, four out of the seven randomized, double-blinded, placebo-controlled intervention trials investigating the effects of antioxidant vitamin supplements on cataract risk have found no effect of supplementation, and that no large-scale intervention trial on cataract prevention has been reported on which vitamin C has been administered as the sole supplement (Chiu and Taylor, 2007; Levin et al., 2006).

The Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the dietary intake of vitamin C and the maintenance of normal vision.

### **3.4. Collagen formation (ID 130, 131, 136, 137, 149)**

Vitamin C is a coenzyme for three different dioxygenase enzymes that catalyse the addition of hydroxyl groups to the amino acids proline and lysine of the collagen molecule to stabilize the triple helix structure. Normal collagen formation is required for the normal structure of many tissues in the body, including bones, cartilage, gums, skin, tendons and blood vessels. Vitamin C deficiency (scurvy) is dominated by clinical signs attributable to impaired collagen synthesis, including bone damage, arthralgia and joint effusions, swollen and friable gums, loss of teeth, perifollicular hyperkeratosis, petechial haemorrhage, erythema and purpura, subcutaneous bleeding, and internal haemorrhage in severe cases of scurvy (Sadler et al., 1999; Shils et al., 2006; IoM, 2000).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C and normal collagen formation.

### **3.5. Function of the nervous system (ID 133)**

Vitamin C is needed as a cofactor of dopamine  $\beta$ -monoxygenase for the biosynthesis of noradrenaline (and adrenaline). Both catecholamines act as neurotransmitters. Manifestations of infantile scurvy include irritability, whereas hypochondriasis, depression and confusion have been described in adults with scurvy. These symptoms have been attributed to an impaired function of dopamine  $\beta$ -monoxygenase (Sadler et al., 1999; Shils et al., 2006; IoM, 2000).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C and normal function of the nervous system.

### **3.6. Function of the immune system (ID 134)**

Evidence of effects of vitamin C on both innate and adaptive immune responses is present in the literature provided. Whereas as such the relation of these effects of vitamin C with clinical outcomes is unclear, studies have also shown that altered values of immune parameters, as seen for instance in the individuals with a low vitamin C status, older people, patients exposed to toxic chemicals, or individuals exposed to severe physical exercise can be restored by vitamin C intake (Delafuente et al., 1986; Heuser et al., 1997; Jacob et al., 1991; Kennes et al., 1983; Nieman et al., 2000; Tauler et al., 2003; Buzina-Suboticaneć et al., 1998; Chavance et al., 1989).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C and the normal function of the immune system.

### **3.7. Function of the immune system during and after extreme physical exercise (ID 144)**

Studies on vitamin C supplementation or status on clinical outcomes unrelated to the claimed effect (e.g., macular degeneration, bronchial responsiveness in asthma or antioxidant status) were not considered as pertinent to support the claimed effect.

It is known that under conditions of immune depression, resistance to infections may be reduced, and certain diseases such as common cold may occur more frequently. Most of the human studies presented have investigated the relationship between vitamin C supplementation and the prevention of common cold. Three systematic Cochrane reviews (with meta-analyses) investigating the role of vitamin C supplementation in the prevention, severity of symptoms and treatment of common cold include the vast majority of the single studies provided for this outcome (Douglas et al., 2000 and 2004; Hemila et al., 2007). Most studies indicate that vitamin C supplementation with doses above the dietary reference values fail to reduce the incidence of colds in the normal population. However, evidence shows that persons exposed to brief periods of severe physical exercise and/or cold environments benefit in terms of duration and severity of the common cold from regular vitamin C intake above 200mg/d.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C and the maintenance of the normal function of the immune system during and after extreme physical exercise.

### **3.8. Non-haem iron absorption (ID 132, 147)**

Iron deficiency is one of the most common micronutrient deficiencies with about 30% of world population being anaemic (Ramakrishnan, 2002; WHO, 2008). There is still a significant prevalence of iron deficiency in Europe especially among pregnant women, children and women in reproductive age (WHO, 1992; Badham et al., 2007). The most common consequence of iron deficiency is microcytic anaemia.

Dietary iron is absorbed as Fe<sup>2+</sup> and not as Fe<sup>3+</sup>. Reducing agents, including vitamin C, promote non-haem iron absorption by keeping it reduced (Fe<sup>2+</sup>). Although the clinical effects of vitamin C intake in raising haemoglobin concentrations when administered with iron are modest, inorganic (non-haem) iron absorption is increased by 1.5 to 10 fold depending on iron status, the dose of vitamin C and the test meal. Vitamin C is administered with iron in clinical practice to increase the absorption of the latter (IoM, 2000, EVM, 2002, Levin et al., 2006).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C and the increase of non-haem iron absorption.

### **3.9. Energy-yielding metabolism (ID 135)**

Carnitine is an essential cofactor in the transport of long-chain fatty acids into the mitochondrial matrix and plays an important role in energy production via beta-oxidation. Vitamin C has been considered an absolute requirement for two dioxygenase enzymes involved in the biosynthesis of carnitine (IoM, 2000; EVM, 2002; Levin et al., 2006).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin C and normal energy-yielding metabolism.

### **3.10. Relief in case of irritation in the upper respiratory tract (ID 1714, 1715)**

One reference was cited to substantiate the health claim which is the administrative guidance to present applications for the registration of cough drops in Switzerland.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of vitamin C and relief in case of irritation in the upper respiratory tract.

## **4. Panel's comments on the proposed wording**

### **4.1. Protection of DNA, proteins and lipids from oxidative damage (ID 129, 138, 143, 148)**

The Panel considers that the following wordings reflect the scientific evidence: "Vitamin C contributes to the protection of cell constituents from oxidative damage."

### **4.2. Collagen formation (ID 130, 131, 136, 137, 149)**

The Panel considers that the following wordings reflect the scientific evidence: "Vitamin C contributes to normal collagen formation and the normal function of bones, teeth, cartilage, gums, skin and blood vessels."

### **4.3. Function of the nervous system (ID 133)**

The Panel considers that the following wordings reflect the scientific evidence: "Vitamin C contributes to the normal function of the nervous system."

### **4.4. Non-haem iron absorption (ID 132, 147)**

The Panel considers that the following wordings reflect the scientific evidence: "Vitamin C increases non-haem iron absorption."

### **4.5. Function of the immune system (ID 134)**

The Panel considers that the following wordings reflect the scientific evidence: "Vitamin C contributes to a normal function of the immune system."

#### **4.6. Function of the immune system during and after extreme physical exercise (ID 144)**

The Panel considers that the following wordings reflect the scientific evidence: “Vitamin C contributes to maintain the normal function of the immune system during and after intense physical exercise.”

#### **4.7. Energy-yielding metabolism (ID 135)**

The Panel considers that the following wordings reflect the scientific evidence: “Vitamin C contributes to normal energy-yielding metabolism.”

### **5. Conditions and restrictions of use**

#### **5.1. Protection of DNA, proteins and lipids from oxidative damage (ID 129, 138, 143, 148), collagen formation (ID 130, 131, 136, 137, 149), function of the nervous system (ID 133), non-haem iron absorption (ID 132), function of the immune system (ID 134), and energy-yielding metabolism (ID 135)**

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 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

#### **5.2. Function of the immune system during and after extreme physical exercise (ID 144)**

The Panel considers that in order to bear the claim a food should contain at least 200 mg vitamin C to be consumed daily in addition to the usual diet. Such amounts can be easily consumed as part of a balanced diet. The target population is subjects performing intense physical exercise.

### **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.

#### **Protection of DNA, proteins and lipids from oxidative damage (ID 129, 138, 143, 148)**

- The claimed effects are “protection of body cells from oxidative damage”, “antioxidant activity/antioxidant”, “antioxidants and aging”, “cell protection from free radical damage” and “antioxidant properties”. The target population is assumed to be the general population. Protection of DNA, proteins and lipids from oxidative damage is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin C and the protection of DNA, proteins and lipids from oxidative damage.
- The following wording reflects the scientific evidence: “Vitamin C contributes to the protection of cell constituents from oxidative damage.”

#### **Antioxidant function of lutein (ID 146)**

- The claimed effects are “promotes the antioxidant function of lutein” The target population is assumed to be the general population. The benefit to human health of the promotion of the antioxidant function of lutein is unknown.
- A cause and effect relationship has not been established between the dietary intake of vitamin C and the promotion of the antioxidant function of lutein.

#### **Maintenance of vision (ID 141, 142)**

- The claimed effects are “eye health, free-radical scavenger” and “eye health”. The target population is assumed to be the general population. Maintenance of normal vision is beneficial to human health.
- The evidence provided is insufficient to establish a cause and effect relationship between the dietary intake of vitamin C and the maintenance of normal vision.

#### **Collagen formation (ID 130, 131, 136, 137, 149)**

- The claimed effects are “structure and function of blood vessels”, “structure and function of blood vessels”, “healthy gums”, “healthy skin” and “cofactor for several enzymes involved in the biosynthesis of collagen”. The target population is assumed to be the general population. Normal collagen formation is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin C and normal collagen formation.
- The following wording reflects the scientific evidence “Vitamin C contributes to normal collagen formation and the normal function of bones, teeth, cartilage, gums, skin and blood vessels.”

#### **Function of the nervous system (ID 133)**

- The claimed effects are “contributes to neurological function” and “needed for normal mental function”. The target population is assumed to be the general population. Normal function of the nervous system is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin C and normal function of the nervous system.
- The following wording reflects the scientific evidence: “Vitamin C contributes to the normal function of the nervous system”.

#### **Immune function (ID 134)**

- The claimed effect is “needed for the normal function of the immune system”. The target population is assumed to be the general population. A normal function of the immune system is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin C and a normal function of the immune system
- The following wording reflects the scientific evidence: “Vitamin C contributes to a normal function of the immune system.”

#### **Function of the immune system during and after extreme physical exercise (ID 144)**

- The claimed effect is “oxidative stress, acts as antioxidant and helps protect the body tissues against potentially damaging effects of free radicals”. In the context of the proposed wording it is assumed that the claim relates to the maintenance of the normal function of the immune system which may be depressed during and after extreme exercise. The target population is subjects performing physical exercise. Maintaining the normal function of the immune system during and after extreme physical exercise is beneficial to human health.

- A cause and effect relationship has been established between the dietary intake of vitamin C and the maintenance of the normal function of the immune system during and after extreme physical exercise.
- The following wording reflects the scientific evidence: “Vitamin C contributes to maintain the normal function of the immune system during and after intense physical exercise.”

#### **Non-haem iron absorption (ID 132, 147)**

- The claimed effect is “improves non-haem iron absorption”. The target population is the general population. Improving non-haem iron absorption may be beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin C and the increase of non-haem iron absorption.
- The following wordings reflect the scientific evidence: “Vitamin C increases non-haem iron absorption.”

#### **Energy-yielding metabolism (ID 135)**

- The claimed effect is “energy metabolism”. The target population is the general population. Normal energy-yielding metabolism is beneficial to health.
- A cause and effect relationship has been established between the dietary intake of vitamin C and normal energy-yielding metabolism.
- The following wordings reflect the scientific evidence: “Vitamin C contributes to normal energy-yielding metabolism.”

#### **Relief in case of irritation in the upper respiratory tract (ID 1714, 1715)**

- The claimed effect is “respiratory health” and “soothing/relief in case of tickle” in the upper respiratory tract. The target population is the general population. Relief in case of irritation in the upper respiratory tract might be beneficial to health.
- A cause and effect relationship has not been established between the dietary intake of vitamin C and relief in case of irritation in the upper respiratory tract.

#### **Conditions/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 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population (ID 129, 143, 148, 130, 131, 136, 137, 149, 133, 132, 134).
- contain at least 200 mg vitamin C to be consumed daily in addition to the usual diet. Such amounts can be easily consumed as part of a balanced diet. The target population is subjects performing intense physical exercise (ID 144).

#### **DOCUMENTATION PROVIDED TO EFSA**

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-916, EFSA-Q-2008-917, EFSA-Q-2008-918, EFSA-Q-2008-919, EFSA-Q-2008-920, EFSA-Q-2008-921, EFSA-Q-2008-922, EFSA-Q-2008-923, EFSA-Q-2008-924, EFSA-Q-2008-925, EFSA-Q-2008-928, EFSA-Q-2008-929, EFSA-Q-2008-930, EFSA-Q-2008-931, EFSA-Q-2008-933, EFSA-Q-2008-934,

EFSA-Q-2008-935, EFSA-Q-2008-936, EFSA-Q-2008-2450, EFSA-Q-2008-2451). 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/EFSA/efsa\\_locale-1178620753812\\_article13.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_article13.htm).

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## APPENDICES

### APPENDIX A

#### BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods<sup>7</sup> (hereinafter "the Regulation") entered into force on 19<sup>th</sup> 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<sup>8</sup>

Foods are commonly involved in many different functions<sup>9</sup> 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.

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

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<sup>7</sup> OJ L12, 18/01/2007

<sup>8</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>9</sup> The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

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 population 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 component	Health Relationship	Proposed wording
129	Vitamin C	Protection of body tissues and cells from oxidative damage. Antioxidant activity/Antioxidant	Vitamin C is an antioxidant that protects the body's cells.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Juices and beverages with vitamin C content of 20-36mg/100g, 60mg/serving</li> <li>- 60 mg per day</li> <li>- Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance Number of nutrients/other substances that are essential to claimed effect: Vitamin C Names of nutrient/other substances and Quantity in Average daily serving: 9 milligrams Vitamin C Daily amount to be consumed to produce claimed effect: 9 miligram(s) Are there factors that could interfere with bioavailability: Don't Know Length of time after consumption for claimed effect to become apparent: Regular consumption Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Don't Know</li> <li>- Agency guidance for supplements is that products containing &gt;1000 mg of Vitamin C should carry the label advisory statement "[This amount of Vitamin C]* may cause mild stomach upset in sensitive individuals.." MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults 30 mg /day equal to 50% of ADI (Acceptable Daily Intake)</li> <li>- Minimum 15% RDA per daily dosage as per 90/496/EC Agency guidance for supplements is that products containing &gt;1000 mg of Vitamin C should carry the label advisory statement "[This amount of Vitamin C]* may cause mild stomach upset in sensitive individuals."</li> <li>- 125-500mgVitamin C =625-2500 mg Camu-Camu</li> </ul>		
130	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Structure and function of blood vessels	'vitamin C is necessary for keeping blood vessels healthy.
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Food supplement with 500-1000mg of vitamin C in the daily dose</li> <li>- Must meet minimum requirements for use of the claim "Vitamin C" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing &gt; 1000 mg mg of Vitamin C should carry the label advisory statement "may cause mild stomach upset in sensitive individuals" Applicable to both children and adults</li> <li>- Mangel an frischem Gemüse und Früchten</li> <li>- Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 9 miligram(s) Vitamin C Daily amount to be consumed to produce claimed effect: 9 miligram(s)</li> <li>- Guidance level is 1000mg/day or less. Agency guidance for supplements is that products containing &gt;1000mg of clacium should carry the label advisory statement "may cause mild stomach upset in sensitive individuals." 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</li> </ul>			

	1924/2006. - 125-500mgVitamin C =625-2500 mg Camu-Camu		
131	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Connective tissue - structure and function: bones, teeth, gums, skin, healing processes. Normal collagen formation	vitamin C is necessary to maintain healthy bone, teeth, cartilage, gums and skin;
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing &gt; 1000 mg mg of Vitamin C should carry the label advisory statement "may cause mild stomach upset in sensitive individuals" Applicable to both children and adults 30 mg /day equal to 50% of ADI (Acceptable Daily Intake)</li> <li>- Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 9 miligram(s) Vitamin C Daily amount to be consumed to produce claimed effect: 9 miligram(s) Are there factors that could interfere with bioavailability: Don't Know Length of time after consumption for claimed effect to become apparent: Regular consumption Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Don't Know</li> <li>- 60 mg per day</li> <li>- 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.</li> <li>- 125-500mgVitamin C =625-2500 mg Camu-Camu</li> <li>- Minimum 15% RDA</li> <li>- 15 % RDA of vitamin C, 90/496/EEC</li> <li>- DLC = 5 à 10 jours. Adultes &amp; enfants.</li> </ul>		
132	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Iron absorption	vitamin C contributes to iron absorption from food.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 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.</li> <li>- MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG</li> <li>- x 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. Agency guidance for supplements is that products containing &gt; 1000 mg mg of Vitamin C should carry the label advisory statement may cause mild upset in sensitive individuals" when consumed with iron-containing foods Applicable to both children and adults 30mg /day equal to 50% of ADI (Acceptable Daily Intake)</li> <li>- Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 12 miligrams vitamin c</li> </ul>		

	<p>Weight of average daily food serving: 100 gram(s) Daily amount to be consumed to produce claimed effect: 100 gram(s) Number of food portions this equates to in everyday food portions: 1 Length of time after consumption for claimed effect to become apparent: depends on the individual's nutritional status Other conditions for use: Product should be consumed in the context of a healthy diet</p> <ul style="list-style-type: none"> <li>- Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 70 milligrams Vitamin C Weight of average daily food serving: 200 millilitre(s) Daily amount to be consumed to produce claimed effect: 200 millilitre(s) Number of food portions this equates to in everyday food portions: 1 Length of time after consumption for claimed effect to become apparent: dependent on the individuals' nutritional status Other conditions for use: Product should be consumed in the context of a healthy diet and lifestyle</li> <li>- 15% RDA per 100 g</li> <li>- DLC = 5 à 10 jours. Adultes &amp; enfants.</li> <li>- Juice with 30mg/100g, 60mg/serving of vitamin C and 2.8mg/100g, 5.6mg/serving of iron</li> <li>- Mangel an frischem Gemüse und Früchten</li> <li>- when consumed with iron-containing foods</li> <li>- 125-500mgVitamin C =625-2500 mg Camu-Camu</li> <li>- Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 9 miligram(s) vitamin Daily amount to be consumed to produce claimed effect: 9 miligram(s) Length of time after consumption for claimed effect to become apparent: Regular consumption Other conditions for use: when consumed with iron containing foods</li> </ul>		
<b>133</b>	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Neurological system function	vitamin C helps the nervous system work; -vitamin C is needed for normal mental function.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 9 miligram(s) vitamin C Daily amount to be consumed to produce claimed effect: 9 miligram(s) Other conditions for use: when consumed with iron containing foods</li> <li>- Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 70 mg vitamin c Weight of average daily food serving: 200 millilitre(s) Daily amount to be consumed to produce claimed effect: 200 millilitre(s) Number of food portions this equates to in everyday food portions: 1 Length of time after consumption for claimed effect to become apparent: dependent on the individuals' nutritional status Other conditions for use: Product should be consumed in the context of a healthy diet and lifestyle</li> <li>- Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 9 milligrams vitamin c Daily amount to be consumed to produce claimed effect: 9 miligram(s) Length of time after consumption for claimed effect to become apparent: Regular consumption</li> <li>- MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing &gt; 1000 mg of Vitamin C should carry the label advisory statement "may cause mild stomach upset in sensitive individuals" Applicable to both children and adults The product must contain at least 15% of the RDA</li> <li>- 125-500mgVitamin C =625-2500 mg Camu-Camu</li> </ul>		

134	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Immune system function.	vitamin C is needed as part of the body's defences; -vitamin C helps support the body's immune system.
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Sports foods and food supplements containing vitamin C and targeted at sports people 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. Agency guidance for supplements is that products containing &gt;1000 mg of Vitamin C should carry the label advisory statement "This amount of Vitamin C may cause mild stomach upset in sensitive individuals"</li> <li>- 500 Milliliter (ml) / Tag über 14 Tage</li> <li>- Minimum 180 mg witaminy C, 10 mg cynku dziennie</li> <li>- 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</li> <li>- 15-50 % RDA</li> <li>- Mangel an frischem Gemüse und Früchten</li> <li>- 180 mg per day</li> <li>- MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing &gt;1000mg of Vitamin C should carry the label advisory statement may cause mild stomach upset in sensitive individuals Agency guidance for supplements is that products containing &gt;1000mg Vitamin C should carry the label statement '[This amount of Vitamin C] may cause mild stomach upset in sensitive individuals.' Only for at least 0.5 g vitamin C, 10 mg zinc</li> </ul>			
135	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Energy metabolism: carnitine biosynthesis	vitamin C is needed/important for the energy metabolism / the transformation of food into energy.
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 60 mg per day</li> <li>- MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing &gt; 1000 mg of Vitamin C should carry the label advisory statement "may cause mild stomach upset in sensitive individuals"</li> </ul>			
136	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Healthy gums	Vitamin C is required for healthy gums
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Number of nutrients/other substances that are essential to claimed effect: 5 Names of nutrient/other substances and Quantity in Average daily serving: 1.44 micrograms vitamin A, 10.8 miligrams vitamin C, 0.9 micrograms vitamin D, 144mg Calcium, 144mg Phosphorus Weight of average daily food serving: 90 gram(s) Daily amount to be consumed to produce claimed effect: 500 gram(s) Number of food portions this equates to in everyday food portions: 1 Length of time after consumption for claimed effect to become apparent: Dependent on the individual's nutritional status Other conditions for use: Product should be consumed in the context of a healthy diet and lifestyle</li> </ul>			

	<p>- Guidance level is 1000mg/day or less. Agency guidance for supplements is that products containing &gt;1000mg of calcium should carry the label advisory statement "may cause mild stomach upset in sensitive individuals." 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.</p>		
137	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Healthy skin	Vitamin C is required for healthy skin
<p><b>Conditions of use</b></p> <p>- Guidance level is 1000mg/day or less. Agency guidance for supplements is that products containing &gt;1000mg of calcium should carry the label advisory statement "may cause mild stomach upset in sensitive individuals." 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.</p>			
138	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Antioxidants and aging	Antioxidant vitamins and minerals act against age-accelerating free radicals
<p><b>Conditions of use</b></p> <p>- 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. Agency guidance for supplements is that products containing &gt;1000 mg of Vitamin C should carry the label advisory statement "[This amount of Vitamin C] may cause mild stomach upset in sensitive individuals"</p>			
141	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Eye health, free radical scavenger	Acts as free radical scavenger. Renders free radicals harmless
<p><b>Conditions of use</b></p> <p>- 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 &gt;1000mg vitamin C should carry the label advisory statement "this amount of vitamin C may cause mild stomach upset in sensitive individuals"</p>			
142	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Eye health	Protects the eye from oxidative and photo-oxidative stress Protects the eye Antioxidant vitamin C, is associated with the health of the retina and lens, which can be damaged over the years by free radical damage e.g. caused by sunlight, smoke & pollution
<p><b>Conditions of use</b></p> <p>- &gt; 135 mg/day</p> <p>- &gt; 135 mg/day ingestion of vitamin C is associated with reduced cataract risk 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. Agency guidance for supplements is that products containing &gt;1000mg vitamin C should carry the label advisory statement "this</p>			

amount of vitamin C may cause mild stomach upset in sensitive individuals"			
143	Food or Food component	Health Relationship	Proposed wording
	Vitamin C	Cell protection from free radical damage	Vitamin C contributes to cell protection from the damage caused by free radicals
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG</li> <li>- Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 12 Miligrams Vitamin C Weight of average daily food serving: 100 gram(s) Daily amount to be consumed to produce claimed effect: 100 gram(s) Number of food portions this equates to in everyday food portions: 1 Are there factors that could interfere with bioavailability: Don't Know Length of time after consumption for claimed effect to become apparent: dependent on the individuals' nutritional status Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Don't Know Other conditions for use: Product should be consumed in the context of a healthy diet and lifestyle</li> <li>- The product must contain at least 15% of the RDA Agency guidance for supplements is that products containing &gt; 1000 mg of Vitamin C should carry the label advisory statement "[This amount of Vitamin C]* may cause mild stomach upset in sensitive individuals. "</li> </ul>			
144	Food or Food component	Health Relationship	Proposed wording
	Vitamin C	OXIDATIVE STRESS. Acts as antioxidant and helps protect the body tissues against the potentially damaging effects of free radicals	Boosts the immune system which is depressed during exercise.
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Claim to be only used for Foods for sport people under the Dir. 89/398/EEC. The DRA for vit C is 90 mg (M) and 75 mg (F). CEDAP recommendations for sports people: vit C is 1000 mg. Agency guidance for supplements is that products containing &gt;1000 mg of Vitamin C should carry the label advisory statement "This amount of Vitamin C may cause mild stomach upset in sensitive individuals"</li> </ul>			
146	Food or Food component	Health Relationship	Proposed wording
	Vitamin C	Promotes the antioxidative function of lutein	Promotes lutein / zeaxanthin function
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 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. Agency guidance for supplements is that products containing &gt;1000mg vitamin C should carry the label advisory statement "this amount of vitamin C may cause mild stomach upset in sensitive individuals"</li> </ul>			

147	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Due to its reducing power vitamin C can, improve absorption of non-haem iron	Vitamin-C enhances absorption of Iron
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 30mg /day equal to 50% of ADI (Acceptable Daily Intake) 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 &gt;1000 mg of vitamin C should carry the label advisory statement "[This amount of vitamin c] may cause mild stomach upset in sensitive individuals"</li> </ul>			
148	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Antioxidant properties	Vitamin C serves as a protective antioxidant
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- bis 100 mg pro Tag</li> <li>- 500 mg Tagesdosis</li> <li>- Minimum 15% RDA (9 mg) dziennie.</li> <li>- 500 Milliliter (ml) /Tag über 14 Tage</li> <li>- 30 mg /day equal to 50% of ADI (Acceptable Daily Intake) 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 &gt;1000 mg of vitamin C should carry the label advisory statement "[This amount of vitamin c] may cause mild stomach upset in sensitive individuals"</li> </ul>			
149	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Vitamin C is a cofactor for several enzymes involved in the biosynthesis of collagen	C-vitamin contributes to generation of collagen - An insoluble protein fibre that is the primary constituent in connective tissue (skin and tendons) and bone.
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 30 mg /day equal to 50% of ADI (Acceptable Daily Intake) 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 &gt;1000 mg of vitamin C should carry the label advisory statement "[This amount of vitamin c] may cause mild stomach upset in sensitive individuals"</li> </ul>			

1714	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Respiratory health	Soothing for mouth and throat / Reliefs in case of tickle in the throat and pharynx / Soothing and pleasant effect on throat, pharynx and vocal cords
<b>Conditions of use</b> No conditions of use provided			
1715	<b>Food or Food component</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Vitamin C	Respiratory health	Soothing for mouth and throat / Reliefs in case of tickle in the throat and pharynx / Soothing and pleasant effect on throat, pharynx and vocal cords
<b>Conditions of use</b> No conditions of use provided			