SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to astaxanthin and maintenance of joints, tendons, and connective tissue (ID 1918, 1978, 3142), protection of DNA, proteins and lipids from oxidative damage (ID 1449, 3141), maintenance of visual acuity (ID 1448), maintenance of blood cholesterol concentrations and maintenance of low plasma concentrations of C-reactive protein (ID 1450) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

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

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to astaxanthin and the following claimed effects: maintenance of joints, tendons, and connective tissue, maintenance of visual acuity, protection of DNA, proteins and lipids from oxidative damage, maintenance of blood cholesterol concentrations and maintenance of low plasma concentrations of C-reactive protein (CRP). 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 astaxanthin, which is a red oxygenated carotenoid measurable in foods by established methods. The Panel considers that the food constituent, astaxanthin, that is the subject of the health claims, is sufficiently characterised.

The Panel concludes that the following claimed effects are beneficial to human health: maintenance of normal joints, tendons, and connective tissue, protection of DNA, proteins and lipids from oxidative damage, maintenance of normal visual acuity, and maintenance of normal blood cholesterol concentrations.

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1 On request from the European Commission, Question No EFSA-Q-2008-2185, EFSA-Q-2008-2186, EFSA-Q-2008-2187, EFSA-Q-2008-2651, EFSA-Q-2008-2711, EFSA-Q-2008-3873, EFSA-Q-2008-3874 adopted on 02 July 2009.

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The Panel concludes that the following claimed effect might be beneficial to human health: maintenance of low plasma concentrations of CRP.

On the basis of the data available, the Panel concludes that a cause and effect relationship has not been established between the consumption of astaxanthin and the maintenance of normal joints, tendons or connective tissue, protection of DNA, proteins or lipids from oxidative damage, maintenance of normal visual acuity, and maintenance of normal blood cholesterol concentrations or the maintenance of low plasma concentrations of CRP.

KEY WORDS

Astaxanthin, joints, tendons, connective tissue, oxidative damage, visual acuity, blood cholesterol, C-reactive protein, health claims.

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[3] submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims. The information provided in the consolidated list for the health claims subject to this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is astaxanthin, which is a red (non-provitamin A) oxygenated carotenoid found in phytoplankton and is responsible for the colour of certain fish (e.g. salmon) and shellfish (e.g. crab).

Astaxanthin is measurable in foods by established methods. Astaxanthin occurs naturally in foods and also in synthetic forms as free form or as esters. Astaxanthin is absorbed into the bloodstream as the free form and bioavailability can be enhanced in lipid matrices. This evaluation applies to astaxanthin naturally present in foods and to those forms authorised for addition to foods.

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

2. Relevance of the claimed effect to human health

2.1. Maintenance of joints, tendons, and connective tissue (ID 1918, 1978, 3142)

The claimed effects are "joint health" and "beneficial for connective tissue and joints". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects relate to the maintenance of normal joints, tendons, and connective tissue.

The Panel considers that maintenance of normal joints, tendons, and connective tissue is beneficial to human health.

2.2. Protection of DNA, proteins and lipids from oxidative damage (ID 1449, 3141)

The claimed effects are "high potent antioxidant" and "supports a healthy oxidative balance". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects relate to the protection of DNA, proteins and lipids 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

[3] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

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.

2.3. Maintenance of visual acuity (ID 1448)

The claimed effect is "beneficial for eye health". The Panel assumes that the target population is the general population.

In the context of the proposed wording, the Panel notes that the claimed effect relates to the maintenance of visual acuity.

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

2.4. Maintenance of blood cholesterol concentrations and maintenance of low plasma concentrations of C-reactive protein (ID 1450)

The claimed effect is "supports a healthy cardiovascular system". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect relates to the maintenance of normal blood cholesterol concentration and to the maintenance of low plasma concentrations of C-reactive protein (CRP).

Low-density lipoproteins (LDL) carry cholesterol from the liver to peripheral tissues, including the arteries. Elevated LDL-cholesterol, by convention >160mg/dL, may compromise the normal function of the arteries.

CRP is an acute-phase protein whose plasma concentrations increase in response to inflammation.

The Panel considers that the maintenance of normal blood cholesterol concentrations is beneficial to human health and that the maintenance of low plasma concentrations of C-reactive protein (CRP) might be beneficial to human health.

3. Scientific substantiation of the claimed effect

3.1. Maintenance of joints, tendons, and connective tissue (ID 1918, 1978, 3142)

Among the publications submitted to support these claims, one notification of placing on the market novel foods or novel food ingredients pursuant to Article 5 of Regulation (EC) No 258/97, one US patent describing the use of astaxanthin in the treatment of muscle diseases and disorders, one US patent describing a method for the prevention and treatment of the carpal tunnel syndrome, the pre-market notification form FDA on astaxanthin, a series of general reviews on the chemical properties and potential health effects of astaxanthin, one animal study and two human studies on the effects of astaxanthin on muscle damage/muscle endurance as a result of intense physical exercise are not considered directly pertinent for the substantiation of the claimed effect.

In addition, two unpublished reports on the effects of astaxanthin in the relief of pain and the improvement of performance in patients with carpal tunnel syndrome (Nir and Spiller, 2002a) and with tennis elbow (Spiller et al., 2006), and one intervention in patients with rheumatoid arthritis were presented to support the claimed effect (Nir and Spiller, 2002b). The Panel notes that the three studies

above are pilot single-centre, double-blind placebo-controlled parallel studies conducted with a product containing high oleic safflower oil, Haematococcus extract, lutein, vitamin A, vitamin E, gelatine and rosemary oil in addition to astaxanthin, and therefore no conclusions can be drawn from these studies on the food that is the subject of the health claim, astaxanthin, in relation to the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of astaxanthin and the maintenance of normal joints, tendons or connective tissue.

3.2. Protection of DNA, proteins and lipids from oxidative damage (ID 1449, 3141)

Among the publications provided to substantiate these claims, some are general reviews on the potential health effects of astaxanthin and other carotenoids and were not considered directly pertinent to the claim.

Studies in cell cultures and algae model systems show that astaxanthin is an efficient antioxidant in vitro (Palozza and Krinsky, 1992; Terao, 1989; O'Connor and O'Brien, 1998; Kobayashi and Okada, 2004).

In humans, the effects of astaxanthin on lipid peroxidation were investigated in a small placebo controlled study conducted in 15 postmenopausal women (YooKyung and JongHee, 2004). Subjects were randomly assigned to consume either 0 (control), 2 or 8 mg/d astaxanthin for 8 weeks (five subjects per group). Blood and urine samples were collected at weeks 0, 4 and 8 of the study and the following parameters were determined as biomarkers of lipid peroxidation: thiobarbituric acid reactive substances (TBARS) in plasma, total antioxidant status (TAS) of plasma, and urinary 8-isoprostanes. TBARS significantly decreased in both of the supplemented groups, whereas they slightly increased in the control group. The effect seen in the astaxanthin groups was not dose dependent (changes observed were similar in the 2 and 8 mg/d groups). TBARS alone are not generally accepted as a valid biomarker of lipid peroxidation and should only be interpreted in context with other markers. No changes in urinary 8-isoprostanes, a validated marker of total lipid peroxidation, were observed in any astaxanthin group during the study. Total antioxidant status of plasma was measured by the ABTS method. This parameter was significantly different from baseline only at 8 weeks and only in the high dose astaxanthin group. The Panel notes that antioxidant status of plasma is not a validated marker of oxidative damage. The Panel also notes the limited number of subjects included in the study and that no comparisons between changes in the outcome variables between intervention and control groups were reported.

Another publication (Karppi et al., 2007) reported a double blind randomized controlled intervention in 39 healthy, non-smoker Finnish men (19-33 years). Subjects were randomised to consume either 8mg/d astaxanthin (n=20) or placebo (n=19) for 12 weeks. Plasma concentrations of astaxanthin significantly increased (0 to 0.032 µmol/L) during the study in the astaxanthin group as compared to placebo. Values in this concentration range are consistent with available literature (Rüfer et al., 2008). Eight different hydroxy fatty acid derivatives and F2-isoprostane concentrations in plasma were assessed as markers of lipid peroxidation. There was a significant decrease in 12-hydroxy fatty acids and 15-hydroxy fatty acids within the astaxanthin group as compared to baseline, but these changes were not statistically significant as compared to placebo. In addition, the Panel notes that the biological validity of 12-hydroxy fatty acids and 15-hydroxy fatty acids as markers of oxidative damage has not been established by the evidence provided.

In weighing the evidence, the Panel took into account that, although astaxanthin has antioxidant properties *in vitro*, the human studies presented do not provide any evidence in support of an *in vivo* antioxidant effect in terms of lipid peroxidation following the consumption of astaxanthin. No studies have been presented using markers of DNA or protein oxidative damage as outcomes.

The Panel concludes that a cause and effect relationship has not been established between the consumption of astaxanthin and the protection of DNA, proteins or lipids from oxidative damage.

3.3. Maintenance of visual acuity (ID 1448)

One notification of placing on the market novel foods or novel food ingredients pursuant to Article 5 of Regulation (EC) No 258/97 and four scientific references were provided to substantiate the claimed effect. Three were human intervention studies with astaxanthin and one was a mechanistic study indicating that carotenoids including astaxanthin were singlet oxygen quenchers in marine organisms (Shimidzu et al., 1996).

In a one-arm study (Takahashi and Kajita, 2005), nine volunteers consumed 6 mg/d of astaxanthin (from Astarioil, a product derived from Haematococcus) for 14 days and were evaluated by ophthalmological examination before and after the intervention. The examination was based on the Objective Diopter Value reading, the Accommodative Reaction Volume and the average value of the High-Frequency Component (HFC) in accommodative micro-fluctuation as well as on subjective measures using questionnaires to evaluate fatigue before and after operating electronic devices. Only the HFC value changed significantly with astaxanthin supplementation; the HCF after operation of the electronic devices decreased at the end of the intervention. The Panel notes the small number of subjects, the uncontrolled nature of the study design, and the limited relevance to the claimed effect of the endpoints measured; all of which limit the conclusions that can be drawn on the role of astaxanthin in supporting visual acuity.

Two small Japanese intervention studies with astaxanthin in humans could be accessed in abstract form only. One was a randomised placebo-controlled intervention study evaluating the effects of astaxanthin on accommodation, critical flicker fusion and pattern visual evoked potential in visual display terminal workers (Nagaki et al., 2002). The other study evaluated the effects of astaxanthin supplementation on visual acuity tests (Sawaki et al., 2002). The Panel notes that for both studies insufficient information was provided in the abstract (full papers in Japanese) for a complete evaluation in relation to the claimed effect.

In weighing the evidence, the Panel took into account the small number of subjects studied, the uncontrolled nature of the study design, and the limited relevance to the claimed effect of the endpoints measured in the only intervention study for which the full text was available.

The Panel concludes that a cause and effect relationship has not been established between the consumption of astaxanthin and the maintenance of visual acuity.

3.4. Maintenance of normal serum cholesterol concentrations and the maintenance of low plasma concentrations of C reactive protein (CRP) (ID 1450)

One notification of placing on the market novel foods or novel food ingredients pursuant to Article 5 of Regulation (EC) No 258/97 and two references reporting the results from two human intervention studies were provided to substantiate the claimed effect.

One study investigated the effects of astaxanthin supplementation on lipid peroxidation (not on blood cholesterol concentrations) and is therefore not considered pertinent to substantiate the claimed effect (Karppi et al., 2007). The second reference is only available in summary form and reports data from a study were 15 healthy postmenopausal women were divided into three groups to consume supplements containing different doses of astaxanthin for 8 weeks (Kim and Chyun, 2004). It is unclear from the abstract the dose of astaxanthin consumed by each group daily (the Panel assumed those to be 0.2mg/d, 2mg/d, and 8mg/d, respectively), the number of subjects assigned to each intervention group, and how the assignment was carried out. Serum concentrations of total cholesterol, low density lipoprotein (LDL)-cholesterol, high density lipoprotein (HDL)-cholesterol,

and triglycerides were assessed at 4 and 8 weeks of the intervention. HDL-cholesterol concentrations in the 2 mg/d and 8 mg/d groups increased significantly and triglycerides decreased significantly in the 2 mg group after 8 weeks of intervention. Whether these changes were significant as compared to the control group (assumed to be the 0.2mg/d group), or whether any changes in either total or LDL-cholesterol were observed in the intervention groups are compared to controls is not reported.

From the information available, the Panel notes that none of these studies have assessed the effects of astaxanthin intake on plasma concentrations of CRP.

The Panel concludes that a cause and effect relationship has not been established between the consumption of astaxanthin and the maintenance of normal blood cholesterol concentrations or the maintenance of low plasma concentrations of C reactive protein.

CONCLUSIONS

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

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

Maintenance of joints, tendons, and connective tissue (ID 1918, 1978, 3142)

- The claimed effects are "joint health" and "beneficial for connective tissue and joints". The target population is assumed to be the general population. Maintenance of normal joints, tendons, and connective tissue is beneficial to human health.

- A cause and effect relationship has not been established between the consumption of astaxanthin and the maintenance or improvement of joint, tendons or connective tissue structure and function.

Protection of DNA, proteins and lipids from oxidative damage (ID 1449, 3141)

- The claimed effects are "high potent antioxidant" and "supports a healthy oxidative balance". 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 not been established between the consumption of astaxanthin and the protection of DNA, proteins or lipids from oxidative damage.

Maintenance of visual acuity (ID 1448)

- The claimed effect is "beneficial for eye health". The target population is assumed to be the general population. Maintaining visual acuity is beneficial to human health.

- A cause and effect relationship has not been established between the consumption of astaxanthin and the maintenance of normal visual acuity.

Maintenance of normal blood cholesterol concentrations and maintenance of low plasma concentrations of C reactive protein (ID 1450)

- The claimed effect is "supports a healthy cardiovascular system". The target population is assumed to be the general population. Maintenance of normal blood cholesterol concentrations is beneficial to human health and maintenance of low plasma concentrations of C reactive protein (CRP) might be beneficial to human health.

- A cause and effect relationship has not been established between the consumption of astaxanthin and the maintenance of normal blood cholesterol concentrations or the maintenance of low plasma concentrations of C-reactive protein.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2185, EFSA-Q-2008-2186, EFSA-Q-2008-2187, EFSA-Q-2008-2651, EFSA-Q-2008-2711, EFSA-Q-2008-3873, EFSA-Q-2008-3874). The scientific substantiation is based on the information provided by the Members States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

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Spiller G, Dewell A, Chaves S, Rakadzich Z, 2006. Effect of daily use of natural astaxanthin on symptoms associated with Tennis Elbow (lateral humeral epicondylitis). On file at Cyanotech Corporation.

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[4] (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

a) the role of a nutrient or other substance in growth, development and the functions of the body; or

b) psychological and behavioural functions; or

c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[5]

Foods are commonly involved in many different functions[6] 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.

[4] OJ L12, 18/01/2007
[5] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[6] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

(a) the claimed effect of the food is beneficial for human health,

(b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

(c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.

- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.

- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.

- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.

- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.

- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to vitamin A, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1448	Astaxanthin from Haematococcus pluvialis	Beneficial for eye health.	Supports the eyes. Visual acuity support. Provides antioxidant support to the retina.
	Conditions of use - 4 – 12 mg dose daily.		
	Food or Food constituent	**Health Relationship**	**Proposed wording**
1449	Astaxanthin from *Haematococcus pluvialis*	Supports a healthy oxidative balance	Supports anti-aging through cellular health. Supports increased energylevels. Helps control excessive free radicals in the body. Supports ahealthy response to oxidative stress. Protects DNA from free radicals.
	Conditions of use - 4 – 12 mg dose daily.		
	Food or Food constituent	**Health Relationship**	**Proposed wording**
1450	Astaxanthin from Haematococcus pluvialis	Supports a healthy cardiovascular system.	Supports healthy cholesterol levels. Maintains low C reactive protein levels.
	Conditions of use - 4 – 12 mg dose daily.		
	Food or Food constituent	**Health Relationship**	**Proposed wording**
1918	Astaxanthin from Haematococcus pluvialis	Beneficial for connective tissue and joints	Supports joint health. Supports Healthy Tendons. Supports Healthy Carpal Tunnel. Supports joint function after heavy exercise.
	Conditions of use - 4 – 12 mg dose daily.		

1978	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Astaxanthin from Haematococcus pluvialis	Beneficial for connective tissue and joints	Supports joint health. Supports Healthy Tendons. Supports Healthy Carpal Tunnel. Supports joint function after heavy exercise.
	Conditions of use - 4 – 12 mg dose daily.		
3141	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Astaxanthin	High potent antioxidant	Astaxanthin helps to protect against free radicals and harmful factors of environment.
	Conditions of use - 3.85 mg astaxanthin (low dose) -19.25 mg astaxanthin (high dose) for 8 weeks - No negative effects on health have been described for 8 weeks		
3142	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Astaxanthin	Joint health	Astaxanthin favourably influence on condition of cartilage.
	Conditions of use - 3.85 mg astaxanthin (low dose) -19.25 mg astaxanthin (high dose) for 8 weeks - No negative effects on health have been described for 8 weeks		