



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to astaxanthin and protection of the skin from UV-induced damage (ID 1687, 1979), defence against *Helicobacter pylori* (ID 1686), contribution to normal spermatogenesis (ID 1688), contribution to normal muscle function (ID 1685), and “immune system” (ID 1689, 1919, 1980) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to astaxanthin and protection of the skin from UV-induced damage (ID 1687, 1979), defence against *Helicobacter pylori* (ID 1686), contribution to normal spermatogenesis (ID 1688), contribution to normal muscle function (ID 1685), and “immune system” (ID 1689, 1919, 1980) 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, 3</sup>**

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to astaxanthin and protection of the skin from UV-induced damage, defence against *Helicobacter pylori*, contribution to normal spermatogenesis, contribution to normal muscle function, and “immune system”. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

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

#### **Protection of the skin from UV-induced damage**

The claimed effects are “skin health” and “protects skin from UV damage and sun exposure”. The target population is assumed to be the general population. The Panel considers that protection of the skin from UV-induced damage is a beneficial physiological effect.

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-2421, EFSA-Q-2008-2422, EFSA-Q-2008-2423, EFSA-Q-2008-2424, EFSA-Q-2008-2425, EFSA-Q-2008-2652, EFSA-Q-2008-2712, EFSA-Q-2008-2713, adopted on 25 March 2011.

<sup>2</sup> Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: [nda@efsa.europa.eu](mailto:nda@efsa.europa.eu)

<sup>3</sup> Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Gut/Immune: Jean-Louis Bresson, Maria Carmen Collado, Miguel Gueimonde, Daisy Jonkers, Martinus Løvik, Bevan Moseley, Maria Saarela, Seppo Salminen, Yolanda Sanz, Stephan Strobel, Daniel Tomé and Hendrik van Loveren.

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No human studies have been provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of astaxanthin and protection of the skin from UV-induced damage.

### **Defence against *Helicobacter pylori***

The claimed effect is “gut health: influence on *Helicobacter pylori* infection”. The target population is assumed to be the general population. The Panel considers that defence against *Helicobacter pylori* is a beneficial physiological effect.

No human studies have been provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of astaxanthin and defence against *Helicobacter pylori*.

### **Contribution to normal spermatogenesis**

The claimed effect is “sperms motility”. The target population is assumed to be the general male population. The Panel considers that contribution to normal spermatogenesis is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the one human intervention study provided did not show an effect of astaxanthin, compared to placebo, on various measures of sperm quality in males.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of astaxanthin and contribution to normal spermatogenesis.

### **Contribution to normal muscle function**

The claimed effect is “muscle function”. The target population is assumed to be the general population. The Panel notes that from the information provided the aspect of muscle function which is the subject of the health claim is unclear.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

### **“Immune system”**

The claimed effects are “immune system” and “supports healthy immune system”. The target population is assumed to be the general population.

The references provided addressed several outcomes, and it was not possible to establish which effect is the target for the claim. Given the multiple roles of the immune system, the specific aspect of immune function that is the subject of the claim needs to be specified, but has not been indicated in the information provided.

The Panel considers that the claimed effects are general and non-specific, and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

**KEY WORDS**

Astaxanthin, UV-induced damage, skin, *Helicobacter pylori*, spermatogenesis, muscle function, immune system, health claims.

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**BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION**

See Appendix A

**TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION**

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**EFSA DISCLAIMER**

See Appendix B

## INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

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

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is astaxanthin.

Astaxanthin 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 occurs naturally in foods and also in synthetic forms as free astaxanthin or in the form of esters. Astaxanthin is absorbed into the bloodstream as the free form, and bioavailability can be enhanced in lipid matrices. Astaxanthin is measurable in foods by established methods.

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

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

#### 2.1. Protection of the skin from UV-induced damage (ID 1687, 1979)

The claimed effects are “skin health” and “protects skin from UV damage and sun exposure”. 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 refer to the protection of the skin from UV-induced damage (sunburn).

The Panel considers that protection of the skin from UV-induced damage is a beneficial physiological effect.

#### 2.2. Defence against *Helicobacter pylori* (ID 1686)

The claimed effect is “gut health: influence on *Helicobacter pylori* infection”. 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> EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

Influence on *Helicobacter pylori* infection could be interpreted as defence against *Helicobacter pylori*.

The Panel considers that defence against *Helicobacter pylori* is a beneficial physiological effect.

### **2.3. Contribution to normal spermatogenesis (ID 1688)**

The claimed effect is “sperms motility”. The Panel assumes that the target population is the general male population.

In the context of the proposed wordings and references provided, the Panel assumes that the claimed effect refers to normal spermatogenesis.

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

### **2.4. Contribution to normal muscle function (ID 1685)**

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

The references provided in relation to this claim included human intervention studies on the effects of astaxanthin on endurance capacity, endurance performance, muscle strength, and muscle fatigue during exercise, and animal studies on the effects of astaxanthin on exercise-induced skeletal and cardiac muscle damage, and skeletal muscle fatigue. The Panel notes that from the information provided the aspect of muscle function which is the subject of the health claim is unclear.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

### **2.5. “Immune system” (ID 1689, 1919, 1980)**

The claimed effects are “immune system” and “supports healthy immune system”. The Panel assumes that the target population is the general population.

The claimed effects are not sufficiently defined, and no further details were given in the proposed wordings or clarifications provided by Member States. The Panel notes that the references provided addressed several outcomes, and that it was not possible to establish which effect is the target for the claim. Given the multiple roles of the immune system, the specific aspect of immune function that is the subject of the claim needs to be specified, but has not been indicated in the information provided.

The Panel considers that the claimed effects are general and non-specific, and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

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

### **3.1. Protection of the skin from UV-induced damage (ID 1687, 1979)**

The references provided included narrative reviews on the effects of carotenoids in general and/or of astaxanthin on different health outcomes, including protection of the skin from UV-induced damage, which did not provide any original data which could be used for the scientific substantiation of the claim, or human intervention studies on the effects of carotenoids other than astaxanthin. The Panel



considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One open label, uncontrolled human intervention study which investigated the effects of astaxanthin consumption (4 mg/day) for two weeks on the minimal erythematous dose in 21 healthy male and female subjects (Cheun et al., year not given) was provided. The Panel considers that no conclusions can be drawn from this uncontrolled study for the scientific substantiation of the claim.

A number of animal and *in vitro* studies reported on the effects of astaxanthin on UV-induced cellular damage to the skin or cultured cells (e.g. cyst cells and fibroblasts). The Panel considers that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of astaxanthin consumption on protection of the skin from UV-induced damage *in vivo* in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of astaxanthin and protection of the skin from UV-induced damage.

### **3.2. Defence against *Helicobacter pylori* (ID 1686)**

Among the references provided for the scientific substantiation of the claim were animal and human intervention studies which addressed health outcomes (i.e. markers of oxidative stress in patients with reflux oesophagitis before and after anti-reflux surgery; experimental gastritis, oesophagitis, gastric ulcers in mice, rat and guinea pig models) unrelated to the claimed effect, and one human intervention study which was not accessible to the Panel after every reasonable effort had been made to retrieve it.

Kupcinskis et al. (2008), in a placebo-controlled, randomised, double-blind study, evaluated the effect of astaxanthin (16 or 40 mg/day) given for four weeks on gastrointestinal discomfort assessed with the Gastrointestinal Symptom Rating Scale questionnaire and the SF-36 quality of life questionnaire. The Panel notes that the effect of astaxanthin on *Helicobacter pylori* infection was not addressed in this study.

The animal studies provided evaluated the effect of astaxanthin on the treatment of *Helicobacter pylori* infection. The Panel considers that evidence provided in animal studies is not sufficient to predict the occurrence of an effect of astaxanthin consumption on defence against *Helicobacter pylori* infection in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of astaxanthin and defence against *Helicobacter pylori*.

### **3.3. Contribution to normal spermatogenesis (ID 1688)**

Two references were submitted for the scientific substantiation of the claim.

In a randomised, double-blind, placebo-controlled human intervention study, 20 men with infertility for  $\geq 12$  months received conventional treatment according to the guidelines of the World Health Organization (WHO), and either astaxanthin (16 mg/day, n=11) or placebo (n=9) for three months. Ten additional patients receiving placebo who had participated in another parallel, placebo-controlled trial were included in the analysis. No statistically significant differences were observed between the astaxanthin and placebo groups with respect to changes in any of the variables used to assess sperm quality (e.g. sperm concentration, linear velocity, grade (a) motility, sperm morphology, ejaculate volume, zona-free hamster oocytes test, spermatozoa firmly attached/oocytes, and decondensed sperm heads/oocytes) during the study. The Panel notes that this study did not show an effect of astaxanthin consumption on sperm quality.

An animal study on the effects of astaxanthin consumption on semen quality and fertility in stallions during the breeding period (Heczko, 2004) was also provided. The Panel considers that evidence provided in animal studies is not sufficient to predict the occurrence of an effect of astaxanthin consumption on contribution to normal spermatogenesis in humans.

In weighing the evidence, the Panel took into account that the one human intervention study provided did not show an effect of astaxanthin, compared to placebo, on various measures of sperm quality in males.

The Panel concludes that a cause and effect relationship has not been established between the consumption of astaxanthin and contribution to normal spermatogenesis.

## CONCLUSIONS

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

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

### Protection of the skin from UV-induced damage (ID 1687, 1979)

- The claimed effects are “skin health” and “protects skin from UV damage and sun exposure”. The target population is assumed to be the general population. Protection of the skin from UV-induced damage is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of astaxanthin and protection of the skin from UV-induced damage.

### Defence against *Helicobacter pylori* (ID 1686)

- The claimed effect is “gut health: influence on *Helicobacter pylori* infection”. The target population is assumed to be the general population. Defence against *Helicobacter pylori* is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of astaxanthin and defence against *Helicobacter pylori*.

### Contribution to normal spermatogenesis (ID 1688)

- The claimed effect is “sperms motility”. The target population is assumed to be the general male population. Contribution to normal spermatogenesis is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of astaxanthin and contribution to normal spermatogenesis.

### Contribution to normal muscle function (ID 1685)

- The claimed effect is “muscle function”. The target population is assumed to be the general population. From the information provided, the aspect of muscle function which is the subject of the health claim is unclear.
- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

### “Immune system” (ID 1689, 1919, 1980)

- The claimed effects are “immune system” and “supports healthy immune system”. The target population is assumed to be the general population. The references provided addressed several outcomes, and it was not possible to establish which effect is the target for the claim.
- The claimed effects are general and non-specific, and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

### DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2421, EFSA-Q-2008-2422, EFSA-Q-2008-2423, EFSA-Q-2008-2424, EFSA-Q-2008-2425, EFSA-Q-2008-2652, EFSA-Q-2008-2712, EFSA-Q-2008-2713). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

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

### REFERENCES

- Cheun O, Shanahan R and Wood C, year not given. Clinical Evaluation of the Potential of an Antioxidant Supplement to Alter Photobiological Responsiveness in Humans using BioAstin®. Protocol: CLCO-001, Final Report.
- Heczko KH, 2004. Effects on semen quality and fertility by feeding carotenoid astaxanthin to stallions during the breeding period. Doctoral thesis, University of Veterinary Medicine, Hanover, 128 pp.
- Kupcinskas L, Lafolie P, Lignell A, Kiudelis G, Jonaitis L, Adamonis K, Andersen LP and Wadstrom T, 2008. Efficacy of the natural antioxidant astaxanthin in the treatment of functional dyspepsia in patients with or without *Helicobacter pylori* infection: A prospective, randomized, double blind, and placebo-controlled study. *Phytomedicine*, 15, 391-399.

## 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>6</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>7</sup>

Foods are commonly involved in many different functions<sup>8</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.

<sup>6</sup> OJ L12, 18/01/2007

<sup>7</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>8</sup> The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

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

#### **SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE**

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

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

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

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

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

#### **WORDING OF HEALTH CLAIMS**

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

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

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

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

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

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

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

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

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

## **TERMS OF REFERENCE**

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

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

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

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

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

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

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

## **APPENDIX B**

### **EFSA DISCLAIMER**

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

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



APPENDIX C

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

ID	Food or Food constituent	Health Relationship	Proposed wording
1685	Naturligt astaxanthin från den encelliga grönalgen <i>Haematococcus pluvialis</i> .  <u>Clarification provided</u>  Natural astaxanthin from unicellular alga <i>Haematococcus pluvialis</i> .	Muskternas funktion.  <u>Clarification provided</u>  Muscle function.	Astaxanthin ger musklerna god uthållighet och alert kropp vid träning.#C  Astaxanthin maintains good muscle persistence and alert body at exercise.#C  Clarification provided  Astaxanthin maintains good muscle persistence and alert body at exercise.#C
	<b>Conditions of use</b>		
	- Daglig dos 4-8 mg astaxanthin. Personer som tränar hårt bör ta 8 mg astaxanthin per dag. Effekt uppnås efter regelbunden användning i 4 – 24 veckor.		
<b>Comments from Member States</b>			
For items 1685-1689, all astaxanthin, EFSA comment is 6, which means only translation. SE is waiting for a validation and probably a new clarification.			
ID	Food or Food constituent	Health Relationship	Proposed wording
1686	Naturligt astaxanthin från den encelliga grönalgen <i>Haematococcus pluvialis</i> .  <u>Clarification provided</u>  Natural astaxanthin from unicellular alga <i>Haematococcus pluvialis</i> .	Inverkan på mag- och tarmhälsa.  <u>Clarification provided</u>  Gut health: Influence on <i>Helicobacter pylori</i> infection.	Astaxanthin främjar en god magfunktion.#C  Astaxanthin improves stomach comfort.#C  <u>Clarification provided</u>  Astaxanthin improves stomach comfort.#C
	<b>Conditions of use</b>		
	- Daglig dos 4-40 mg astaxanthin per dag. Dosering om mer än 20 mg astaxanthin per dag under högst 4 veckor i följd. Effekt uppnås vid regelbunden användning efter 1-2 veckor.		
<b>Comments from Member States</b>			
For items 1685-1689, all astaxanthin, EFSA comment is 6, which means only translation. SE is waiting for a validation and probably a new clarification.			
ID	Food or Food constituent	Health Relationship	Proposed wording
1687	Naturligt astaxanthin från den encelliga grönalgen <i>Haematococcus pluvialis</i> .  <u>Clarification provided</u>  Natural astaxanthin from unicellular alga	Inverkan på hudens egenskaper.  <u>Clarification provided</u>  Skin health.	Astaxanthin är bra för hudens fuktighet och elasticitet samt skyddar mot UV-strålning.#A  Astaxanthin promotes skin moisture and elasticity plus protect against UV-irradiation.#A

	Haematococcus pluvialis.		<p><u>Clarification provided</u></p> <p>Astaxanthin promotes skin moisture and elasticity plus protect against UV-irradiation.#A see MS comment</p>
<p><b>Conditions of use</b></p> <p>- Daglig dos 2-4 mg astaxanthin. Effekt uppnås efter regelbunden användning i 2-4 veckor.</p>			
<p><b>Comments from Member States</b></p> <p>For items 1685-1689, all astaxanthin, EFSA comment is 6, which means only translation. SE is waiting for a validation and probably a new clarification.</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
1688	<p>Naturligt astaxanthin från den encelliga grönalgen Haematococcus pluvialis.</p> <p><u>Clarification provided</u></p> <p>Natural astaxanthin from unicellular alga Haematococcus pluvialis.</p>	<p>Spermiernas funktion.</p> <p><u>Clarification provided</u></p> <p>Sperms motility.</p>	<p>Astaxanthin främjar spermierna/sädescellernas rörlighet och funktion.#C</p> <p>Astaxanthin promotes sperms motility and functionality.#C</p> <p><u>Clarification provided</u></p> <p>Astaxanthin promotes sperms motility and functionality.#C see MS comment.</p>
	<p><b>Conditions of use</b></p> <p>- Daglig dos 16 mg astaxanthin. Effekt uppnås efter regelbunden användning i 3 månader.</p>		
	<p><b>Comments from Member States</b></p> <p>For items 1685-1689, all astaxanthin, EFSA comment is 6, which means only translation. SE is waiting for a validation and probably a new clarification.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1689	<p>Naturligt astaxanthin från den encelliga grönalgen Haematococcus pluvialis.</p> <p><u>Clarification provided</u></p> <p>Natural astaxanthin from unicellular alga Haematococcus pluvialis.</p>	<p>Immunsystemet.</p> <p><u>Clarification provided</u></p> <p>Immune system.</p>	<p>Astaxanthin är en biologiskt aktiv antioxidant som skyddar kroppens celler och bidrar till att främja immunsystemets funktion.</p> <p>Astaxanthin is strong antioxidant protecting the cells in the body and it helps to maintain the immune system.</p> <p><u>Clarification provided</u></p> <p>Astaxanthin is strong antioxidant protecting the cells in the body and it helps to maintain the immune system.</p>
	<p><b>Conditions of use</b></p> <p>- Daglig dos 2-16 mg astaxanthin. Effekt uppnås efter regelbunden användning 2-16 veckor.</p>		
	<p><b>Comments from Member States</b></p> <p>For items 1685-1689, all astaxanthin, EFSA comment is 6, which means only translation. SE is waiting for a validation and probably a new clarification.</p>		

ID	Food or Food constituent	Health Relationship	Proposed wording
1919	Astaxanthin from Haematococcus pluvialis	Supports Healthy Immune System	Supports anti-aging through cellular health. Supports a healthy response to physiological stress. Supports healthy immune function. Protects DNA.
		<u>Clarification provided</u> Supports Healthy Immune System by modulation of biochemicals that cause inflammation	
<b>Conditions of use</b> - 4 – 12 mg dose daily.			
ID	Food or Food constituent	Health Relationship	Proposed wording
1979	Astaxanthin from Haematococcus pluvialis.	Protects skin from UV damage and sun exposure.	Supports skin structure during sun exposure. Supports healthy skin.
		<b>Conditions of use</b> - Minimum dose of 4 mg astaxanthin daily. - 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.	
		<b>No clarification provided by Member States</b>	
ID	Food or Food constituent	Health Relationship	Proposed wording
1980	Astaxanthin from Haematococcus pluvialis.	Supports Healthy Immune System.	Supports anti-aging through cellular health. Supports a healthy response to physiological stress. Supports healthy immune function. Protects DNA.
		<b>Conditions of use</b> - 4 – 12 mg dose daily.	
		<b>No clarification provided by Member States</b>	