

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to iron and formation of red blood cells and haemoglobin (ID 249, ID 1589), oxygen transport (ID 250, ID 254, ID 256), energy-yielding metabolism (ID 251, ID 1589), function of the immune system (ID 252, ID 259), cognitive function (ID 253) and cell division (ID 368) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

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 (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to iron and the following claimed effects: formation of red blood cells and haemoglobin, oxygen transport, energy-yielding metabolism, function of the immune system, cognitive function and cell division. 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 iron which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that iron is sufficiently characterised.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of iron and normal formation of red blood cells and haemoglobin, normal oxygen transport, normal energy-yielding metabolism, normal function of the immune system, normal cognitive function and normal cell division.

1 On request from the European Commission, Question No EFSA-Q-2008-1036, EFSA-Q-2008-1037, EFSA-Q-2008-1038, EFSA-Q-2008-1039, EFSA-Q-2008-1040, EFSA-Q-2008-1041, EFSA-Q-2008-1043, EFSA-Q-2008-1046, EFSA-Q-2008-1155, EFSA-Q-2008-2326 adopted on 02 July 2009.

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The Panel considers that, in order to bear the claims, a food should be at least a source of iron as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

KEY WORDS

Iron, red blood cells, haemoglobin, oxygen transport, energy-yielding metabolism, immune system, cognitive function, cell division, 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. Formation of red blood cells and haemoglobin (ID 249, ID 1589)	5
2.2. Oxygen transport (ID 250, ID 254, ID 256)	5
2.3. Energy-yielding metabolism (ID 251, ID 1589).....	6
2.4. Function of the immune system (ID 252, ID 259).....	6
2.5. Cognitive function (ID 253)	6
2.6. Cell division (ID 368).....	6
3. Scientific substantiation of the claimed effect	6
3.1. Formation of red blood cells and haemoglobin (ID 249, ID 1589)	6
3.2. Oxygen transport (ID 250, ID 254, ID 256)	7
3.3. Energy-yielding metabolism (ID 251, ID 1589).....	7
3.4. Function of the immune system (ID 252, ID 259).....	7
3.5. Cognitive function (ID 253)	8
3.6. Cell division (ID 368).....	8
4. Panel’s comments on the proposed wording	8
4.1. Formation of red blood cells and haemoglobin (ID 249, 1589)	8
4.2. Oxygen transport (ID 250, 254, 256).....	8
4.3. Energy-yielding metabolism (ID 251, 1589)	8
4.4. Function of the immune system (ID 252, 259).....	8
4.5. Cognitive function (ID 253)	8
4.6. Cell division (ID 368).....	9
5. Conditions and possible restrictions of use	9
Conclusions	9
Documentation provided to EFSA	10
References	11
Appendices	12
Glossary / Abbreviations.....	20

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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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006³ 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 claims is iron which is a well recognised nutrient and is measurable in foods by established methods.

Iron occurs naturally in foodstuffs in different oxidation states. The primarily occurring oxidation states in biological systems are +2 (ferrous state) and +3 (ferric state).

Iron occurs naturally in foods in two forms, haem iron which is primarily derived from haemoglobin and myoglobin in meat and non-haem iron from plants in the form of iron complexes (IoM, 2001). Different forms of iron are authorised for addition to foods (Annex I of Regulation (EC) No 1925/2006⁴ and Annex II of Directive 2002/46/EC⁵). This evaluation applies to iron 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, iron, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Formation of red blood cells and haemoglobin (ID 249, ID 1589)

The claimed effect is “red blood cell and haemoglobin formation”. The Panel assumes that the target population is the general population.

The Panel considers that normal formation of red blood cells and haemoglobin are beneficial to human health.

2.2. Oxygen transport (ID 250, ID 254, ID 256)

The claimed effect is “oxygen transport”. The Panel assumes that the target population is the general population.

The Panel considers that normal oxygen transport is beneficial to human health.

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.

⁴ 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.

⁵ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57.

2.3. Energy-yielding metabolism (ID 251, ID 1589)

The claimed effect is “energy production”. The Panel assumes that the target population is the general population.

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

2.4. Function of the immune system (ID 252, ID 259)

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

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

2.5. Cognitive function (ID 253)

The claimed effect is “cognitive development and function”. The Panel assumes that the target population is the general population.

The Panel considers that cognitive development is related to children’s development and health. Cognitive function includes different functions such as memory, attention (concentration), learning, intelligence and problem solving.

The Panel considers that normal cognitive function is beneficial to human health.

2.6. Cell division (ID 368)

The claimed effect is “cell division”. The Panel assumes that the target population is the general population.

The Panel notes that cell division is a crucial process for tissue growth and development and for tissue maintenance through cell turnover.

The Panel considers that normal cell division is beneficial to human health.

3. Scientific substantiation of the claimed effect

Iron is an essential trace element that has important metabolic functions, including oxygen transport and is involved in many redox reactions. Insufficient intake results in the deficiency condition anaemia, adverse outcomes of pregnancy, impaired psychomotor development and cognitive performance and reduced immune function (EFSA, 2004).

3.1. Formation of red blood cells and haemoglobin (ID 249, ID 1589)

In humans, iron is mainly found in porphyrins. In haemproteins (haemoglobin and myoglobin) iron is found in its ferrous state (Fe^{2+}) which allows it to bind oxygen reversibly. Haemoglobin transports oxygen in the erythrocytes to the tissues (Hunt, 2005).

It is well established that inadequate dietary iron intake in humans leads to hypochromic and microcytic anaemia.

The Panel concludes that a cause and effect relationship has been established between the intake of iron and normal formation of red blood cells and haemoglobin.

3.2. Oxygen transport (ID 250, ID 254, ID 256)

In humans, iron is mainly found in porphyrins. In haemproteins (haemoglobin and myoglobin) iron is found in its ferrous state (Fe^{2+}) which allows it to bind oxygen reversibly. Haemoglobin transports oxygen in the erythrocytes to the tissues (Hunt, 2005).

It is well established that inadequate dietary iron intake in humans leads to hypochromic and microcytic anemia.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of iron and normal oxygen transport to tissues.

3.3. Energy-yielding metabolism (ID 251, ID 1589)

Iron containing porphyrins are also found in cytochromes of the electron transport chains. Cytochromes are electron transport enzymes in mitochondria and other cellular membranes. They are able to undergo reversible oxidation by way of changes in the oxidation state of iron and are essential for the oxidative production of cellular energy in the form of ATP. Other non-haem iron containing enzymes are also involved in the electron transport chain. These are for example cytochrome c reductase, NADH-dehydrogenase and succinate dehydrogenase which are involved in energy-yielding metabolism (Elmadfa and Leitzmann, 1988). Impaired oxygen transport caused by anaemia exerts an indirect effect on the electron transport chain where oxygen acts as electron acceptor (Koolman and Röhm, 1994). It is difficult to determine whether any particular functional abnormality caused by iron deficiency is a specific consequence of the anaemia per se and impaired oxygen delivery or the result of iron deficiency in tissues. However, it has been shown that anaemia and tissue iron deficiency exert independent effects on skeletal muscle (IoM, 2001).

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

3.4. Function of the immune system (ID 252, ID 259)

It has been demonstrated, mainly with the use of *in vitro* tests and animal models, that iron deficiency is associated with changes in the cell-mediated immune response. Amongst other effects, the following effects of iron deficiency in the immune system have been described: impaired neutrophil function, reduction of numbers of T-cells, B-cells and natural killer cells, defective T-lymphocyte-induced proliferative response, reduction of secretory IgA, reduction of levels of complement C3 and C4, and inhibition of the activity of $\text{IFN-}\gamma$ (Biesalski et al., 1995; FAO/WHO, 2004; IoM, 2001; Oppenheimer, 2001; Hunt, 2005; Weiss, 2002). Data confirming these effects of iron on immune parameters in humans are scarce. In a review by Munoz et al. (2007), a decrease in the numbers of naïve T-helper and T-cytotoxic cells in blood from iron deficient subjects was reported, suggesting that iron is required for the regeneration of new CD4^+ T lymphocytes and maintenance of T cell cytolytic processes. It is also reported that serum IL-2 and IL-6 were reduced in iron-deficient children, suggesting that iron alters the balance between pro- and anti-inflammatory cytokines. In a study conducted in iron-deficient women, secretion and mRNA levels of $\text{TNF-}\alpha$, but not its membrane expression, was significantly lower in iron deficient subjects (Munoz et al., 2007).

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

3.5. Cognitive function (ID 253)

A total of 84 references were provided to substantiate the claimed effect. The great majority of the human studies were in infants and children. One study by Murray-Kolb and Beard (2007) showed an effect of iron supplementation on cognitive function in healthy women between 18-35 years of age.

It is well established that inadequate dietary iron intake in humans leads to reduced oxygen transport, which could have an impact on cognitive function. The cognitive deficiency symptoms observed with iron-deficient anaemia include deficits in attention, perceptual motor speed, memory and verbal fluency (Malestrom, 2002).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of iron and normal cognitive function.

3.6. Cell division (ID 368)

No references have been provided to substantiate the claimed effect.

As all essential nutrients, iron is needed for cell division. Iron's role in this process is connected to its function in oxygen transport and energy-yielding metabolism, and more specific through the control of the activities of iron containing enzymes involved either in DNA synthesis (ribonucleotide reductase) or in the phase progression during the cell cycle (cyclin-dependent kinase complexes 4 and 6) (Bohnsack and Hirschi, 2004).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of iron and normal cell division.

4. Panel's comments on the proposed wording

4.1. Formation of red blood cells and haemoglobin (ID 249, 1589)

The Panel considers that the following wording reflects the scientific evidence: "Iron contributes to normal formation of red blood cells and haemoglobin."

4.2. Oxygen transport (ID 250, 254, 256)

The Panel considers that the following wording reflects the scientific evidence: "Iron contributes to normal oxygen transport in the body."

4.3. Energy-yielding metabolism (ID 251, 1589)

The Panel considers that the following wording reflects the scientific evidence: "Iron contributes to normal energy-yielding metabolism."

4.4. Function of the immune system (ID 252, 259)

The Panel considers that the following wording reflects the scientific evidence: "Iron contributes to a normal function of the immune system."

4.5. Cognitive function (ID 253)

The Panel considers that the following wording reflects the scientific evidence: "Iron contributes to normal cognitive function."

4.6. Cell division (ID 368)

The Panel considers that the following wording reflects the scientific evidence: “Iron contributes to normal cell division.”

5. Conditions and possible restrictions of use

In order to bear the claims a food should be at least source of iron as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population. No Upper Tolerable Intake Levels (UL) have been set for iron (EFSA, 2004).

CONCLUSIONS

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

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

Formation of red blood cells and haemoglobin (ID 249, 1589)

- The claimed effect is “red blood cell and haemoglobin formation”. The target population is assumed to be the general population. Normal formation of red blood cells and haemoglobin are beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of iron and normal formation of red blood cells and haemoglobin.
- The following wording reflects the scientific evidence: “Iron contributes to normal formation of red blood cells and haemoglobin”.

Oxygen transport (ID 250, 254, 256)

- The claimed effect is “oxygen transport”. The target population is assumed to be the general population. Normal oxygen transport is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of iron and normal oxygen transport to tissues.
- The following wording reflects the scientific evidence: “Iron contributes to normal oxygen transport in the body”.

Energy-yielding metabolism (ID 251, 1589)

- The claimed effect is “energy production”. The target population is assumed to be the general population. Normal energy-yielding metabolism is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of iron and normal energy-yielding metabolism.
- The following wording reflects the scientific evidence: “Iron contributes to normal energy-yielding metabolism”.

Function of the immune system (ID 252, 259)

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

Cognitive development and function (ID 253)

- The claimed effect is “cognitive development and function”. The target population is assumed to be the general population. Normal cognitive function is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of iron and normal cognitive function.
- The following wording reflects the scientific evidence: “Iron contributes to normal cognitive function”.

Cell division (ID 368)

- The claimed effect is “cell division”. The target population is assumed to be the general population. Normal cell division is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of iron and normal cell division.
- The following wording reflects the scientific evidence: “Iron contributes to normal cell division”.

Conditions and possible restrictions of use

- In order to bear the claims a food should be at least a source of iron as per Annex to Regulation (EC) No 1924/2006. The target population is the general population. Such amounts can be easily consumed as part of a balanced diet.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1036, EFSA-Q-2008-1037, EFSA-Q-2008-1038, EFSA-Q-2008-1039, EFSA-Q-2008-1040, EFSA-Q-2008-1041, EFSA-Q-2008-1043, EFSA-Q-2008-1046, EFSA-Q-2008-1155, EFSA-Q-2008-2326). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

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

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁶ (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 FOOD⁷

Foods are commonly involved in many different functions⁸ 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.

⁶ OJ L12, 18/01/2007

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

⁸ 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 biotin, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
249	Iron	Red blood cell and haemoglobin formation	Iron is needed for blood formation. Iron is needed/important for making hemoglobin and red-blood cells
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Tagesbedarf gemäß NwKVO 14 mg pro Tag - Agency guidance for supplements is that products containing >20mg of Iron should carry the label statement: '[This amount of iron] may cause mild stomach upset in sensitive individuals.' Must at least be a source of mineral/s as per annex to regulation 1924/2006 To also present a statement which conveys that iron levels above 60mg/kg body weight in infants, 200mg in children and 1400mg/kg bw in adults is toxic and may be fatal. Applicable to both children and adults - Jugendliche, Erwachsene 3 bis 10 Milligramm (mg), max 14 Milligramm (mg) - Blood pancakes with iron content of 19,5mg/100g = serving = daily serving 		
250	Iron	Oxygen transport to the tissues	Iron is necessary for the transport of oxygen in the body
	<p>Conditions of use</p> <ul style="list-style-type: none"> - The product must contain at least 15% of the RDA Adults: typically 2-30 mg supplementary iron. As organic salt (e.g. citrate, malate) or inorganic salt (e.g. sulphate). May be delivered in non-heme (plant-derived) sources but because bioavailability is lower (as low as 2%), higher dosages may be necessary than for heme iron sources. Precautions that should be included on the label of iron supplements may include: "Children or People with a history of kidney disease, intestinal disease, peptic ulcer disease, enteritis, colitis, pancreatitis, hepatitis, who consume excessive alcohol, plan to become pregnant, or are over age 55 and have a family history of heart disease, should consult a doctor and pharmacist before taking iron supplements." - Mindestens 15 % RDA je 100 g oder 100 mL oder je Portion gemäß 90/496/EWG - Juices with iron content of 2.8mg/100g, 5.7mg/serving - Oat and wheat bran and oat flakes with iron content of 6.9-14mg/100g, 2.8-3.5mg/serving Phytic acid in cereals may interfere with the absorption of iron. 		
251	Iron	Energy production	The body needs iron for energy production.
	<p>Conditions of use</p>		

	<p>Conditions of use</p> <ul style="list-style-type: none"> - Minimum 15% RDA (2,1 mg) dziennie. - Mindestens 15 % RDA je 100 g oder 100 mL oder je Portion gemäß 90/496/EWG - Must at least be a source of mineral/s as per annex to regulation 1924/2006 Agency guidance for supplements is that products containing >20mg Iron should carry the label statement: '[This amount of iron] may cause mild stomach upset in sensitive individuals.' <p>Applicable to both children and adults</p>								
252	<table border="1"> <thead> <tr> <th>Food or Food constituent</th> <th>Health Relationship</th> <th>Proposed wording</th> </tr> </thead> <tbody> <tr> <td>Iron</td> <td>Immune system</td> <td>Iron is necessary for the function of the immune system.</td> </tr> </tbody> </table>	Food or Food constituent	Health Relationship	Proposed wording	Iron	Immune system	Iron is necessary for the function of the immune system.	<p>Conditions of use</p> <ul style="list-style-type: none"> - Must at least be a source of mineral/s as per annex to regulation 1924/2006 - Mindestens 15 % RDA je 100 g oder 100 mL oder je Portion gemäß 90/496/EWG 	
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	Food or Food constituent	Health Relationship	Proposed wording						
Iron (heme and non-heme) (including from botanical sources)	Blood, oxygen transport	Iron is necessary for the transport of oxygen to tissues throughout the body							

	<p>enthalten</p> <ul style="list-style-type: none"> - Jugendliche, Erwachsene 3 bis 10 Milligramm (mg), max 14 Milligramm (mg) 		
259	Food or Food constituent	Health Relationship	Proposed wording
	Iron	Normal functioning of the immune system	Iron supports the functioning of the immune system
<p>Conditions of use</p> <ul style="list-style-type: none"> - The product must contain at least 15% of the RDA Agency guidance for supplements is that products containing >20 mg of Iron should carry the label advisory statement "[This amount of Iron]* may cause mild stomach upset in sensitive individuals" - Jugendliche, Erwachsene 3 bis 10 Milligramm (mg), max 14 Milligramm (mg) 			
368	Food or Food constituent	Health Relationship	Proposed wording
	Iron	Cell division	Iron is necessary for cell division.
<p>Conditions of use</p> <p>---</p>			
1589	Food or Food constituent	Health Relationship	Proposed wording
	Iron-Micronised microencapsulated ferric pyrophosphate	Blood, haemoglobin and energy production	Iron need for energy production. Iron necessary for blood formation. Iron improves anaemia.
<p>Conditions of use</p> <ul style="list-style-type: none"> - Recommended dosage: 2-12 mg/day. LD50 = 5000mg/kg BW was observed in rats. No toxicity observed in Ames Salmonella/Microsome Plate Test for Mutagenicity. High gastric tolerance - No harmful effects observed. 			

GLOSSARY / ABBREVIATIONS

ATP Adenosine-5'-triphosphate

DNA Deoxyribonucleic acid

NADH Nicotinamide adenine dinucleotide

UL Tolerable Upper Intake Levels