SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to iron and formation of red blood cells and haemoglobin (ID 374, 2889), oxygen transport (ID 255), contribution to normal energy-yielding metabolism (ID 255), reduction of tiredness and fatigue (ID 255, 374, 2889), biotransformation of xenobiotic substances (ID 258), and "activity of heart, liver and muscles" (ID 397) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

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 formation of red blood cells and haemoglobin, oxygen transport, contribution to normal energy-yielding metabolism, reduction of tiredness and fatigue, biotransformation of xenobiotic substances and "activity of heart, liver and muscles". 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. The Panel considers that iron is sufficiently characterised.

Formation of red blood cells and haemoglobin

The claimed effect is "fights against anaemia/ tiredness". The target population is assumed to be the general population. The Panel assumes that the claimed effect is related to the formation of red blood cells and haemoglobin.

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[1] On request from the European Commission, Question No EFSA-Q-2008-1042, EFSA-Q-2008-1045, EFSA-Q-2008-1161, EFSA-Q-2008-1184, EFSA-Q-2008-3622, adopted on 09 July 2010.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: 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.

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A claim on iron and normal formation of red blood cells and haemoglobin has already been assessed with a favourable outcome.

Oxygen transport

The claimed effect is "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status". The target population is assumed to be the general population. In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect is related to oxygen transport.

A claim on iron and normal oxygen transport has already been assessed with a favourable outcome.

Contribution to normal energy-yielding metabolism

The claimed effect is "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status". The target population is assumed to be the general population. In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect is related to energy-yielding metabolism.

A claim on iron and normal energy-yielding metabolism has already been assessed with a favourable outcome.

Reduction of tiredness and fatigue

The claimed effects are "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status" and "fights against anaemia/ tiredness". The target population is assumed to be the general population. The Panel considers that reduction of tiredness and fatigue is a beneficial physiological effect.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of iron and reduction of tiredness and fatigue.

Biotransformation of xenobiotic substances

The claimed effect is "metabolism of foreign substances". The target population is assumed to be the general population. The Panel notes that from the proposed wording it could not be established which xenobiotic substance or which biotransformation reaction related to the elimination of xenobiotic substances is the target for the claim.

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.

"Activity of heart, liver and muscles"

The claimed effect is "activity of heart, liver and muscles". The target population is assumed to be the general population. "Activity of heart, liver and muscles" is not sufficiently defined and no clarifications have been provided by Member States.

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.

Conditions and possible restrictions of use

The Panel considers that in order to bear the claim a food should be at least a source of 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, xenobiotics, fatigue, heart, liver, muscles, 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[4] 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[5]. 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 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 II of Regulation (EC) No 1925/2006[6] and Annex II of Directive 2002/46/EC[7]). 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 effects to human health

2.1. Formation of red blood cells and haemoglobin (ID 374, 2889)

The claimed effect is “fights against anaemia/ tiredness”. The Panel assumes that the target population is the general population.

The Panel assumes that the claimed effect is related to the formation of red blood cells and haemoglobin.

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.
[5] Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims: http://www.efsa.europa.eu/en/ndameetings/docs/nda100601-ax01.pdf
[6] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38.
[7] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57.

A claim on iron and normal formation of red blood cells and haemoglobin has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009).

2.2. Oxygen transport (ID 255)

The claimed effect is "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status". The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect is related to oxygen transport.

A claim on iron and normal oxygen transport has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009).

2.3. Contribution to normal energy-yielding metabolism (ID 255)

The claimed effect is "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status". The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect is related to energy-yielding metabolism.

A claim on iron and normal energy-yielding metabolism has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009).

2.4. Reduction of tiredness and fatigue (ID 255, 374, 2889)

The claimed effects are "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status" and "fights against anaemia/ tiredness". The Panel assumes that the target population is the general population.

The Panel considers that the reduction of tiredness and fatigue is a beneficial physiological effect.

2.5. Biotransformation of xenobiotic substances (ID 258)

The claimed effect is "metabolism of foreign substances". The Panel assumes that the target population is the general population.

Enzymatic biotransformation reactions of xenobiotic substances after absorption involve Phase I and Phase II biotransformation reactions, which usually work together in a sequential manner to convert xenobiotics into more readily excretable metabolites (Yu, 2005; Buhler and Williams, 1988). Phase I biotransformation reactions include oxidation, reduction, and hydrolysis, while Phase II biotransformation consists essentially of conjugation reactions (Yu, 2005). Whereas biotransformation reactions normally result in detoxification, some chemicals may also be enzymatically converted to highly reactive, electrophilic metabolites which may induce cytotoxic, teratogenic, mutagenic or carcinogenic effects through reaction with various cellular constituents (Buhler and Williams, 1988).

The Panel notes that from the proposed wording it could not be established which xenobiotic substance or which biotransformation reaction related to the elimination of xenobiotic substances is the target for the claim.

In the absence of such information, 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.

2.6. "Activity of heart, liver and muscles" (ID 397)

The claimed effect is "activity of heart, liver and muscles". The Panel assumes that the target population is the general population.

"Activity of heart, liver and muscles" is not sufficiently defined and no clarifications have been provided by Member States.

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.

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. Reduction of tiredness and fatigue (ID 255, 374, 2889)

Insufficient intake of iron results in the deficiency condition anaemia. Most patients with significant anaemia are fatigued and tire easily after exertion (Chitambar and Antony, 2006).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of iron and reduction of tiredness and fatigue.

4. Panel's comments on the proposed wording

4.1. Reduction of tiredness and fatigue (ID 255, 374, 2889)

The Panel considers that the following wording reflects the scientific evidence: "Iron can contribute to the reduction of tiredness and fatigue".

5. Conditions and possible restrictions of use

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. 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 374, 2889)

- The claimed effect is "fights against anaemia/tiredness". The target population is assumed to be the general population. It is assumed that the claimed effect is related to the formation of red blood cells and haemoglobin.

- A claim on iron and normal formation of red blood cells and haemoglobin has already been assessed with a favourable outcome.

Oxygen transport (ID 255)

- The claimed effect is "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status". The target population is assumed to be the general population. In the context of the clarifications provided by Member States, it is assumed that the claimed effect is related to oxygen transport.

- A claim on iron and normal oxygen transport has already been assessed with a favourable outcome.

Contribution to normal energy-yielding metabolism (ID 255)

- The claimed effect is "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status". The target population is assumed to be the general population. In the context of the clarifications provided by Member States, it is assumed that the claimed effect is related to energy-yielding metabolism.

- A claim on iron and normal energy-yielding metabolism has already been assessed with a favourable outcome.

Reduction of tiredness and fatigue (ID 255, 374, 2889)

- The claimed effects are "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status" and "fights against anaemia/tiredness". The target population is assumed to be the general population. Reduction of tiredness and fatigue is a beneficial physiological effect.

- A cause and effect relationship has been established between the dietary intake of iron and reduction of tiredness and fatigue.

- The following wording reflects the scientific evidence: "Iron can contribute to the reduction of tiredness and fatigue".

Biotransformation of xenobiotic substances (ID 258)

- The claimed effect is "metabolism of foreign substances". The target population is assumed to be the general population. From the proposed wording, it could not be established which xenobiotic substance or which biotransformation reaction related to the elimination of xenobiotic substances is the target for the claim.

- 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.

"Activity of heart, liver and muscles" (ID 397)

- The claimed effect is "activity of heart, liver and muscles". The target population is assumed to be the general population. "Activity of heart, liver and muscles" is not sufficiently defined and no clarifications have been provided by Member States.

- 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.

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.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1042, EFSA-Q-2008-1045, EFSA-Q-2008-1161, EFSA-Q-2008-1184, EFSA-Q-2008-3622). 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

REFERENCES

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EFSA (European Food Safety Authority), 2004. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Levels of Iron. The EFSA Journal 125, 1-34.

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009. 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 1924/2006. EFSA Journal , 7(9):1215, 20 pp.

IoM (Institute of Medicine), 2001. Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc. National Academy Press, Washington, D.C.

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[8] (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[9]

Foods are commonly involved in many different functions[10] of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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

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

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

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

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

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

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

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

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

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

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

WORDING OF HEALTH CLAIMS

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

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

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

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

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

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

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

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

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

TERMS OF REFERENCE

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

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

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

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

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

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

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

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

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

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

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

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

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

APPENDIX B

EFSA DISCLAIMER

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

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

APPENDIX C

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

ID	Food or Food constituent	Health Relationship	Proposed wording
255	Iron	Vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status Clarification provided Iron is required for optimal circulating levels of oxygen and energy use by the body	Supplementation with B-vitamins, iron, magnesium as well as vitamin C can reduce fatigue and tiredness in situations of inadequate micro-nutrient status
	Conditions of use – Erwachsene: 2-15 Milligramm (mg) 14 - 30 Tage – Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
258	Iron	Metabolism of foreign substances	Iron is needed to allow the body metabolise drugs and other substances. Iron contributes to the body's ability to metabolise drugs and other substances. Iron is needed for the metabolism of drugs.
	Conditions of use – Jugendliche, Erwachsene: 3 bis 10 Milligramm (mg) – 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.', Applicable to both children and adults		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
374	Fer Clarification provided iron	lutte contre l'anémie/ la fatigue Clarification provided fights against anemia/ tiredness	le fer vous aidera à lutter contre la fatigue Clarification provided iron will help you to fight against tiredness.
	Conditions of use – source de (selon annexe règlement CE/1924/2006)		

ID	Food or Food constituent	Health Relationship	Proposed wording
397	Iron	activity of heart, liver and muscles	Iron affects activity of heart, liver and muscles.
	Conditions of use – The product must contain at least 15 % of the RDA		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2889	Fer	lutte contre l'anémie/ la fatigue	le fer vous aidera à lutter contre la fatigue
	Conditions of use – source de (selon annexe règlement CE/1924/2006)		
	No clarification provided by Member States		