

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to various food(s)/food constituent(s) and protection of cells from premature ageing (ID 1668, 1917, 2515, 2527, 2530, 2575, 2580, 2591, 2620, 3178, 3179, 3180, 3181, 4329, 4415), antioxidant activity, antioxidant content and antioxidant properties (ID 857, 1306, 2515, 2527, 2530, 2575, 2580, 2591, 2629, 2728, 4327, 4365, 4380, 4390, 4394, 4455, 4464, 4507, 4694, 4705), protection of DNA, proteins and lipids from oxidative damage (ID 1196, 1211, 1216, 1306, 1312, 1440, 1441, 1666, 1668, 1692, 1900, 1914, 1948, 2023, 2158, 2517, 2522, 2527, 2575, 2591, 2620, 2637, 2639, 2663, 2860, 3079, 3276, 3564, 3818, 4324, 4329, 4351, 4397, 4416, 4424, 4507, 4527, 4528, 4542, 4611, 4629, 4659) and bioavailability of anthocyanins in black currants (ID 4220) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

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SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to various food(s)/food constituent(s) and protection of cells from premature ageing, antioxidant activity, antioxidant content and antioxidant properties, protection of DNA, proteins and lipids from oxidative damage, and bioavailability of anthocyanins in black currants. 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.

Protection of cells from premature ageing

The claimed effects are “antioxidant”, “anti-cancer”, “anti-ageing”, “healthy ageing”, “antioxidant mainly due to phenolic compounds as well as high amounts of carotenoids and vitamin C and E” and “skin anti-ageing agent”. The target population is assumed to be the general population. The proposed wordings and clarifications provided by Member States include “lowers the ageing process”, “fighting oxidation induced ageing”, “fights against cellular ageing”, and “protects the skin from the effects of premature ageing”.

The Panel considers that the claimed effect “anti-cancer” relates to the prevention of a human disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

No definition has been provided of “premature (skin) ageing”, “healthy ageing”, “oxidation-induced ageing” or “cellular ageing” in relation to the antioxidant properties of foods. The Panel considers that these claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

Antioxidant activity, antioxidant content and antioxidant properties

The claimed effects are “antioxidant”, “antioxidative capacity”, “antioxidant properties”, “antioxidant activity”, “purifying/detoxifying properties”, and “antioxidant effect”. The target population is assumed to be the general population. The Panel considers that claims made on the antioxidant capacity/content or properties of foods/food constituents based on their capability of scavenging free radicals *in vitro* refer to a property of the food/food constituent measured in model systems. The information provided does not establish that this capability as such exerts a beneficial physiological effect in humans. No evidence has been provided to establish that having antioxidant activity/content and/or antioxidant properties is a beneficial physiological effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of this opinion and a beneficial physiological effect related to antioxidant activity, antioxidant content or antioxidant properties.

Protection of DNA, proteins and lipids from oxidative damage

The claimed effects refer to the protection of body cells and molecules (such as DNA, proteins and lipids) from oxidative damage, including UV-induced oxidative damage. The target population is assumed to be the general population. The Panel considers that protection of DNA, proteins and lipids from oxidative damage may be a beneficial physiological effect.

No human studies that investigated the effects of the consumption of the food(s)/food constituent(s) on reliable markers of oxidative damage to body cells or to molecules such as DNA, proteins and lipids have been provided in relation to any of the health claims evaluated in this opinion.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of this opinion and the protection of DNA, proteins and lipids from oxidative damage.

Bioavailability of anthocyanins in black currants

The claimed effect is “Les antioxydants du cassis (anthocyanines) sont assimilés par l'organisme. Ils sont ensuite excrétés dans les urines”. The target population is assumed to be the general population.

The Panel assumes that the claimed effect refers to the bioavailability of the food constituent (“anthocyanins in black currant”).

The Panel considers that the claim refers to the bioavailability of the food constituent rather than to a relationship between the food constituent and health as required by Regulation (EC) No 1924/2006.

KEY WORDS

Antioxidants, oxidative damage, DNA, lipids, proteins, ageing, 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

See Appendix A

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 1924/2006⁴ 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 out⁵. 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

The approach used in the evaluation of Article 13(1) health claims is explained in the briefing document for stakeholders published by EFSA⁶.

In assessing each specific food/health relationship that forms the basis of a health claim the NDA Panel considers the extent to which:

1. the food/constituent is defined and characterised;
2. the claimed effect is defined and is a beneficial physiological effect (“beneficial to human health”);
3. a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use).

Substantiation of the claim is dependent on a favourable outcome of the assessment of 1, 2 and 3 above. Thus, a cause and effect relationship is considered not to be established if the outcome of any one of these assessments is unfavourable.

For a claim, each relationship between a food/constituent and a claimed effect is assessed separately and individual assessments are combined, as appropriate, to form coherent opinions.

1. Relevance of the claimed effect to human health

1.1. Protection of cells from premature ageing (ID 1668, 1917, 2515, 2527, 2530, 2575, 2580, 2591, 2620, 3178, 3179, 3180, 3181, 4329, 4415)

The claimed effects are “antioxidant”, “anti-cancer”, “anti-ageing”, “healthy ageing”, “antioxidant mainly due to phenolic compounds as well as high amounts of carotenoids and vitamin C and E” and “skin anti-ageing agent”. The Panel assumes that the target population is the general population.

The proposed wordings and clarifications provided by Member States include “lowers the ageing process”, “fighting oxidation induced ageing”, “fights against cellular ageing”, and “protects the skin from the effects of premature ageing”.

The Panel considers that the claimed effect “anti-cancer” relates to the prevention of a disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

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 See footnote 5

No definition has been provided of “premature (skin) ageing”, “healthy ageing”, “oxidation-induced ageing”, “ageing process” or “cellular ageing” in relation to the antioxidant properties of foods.

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.

1.2. Antioxidant activity, antioxidant content and antioxidant properties (ID 857, 1306, 2515, 2527, 2530, 2575, 2580, 2591, 2629, 2728, 4327, 4365, 4380, 4390, 4394, 4455, 4464, 4507, 4694, 4705)

The claimed effects are “antioxidant”, “antioxidative capacity”, “antioxidant properties”, “antioxidant activity”, “purifying/ detoxifying properties” and “antioxidant effect”. The Panel assumes that the target population is the general population.

In the context of the proposed wording, the Panel assumes that the claimed effect refers to the capacity of foods/food constituents to scavenge free radicals and/or to their reducing capacity.

The Panel considers that claims made on the antioxidant capacity/content or properties of foods/food constituents based on their capability of scavenging free radicals in vitro refer to a property of the food/food constituent measured in model systems, and that the information provided does not establish that this capability as such exerts a beneficial physiological effect in humans.

The Panel considers that no evidence has been provided to establish that having antioxidant activity/content and/or antioxidant properties is a beneficial physiological effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of this opinion and a beneficial physiological effect related to antioxidant activity, antioxidant content or antioxidant properties.

1.3. Protection of DNA, proteins and lipids from oxidative damage (ID 1196, 1211, 1216, 1306, 1312, 1440, 1441, 1666, 1668, 1692, 1900, 1914, 1948, 2023, 2158, 2517, 2522, 2527, 2575, 2591, 2620, 2637, 2639, 2663, 2860, 3079, 3276, 3564, 3818, 4324, 4329, 4351, 4397, 4416, 4424, 4507, 4527, 4528, 4542, 4611, 4629, 4659)

The claimed effects refer to the protection of body cells and molecules (such as DNA, proteins and lipids) from oxidative damage, including UV-induced oxidative damage. The Panel assumes that the target population is the general population.

Reactive oxygen species (ROS) including several kinds of radicals are generated in biochemical processes (e.g. respiratory chain) and as a consequence of exposure to exogenous factors (e.g. radiation, pollutants). These reactive intermediates can damage molecules such as DNA, proteins and lipids if they are not intercepted by the antioxidant network which includes free radical scavengers such as antioxidant nutrients.

The Panel considers that protection of DNA, proteins and lipids from oxidative damage may be a beneficial physiological effect.

1.4. Bioavailability of anthocyanins in black currants (ID 4220)

The claimed effect is “Les antioxydants du cassis (anthocyanines) sont assimilés par l'organisme. Ils sont ensuite excrétés dans les urines”. The Panel assumes that the target population is the general population.

The Panel assumes that the claimed effect refers to the bioavailability of the food constituent (“anthocyanins in black currant”).

Regulation (EC) No 1924/2006 defines health claims made on foods 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” (Article 2.5), whereas that “the nutrient or other substance for which the claim is made is in a form that is available to be used by the body” (Article 5.1(c)) is a general condition for all claims.

The Panel considers that the claim refers to the bioavailability of the food constituent rather than to a relationship between the food constituent and health as required by Regulation (EC) No 1924/2006.

2. Scientific substantiation of the claimed effect

2.1. Protection of DNA, proteins and lipids from oxidative damage (ID 1196, 1211, 1216, 1306, 1312, 1440, 1441, 1666, 1668, 1692, 1900, 1914, 1948, 2023, 2158, 2517, 2522, 2527, 2575, 2591, 2620, 2637, 2639, 2663, 2860, 3079, 3276, 3564, 3818, 4324, 4329, 4351, 4397, 4416, 4424, 4507, 4527, 4528, 4542, 4611, 4629, 4659)

Most of the references provided addressed potential health effects of dietary antioxidants in general, or of foods/food constituents other than those for which the specific claims are proposed, and/or health outcomes other than the protection of body cells and molecules from oxidative damage. These health outcomes refer to the development or progression of acute or chronic diseases presumed to be associated with increased levels of oxidative stress (e.g. immune dysfunction/susceptibility to infections, cardiovascular diseases, cancer and degenerative diseases) where oxidative damage to cells or molecules has not been considered as an outcome. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

No human studies that investigated the effects of the consumption of the food(s)/food constituent(s) on reliable markers of oxidative damage to body cells or to molecules such as DNA, proteins and lipids have been provided in relation to any of the health claims evaluated in this opinion.

Some intervention studies in humans which investigated the effects of the consumption of the food(s)/food constituent(s) on the overall antioxidant capacity of plasma assessed by different methods have been provided. These methods include total reactive antioxidant potential (TRAP), trolox-equivalent antioxidant capacity (TEAC), ferric reducing ability of plasma (FRAP), oxygen radical absorbance capacity (ORAC) and ferrous oxidation-xylenol orange (FOX). The Panel considers that the evidence provided in these studies does not predict the occurrence of an effect of the consumption of the food(s)/food constituent(s) on the protection of body cells and molecules from oxidative damage (Griffiths et al., 2002; Mayne, 2003; Dalle-Donne, et al., 2006; Knasmuller et al., 2008). A number of intervention studies assessed changes in antioxidant enzymes (e.g. superoxide dismutase (SOD), catalase (CAT), glutathione peroxidase (GPx), haemeoxygenase) and compounds (e.g. glutathion (GSH)) belonging to the antioxidant network system, or on HDL-associated paraoxonases (e.g. PON-1). The Panel notes that induction of antioxidant enzymes and HDL-associated paraoxonases provides an indication of response to oxidative stress, but it is non specific and does not reflect oxidative damage to cells or molecules (e.g. induction of antioxidant enzymes may also be achieved in response to the pro-oxidant effect of a dietary component) (Niki, 2009).

Some intervention studies in humans that have investigated the effects of the consumption of specific food(s)/food constituent(s) for which the claims are made on markers of lipid peroxidation were provided (ID 1196, 2620, 2860, 4528). Such markers are thiobarbituric acid-reactive substances (TBARS), malondialdehyde (MDA), conjugated dienes and/or oxidation lag time of low-density lipoproteins (LDL) *ex vivo*. The Panel considers that MDA (when used alone), and TBARS and conjugated dienes (when used either alone or in combination) are not reliable markers of lipid peroxidation (Griffiths et al., 2002; Lykkesfeldt, 2007; Knasmuller et al., 2008). The Panel also considers that no evidence has been provided to establish that the oxidation lag time of LDL particles *ex vivo* predicts the resistance of LDL particles to oxidation *in vivo* (Griffiths et al., 2002; Lapointe et al., 2006; Verhoye and Langlois, 2009).

Thus, for claims supported by references to human studies on the overall antioxidant capacity of plasma only, or on MDA/TBARS/conjugated dienes and/or oxidation lag time of LDL particles *ex vivo* as the only markers of lipid peroxidation, either alone or in combination with animal and/or *in*

vitro studies, the Panel considers that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) and the claimed effect.

A number of *in vitro* studies were provided which addressed the antioxidant properties of different food(s)/food constituent(s), either by testing their capacity to scavenge free radicals under controlled conditions or by testing their capacity to prevent or delay protein, lipid or DNA oxidation in different *in vitro* models. Also, studies were provided on the relationship between the consumption of the food(s)/food constituent(s) and the claimed effect by measuring markers of protein, lipid and/or DNA oxidation in animals, either *in vivo* or *ex vivo*. The Panel considers that the evidence provided in the animal and *in vitro* studies submitted is not sufficient to predict the occurrence of an effect of the consumption of the food(s)/food constituent(s) on the protection of body cells and molecules from oxidative damage *in vivo* in humans. The Panel considers that while effects shown in animal and *in vitro* studies may be used as supportive evidence, human studies are required for the substantiation of a claim. Thus, for claims supported by references to animal studies and/or *in vitro* studies only, the Panel considers that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) and the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of this opinion and the protection of DNA, proteins and lipids from oxidative damage.

CONCLUSIONS

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

Protection of cells from premature ageing (ID 1668, 1917, 2515, 2527, 2530, 2575, 2580, 2591, 2620, 3178, 3179, 3180, 3181, 4329, 4415)

- The claimed effects are “antioxidant”, “anti-cancer”, “anti-ageing”, “healthy ageing”, “antioxidant mainly due to phenolic compounds as well as high amounts of carotenoids and vitamin C and E” and “skin anti-ageing agent”. The target population is assumed to be the general population. The proposed wordings and clarifications provided by Member States include “lowers the ageing process”, “fighting oxidation induced ageing”, “fights against cellular ageing” and “protects the skin from the effects of premature ageing”.
- The claimed effect “anti-cancer” relates to the prevention of a human disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.
- No definition has been provided of “premature (skin) ageing”, “healthy ageing”, “oxidation-induced ageing” or “cellular ageing” in relation to the antioxidant properties of foods. These claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

Antioxidant activity, antioxidant content and antioxidant properties (ID 857, 1306, 2515, 2527, 2530, 2575, 2580, 2591, 2629, 2728, 4327, 4365, 4380, 4390, 4394, 4455, 4464, 4507, 4694, 4705)

- The claimed effects are “antioxidant”, “antioxidative capacity”, “antioxidant properties”, “antioxidant activity”, “purifying/ detoxifying properties” and “antioxidant effect”. The target population is assumed to be the general population. Claims made on the antioxidant capacity/content or properties of foods/food constituents based on their capability of scavenging free radicals *in vitro* refer to a property of the food/food constituent measured in model systems. The information provided does not establish that this capability as such exerts a beneficial physiological effect in humans. No evidence has been provided to establish that having antioxidant activity/content and/or antioxidant properties is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of this opinion and a beneficial physiological effect related to antioxidant activity, antioxidant content or antioxidant properties.

Protection of DNA, proteins and lipids from oxidative damage (ID 1196, 1211, 1216, 1306, 1312, 1440, 1441, 1666, 1668, 1692, 1900, 1914, 1948, 2023, 2158, 2517, 2522, 2527, 2575, 2591, 2620, 2637, 2639, 2663, 2860, 3079, 3276, 3564, 3818, 4324, 4329, 4351, 4397, 4416, 4424, 4507, 4527, 4528, 4542, 4611, 4629, 4659)

- The claimed effects refer to the protection of body cells and molecules (such as DNA, proteins and lipids) from oxidative damage, including UV-induced oxidative damage. The target population is assumed to be the general population. The protection of DNA, proteins and lipids from oxidative damage may be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of this opinion and the protection of DNA, proteins and lipids from oxidative damage.

Bioavailability of anthocyanins in black currants (ID 4220)

- The claimed effect is “Les antioxydants du cassis (anthocyanines) sont assimilés par l'organisme. Ils sont ensuite excrétés dans les urines”. The target population is assumed to be the general population.
- The claim refers to the bioavailability of the food constituent rather than to a relationship between the food constituent and health 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-2008-1644, EFSA-Q-2008-1935, EFSA-Q-2008-1949, EFSA-Q-2008-1954, EFSA-Q-2008-2043, EFSA-Q-2008-2049, EFSA-Q-2008-2177, EFSA-Q-2008-2178, EFSA-Q-2008-2402, EFSA-Q-2008-2404, EFSA-Q-2008-2428, EFSA-Q-2008-2633, EFSA-Q-2008-2647, EFSA-Q-2008-2650, EFSA-Q-2008-2681, EFSA-Q-2008-2756, EFSA-Q-2008-2891, EFSA-Q-2008-3248, EFSA-Q-2008-3250, EFSA-Q-2008-3255, EFSA-Q-2008-3260, EFSA-Q-2008-3263, EFSA-Q-2008-3308, EFSA-Q-2008-3313, EFSA-Q-2008-3324, EFSA-Q-2008-3353, EFSA-Q-2008-3362, EFSA-Q-2008-3370, EFSA-Q-2008-3372, EFSA-Q-2008-3396, EFSA-Q-2008-3461, EFSA-Q-2008-3593, EFSA-Q-2008-3811, EFSA-Q-2008-3910, EFSA-Q-2008-3911, EFSA-Q-2008-3912, EFSA-Q-2008-3913, EFSA-Q-2008-4008, EFSA-Q-2008-4290, EFSA-Q-2008-4535, EFSA-Q-2008-4930, EFSA-Q-2010-00277, EFSA-Q-2010-00280, EFSA-Q-2010-00282, EFSA-Q-2010-00304, EFSA-Q-2010-00318, EFSA-Q-2010-00333, EFSA-Q-2010-00343, EFSA-Q-2010-00347, EFSA-Q-2010-00350, EFSA-Q-2010-00368, EFSA-Q-2010-00369, EFSA-Q-2010-00377, EFSA-Q-2010-00408, EFSA-Q-2010-00417, EFSA-Q-2010-00460, EFSA-Q-2010-00480, EFSA-Q-2010-00481, EFSA-Q-2010-00495, EFSA-Q-2010-00564, EFSA-Q-2010-00582, EFSA-Q-2010-00612, EFSA-Q-2010-00647, EFSA-Q-2010-00658). 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 (EC) No 1924/2006 on nutrition and health claims made on foods⁷ (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 FOOD⁸

Foods are commonly involved in many different functions⁹ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

⁷ OJ L12, 18/01/2007

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

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

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

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

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

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

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

WORDING OF HEALTH CLAIMS

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

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

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

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

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

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

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

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target 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 various food(s)/food constituent(s) with antioxidant properties, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
857	Bioaktive Oligosaccharide, wie z. B. glykosylierte Phenylethanoide <u>Clarification provided</u> bioactive oligosaccharide, e.g. glucosylated phenylethanoides	Glykosylierte Phenylethanoide haben in vitro eine hohe antioxidative Kapazität gezeigt, die derjenigen von Vitamin E überlegen ist. <u>Clarification provided</u> Glucosylated phenylethanoides have in vitro a high antioxidant capacity (more effective than vitamin E)	[In german:] Bioaktive Oligosaccharide gehören zu den stärksten Radikalfängern Antioxidantien aus der Natur. Bioaktive Oligosaccharide fangen freie Radikale ab. <u>Clarification provided</u> Bioactive oligosaccharides are among the strongest natural radical scavenger/ natural antioxidants so that they can trap radicals effectively
	Conditions of use - none provided		
ID	Food or Food constituent	Health Relationship	Proposed wording
1196	Apple juice	Maintenance of cardiovascular system <u>Clarification provided</u> Antioxidant properties : increase resistance of low density lipoprotein against oxidation	Apple juice helps to maintain a healthy cardiovascular system <u>Clarification provided</u> Apple juice : - helps to maintain a healthy cardiovascular system - plays an important antioxidant function on cardiovascular system
	Conditions of use - 375 ml per day over 6 weeks		
ID	Food or Food constituent	Health Relationship	Proposed wording
1211	Fruits (fresh, frozen, canned, bottled, dried, juiced)	Protection of body tissues and cells from oxidative damage	-fruit protects the body's cells; -protects you from free radicals; -protects your cells and tissues from oxidation; -antioxidants help strengthen our body's natural defences against oxidative stress.
	Conditions of use - Significant presence of active substance. See conditions of use of claims concerning other substances of fruit and vegetables (claims 330, 361, 410, 423) - 5 a day (80g = 1 portion; only one portion can be juice at 150ml) - At least 400 g/day of fruit and vegetables, at least 5 portions/day		

ID	Food or Food constituent	Health Relationship	Proposed wording
1216	Vegetables (fresh, frozen, canned, bottled, dried, juiced)	Protection of body tissues and cells from oxidative damage	-vegetables help protect the body's cells; -protect you from free radicals; -protect your cells and tissues from oxidation; -antioxidants help strengthen our body's natural defences against oxidative stress; -people should consume a wide variety of fruits and vegetables, choosing among colours present in nature, to incorporate the various phytochemical and maximise protection; -Brassica vegetables (e.g. X) provide particular protection against oxidation.
			<p>Conditions of use</p> <ul style="list-style-type: none"> - Significant presence of active substance. See conditions of use of claims concerning other substances of fruit and vegetables (claims 330, 361, 410, 423) - Drinks containing 150ml vegetable juice per serving
ID	Food or Food constituent	Health Relationship	Proposed wording
1306	Antioxidant from processed fruits and vegetables and juices	Antioxidant properties	Antioxidant contained in this product contribute to the anti-oxidative functions of the body/ensure protective effect on the organism
			<p>Conditions of use</p> <ul style="list-style-type: none"> - possible if one of the other claims concerning a specific antioxidant is acceptable
			<p>No clarification provided by Member States</p> <p>Comments from Member States</p> <p>Claims 1439 is identical and was accepted by EFSA: that is clarification was not required.</p>
ID	Food or Food constituent	Health Relationship	Proposed wording
1312	Brassicaceae (Cruciferae) (Common Name : Botanical family that include broccoli, couiflower, cabbage, Bruxelles sprouts etc.)	Antioxidant activity	Are particularly rich of protective compounds that protect cells and DNA from oxidative damage/are particularly rich of compounds that help our body to eliminate toxic substances
			<p>Conditions of use</p> <ul style="list-style-type: none"> - Plant / Consumed as regular food. > 1/2 cup (serving) per day = 3-4 servings per week (see Ada position paper in the references list, p.816).

ID	Food or Food constituent	Health Relationship	Proposed wording
1440	Antioxidants <u>Clarification provided</u> Antioxidants (Source of antioxidants from the list of health claims given a positive opinion by EFSA)	Heart Health <u>Clarification provided</u> (Antioxidant properties - contributes to the protection from damaging free radicals. Helps prevent/reduce oxidation of LDL, helping to maintain a health heart.)	Inclusion of antioxidants in the diet may help maintain a healthy heart <u>Clarification provided</u> Inclusion of antioxidants in the diet may help maintain a healthy heart
	Conditions of use - Inclusion of fortified products in a healthy diet		
ID	Food or Food constituent	Health Relationship	Proposed wording
1441	Antioxidant substance <u>Clarification provided</u> Antioxidants (from fruits, vegetables and processed fruits and vegetables and juices; vitamins as vitamins C and E; minerals as selenium; polyphenols from fruits, vegetables and processed fruits and vegetables and juices)	Protects against damage caused by free radicals and other reactive oxygen species	Antioxidants protect cells from the harmful/ damaging effects of free radicals. Antioxidants protect against oxidation, which causes cell damage. Contains antioxidants.
	Conditions of use - As per the dosages listed for the various antioxidant food substances, vitamins and minerals, approved by EFSA under Article 13 of the Nutrition Health Claims Regulation for health claims based on generally accepted scientific evidence. - Possible if one of the other claims concerning a specific antioxidant is acceptable		
	Comments from Member States As per the dosages listed for the various antioxidant food substances, vitamins and minerals, approved by EFSA under Article 13 of the Nutrition Health Claims Regulation for health claims based on generally accepted scientific evidence.		
ID	Food or Food constituent	Health Relationship	Proposed wording
1666	Tomato extract, grape seeds extract, vitamin C and E, Selenium (Seresis Pharmaton) <u>Clarification provided</u> Standardized tomato extract [Oleoresin extracted from ripe fruits of <i>Lycopersicon esculentum</i> , solvent of extraction Ethyl acetate, 5% lycopene; Standardized grape seed extract [dry extract from grape seeds of <i>Vitis vinifera</i> L. (Vitaceae), solvent of extraction acetone/water 8.5-13.0%	Antioxidant combination, for antioxidant protection system	scientifically proven mix of naturally occurring antioxidants that work in synergy helping to protect cells from free radical damage scientifically proven to help maintaining a good level of vitamins and antioxidants in the whole body for maintenance and functions of cells (scientifically proven with product-related studies)

	proanthocyanidins], vitamin C and E, Selenium + Beta-carotene (Seresis Pharmaton)		
Conditions of use - Target groups: Adults . Applicable to products which contain following daily dosage ranges: Vitamin C: 60-120 mg, Selenium: 25-50 mcg, Vitamin E: 6.7-13.4 mg, Beta-carotene: 2.4-4.8 mg, Tomato extract standardized to 5% lycopene (25-50 mg / day), Grape seed extract standardized 5 - 20% proanthocyanidins (25-50 mg / day)			
ID	Food or Food constituent	Health Relationship	Proposed wording
1668	Tomato extract, grape seeds extract, vitamin C and E, Selenium (Seresis Pharmaton)	Skin anti-ageing agent <u>Clarification provided</u> Supports the protection of the skin from premature ageing /environmental stress by acting as an antioxidant (decreasing oxidative damage, increasing the concentration of antioxidants in the skin and the blood and reducing the concentration of collagen degrading enzymes)	Helps to improve general ageing process, protecting skin from environmental stress, scientifically proven to help protecting the skin from premature ageing
Conditions of use - Target groups: Adults, Applicable to products which contain following daily dosage ranges: Vitamin C: 60-120 mg, Selenium: 25-50 mcg, Vitamin E: 6.7-13.4 mg, Beta-carotene: 2.4-4.8 mg, Tomato extract standardized to 5% lycopene (25-50 mg / day), Grape seed extract standardized 5 - 20% proanthocyanidins (25-50 mg / day)			
ID	Food or Food constituent	Health Relationship	Proposed wording
1692	Bioalfa plus e biogenina, associati a sostanze antiossidanti (quercitina, zinco e rame) [1] <u>Clarification provided</u> Bioalfa plus and biogenina, associated to antioxidant agent (quercitine, zinc and copper) [1]	Interazione con ossidanti <u>Clarification provided</u> Interaction with antioxidant	Contrastano gli effetti nocivi dei radicali liberi sul bulbo del capello e controbuiscono a ridargli vitalità. <u>Clarification provided</u> work against the negative effect of free radicals on the hair bulb revitalizing the hair
Conditions of use - 94,25 mg/tbl			
ID	Food or Food constituent	Health Relationship	Proposed wording
1900	Polyphenols from processed fruits and tea <u>Clarification provided</u> Polyphenols (catechins, epicatechins, epigallocatechin, anthocyanins, proanthocyanidins and other flavonoids, tannins	Antioxidant Properties (namelly reduces celular oxidative stress)	Protects the cells; Antioxidant Properties; With Natural Fruit and Tea Antioxidants

	and phenolic acids) from processed fruits (grape, pomegranate and others), berries (blackberry, cranberry, strawberry, lignoberry and blueberry) and tea (Camelia sinensis)		
<p>Conditions of use</p> <ul style="list-style-type: none"> - Min. 150mg of polyphenols expressed in EAG - equivalent to 25% of the daily intake needs 			
<p>Comments from Member States</p> <p>This proposal is closely related with other health claims submitted by other Member States, MS, referred in the same consolidated list and already accepted by EFSA with no comment from this Authority, namely:</p> <p>Main Entry # 1103 (27 similar health relationships submitted), particularly COM ID 15766 and 51366, from DE and UK, respectively; Main Entry # 1184, COM ID 60951 from FI; Main Entry # 1186, COM ID 60950 from FI; Main Entry # 1201 (2 similar health relationship submitted), particularly COM ID 61458 and 63455, from FR and HU; Main Entry # 1319, COM ID 63243 MS GR; Main Entry # 1439 (19 similar health relationship submitted), particularly COM ID 63901 and 51057, from IT and UK, respectively; Main Entry # 1636 (4 similar health relationship submitted), particularly COM ID 64375, 52255, 79215 and 62403, from IT, UK, PT and FR, respectively; Main Entry # 1643 (3 similar health relationship submitted), particularly COM ID 63451 and 52257, from HU and UK, respectively; Main Entry # 2059, COM ID 52100, from UK, and</p> <p>Main Entry # 2060 (3 similar health relationship submitted), particularly COM ID 51779, 61210 and 63457, from UK, FI and HU, respectively.</p> <p>The health relationship between “Antioxidant Properties (namely reduces cellular stress)” and the food that is subject of the claim is largely accepted and well supported by scientific evidences, as documented in scientific references already cited by the applicant or referred in the above mentioned entries.</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
1914	Lutein;/Zeaxanthin	Antioxidant	Due to the antioxidant properties lutein/ zeaxanthin/ contributes to the hindrance of harmful oxidative processes in the body, in this way to the maintenance of our health/ to the defence of the tissues.
<p>Conditions of use</p> <ul style="list-style-type: none"> - 2 mg in the daily portion of the product (average intake). 			
ID	Food or Food constituent	Health Relationship	Proposed wording
1917	Antioxidants <u>Clarification provided</u> Antioxidants (Source of antioxidants from the list of health claims given a positive opinion by EFSA)	Skin Anti-ageing <u>Clarification provided</u> Contributes to the protection against skin ageing. Contributes to the protection against skin ageing due to the sun	Inclusion of antioxidants in the diet may help protect the skin from the effects of ageing
<p>Conditions of use</p>			

ID	Food or Food constituent	Health Relationship	Proposed wording
- Inclusion of fortified products in a healthy diet			
1948	caroténoïdes	antioxydant	caroténoïdes comme le bêta-carotène, le lycopène et la lutéine sont des anti-oxydants protecteurs des lipides des couches profondes
Conditions of use bêta-carotène: 2mg/j, lutéine 2mg/j et lycopène 1mg/j			
No clarification provided by Member States			
ID	Food or Food constituent	Health Relationship	Proposed wording
2023	Cherries (Prunus cerasus), including Montmorency, Balaton or other sour/tart cherry varieties	Cardiovascular / heart health support <u>Clarification provided</u> Cardiovascular health: Reduces LDL-oxidation through antioxidant activity	[Tart/sour] cherries help support a healthy heart
Conditions of use - Variable, depending on formulation e.g. concentrate for dilution in water (typically 30 ml per day) or freeze-dried extract (typically, 1-2 capsules daily)			
ID	Food or Food constituent	Health Relationship	Proposed wording
2158	Vitis vinifera (Common Name : Grape)	Skin health/Antioxidative properties <u>Clarification provided</u> Antioxidant. May help protect the skin from free-radical damage	Helps improve the overall health and appearance of the skin
Conditions of use - owoc, liście, nasiona/ zwykle konsumowane jako tradycyjny artykuł żywnościowy w normalnej diecie/ równowartość 5g liścia na dzień - Fruit, leaf, seed / Usual consumption as traditional foodstuff in a normal diet / The equivalent of 5 g of leaf per day			
ID	Food or Food constituent	Health Relationship	Proposed wording
2515	Ballote <u>Clarification provided</u> Ballota nigra (Black horehound) flowering top	Anti-oxidant <u>Clarification provided</u> Antioxidant	Combat la formation des radicaux libres A utiliser pour se protéger des radicaux libres Lutte contre le vieillissement A utiliser en tant que piègeur de radicaux libres Anti-oxidant <u>Clarification provided</u> acts against age-accelerating free radicals/ serves as a protective antioxidant/has antioxidative properties

	Conditions of use - Fleur et tige - 5-10g/jour		
ID	Food or Food constituent	Health Relationship	Proposed wording
2517	Bardane racine	Anti-inflammatoire/anti-oxidant de la peau	Combat la formation des radicaux libres Soulage les douleurs inflammatoires Apaie les inflammations de la peau Participe à la santé de la peau
	Conditions of use - Racine - 6x220mg/jour		
	No clarification provided by Member States		
ID	Food or Food constituent	Health Relationship	Proposed wording
2522	Carotte racine <u>Clarification provided</u> Daucus carota (root) (Common Name: Carrot)	Anti-oxidant Photoprotection <u>Clarification provided</u> Antioxydant / Photoprotection: root contains pigments (beta-caroten) that have antioxidant properties and that protects the skin from photooxidative stress	Combat la formation des radicaux libres Protection cellulaire active Nourrit et protège la peau Protège la peau des agressions extérieures Active et prolonge le bronzage <u>Clarification provided</u> Helps to keep the skin healthy/helps to retard skin aging Helps to protect your skin from excessive UV-radiation and sunburns Can promote healthy skin pigmentation and tanning Antioxydant that protects the body's cells/Has an antioxidant action that helps to neutralize free radicals and counteracts cellular ageing
	Conditions of use - Racine - 3600µg vitamine a/jour		
ID	Food or Food constituent	Health Relationship	Proposed wording
2527	Christe marine <u>Clarification provided</u> Crithmum maritimum (Seafennel) plant	Anti-oxidant <u>Clarification provided</u> Antioxydant	Combat la formation des radicaux libres <u>Clarification provided</u> acts against age-accelerating free radicals/ serves as a protective antioxidant/has antioxidative properties
	Conditions of use		

ID	Food or Food constituent	Health Relationship	Proposed wording
	- Plante - 6x220mg/jour		
2530	Chrysanthellum americanum <u>Clarification provided</u> Chrysanthellum americanum (syn.: Chrysanthellum indicum) flowering top	Anti-oxidant <u>Clarification provided</u> Antioxidant	Combat la formation des radicaux libres <u>Clarification provided</u> acts against age-accelerating free radicals/ serves as a protective antioxidant/has antioxidative properties
	Conditions of use - Plante - 6x200mg/jour		
ID	Food or Food constituent	Health Relationship	Proposed wording
2575	Prêle <u>Clarification provided</u> Equisetum arvense (horsetail) green and sterile areal stems	Anti-oxidant <u>Clarification provided</u> antioxidant properties	Combat la formation des radicaux libres Lutte contre le vieillissement cellulaire A utiliser pour se protéger des radicaux libres <u>Clarification provided</u> Helps maintain cognitive functions in elderly thanks to its antioxidant action/Antioxidant that protects the body's cells/Has an antioxidant action that helps to neutralize free radicals and counteracts cellular ageing.
	Conditions of use - Plante - 6x200mg/jour		
ID	Food or Food constituent	Health Relationship	Proposed wording
2580	Sauge sclarée plante	Anti-oxidant	Combat la formation des radicaux libres Lutte contre le vieillissement cellulaire A utiliser pour se protéger des radicaux libres
	Conditions of use - Feuille - 6x150mg/jour		
	No clarification provided by Member States		
ID	Food or Food constituent	Health Relationship	Proposed wording
2591	Marjolaine feuille <u>Clarification provided</u> Origanum majorana (leaves)	Anti-oxidant <u>Clarification provided</u> Potent antioxidant/has a scavenging activity on superoxide anion radical	Combat la formation des radicaux libres A utiliser pour se protéger des radicaux libres Lutte contre le vieillissement Anti-oxidant

			<p><u>Clarification provided</u> Has an antioxidant action that helps to neutralize free radicals and counteracts cellular ageing/Antioxidant that protects the body's cells</p>
<p>Conditions of use - Feuille - 4g/jour en infusion</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
2620	<p>Argan <u>Clarification provided</u> Argania spinosa (argan oil) seeds oil</p>	<p>Anti-oxidant Anticancer <u>Clarification provided</u> Has an antiproliferative effect on human prostate cancer/has antioxydant properties/enhance the cancer prevention</p>	<p>Combat la formation des radicaux libres Lutte contre le vieillissement cellulaire Anti-oxidant A utiliser pour freiner la croissance cellulaire incontrôlée A utiliser afin de limiter la prolifération spontanée de cellules <u>Clarification provided</u> Helps prevent prostate troubles/contributes to the health of the prostate/helps to maintain a healthy prostate/helps to manage normal cell division/has antioxydant properties</p>
<p>Conditions of use - Huile - 3x500mg/jour</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
2629	Chataigné	Astringent, anti-oxidant	<p>Soutient la circulation Fortifie la circulation</p>
<p>Conditions of use - Bourgeon/feuille - 0,5 ml d'extrait à 5% de matière sèche</p>			
<p>No clarification provided by Member States</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
2637	Cranberry extract powder (Vaccinium macrocarpon)	natural antioxidant	<p>natural antioxidant, protect organism from oxidative damage, natural way to avoid risks caused by oxidation and peroxidation process</p>
<p>Conditions of use - Fruit. / Usual consumption als traditional foodstuff in a normal diet / The equivalent of mininum 15 ml of cranberry juice or 800 mg of cranberry solids per day - 500mg of cranberry powder per day</p>			

No clarification provided by Member States			
ID	Food or Food constituent	Health Relationship	Proposed wording
2639	blueberry extracts <u>Clarification provided</u> phenolic compounds of blueberry extract 'blueberry extracts	natural antioxidant	natural antioxidant, protect organism from oxidative damage, natural way to avoid risks caused by oxidation and peroxidation process
	Conditions of use - 18 mg of blueberry extract per day		
ID	Food or Food constituent	Health Relationship	Proposed wording
2663	extract of guarana (Paullinia cupana) <u>Clarification provided</u> guarana seeds {Paullinia cupana}'extract of guarana (Paullinia cupana) suggested conditions of use: Guarana showed {in vitro} an antioxidant effect even at low concentrations (1.2 microg/ml)	natural antioxidant	natural antioxidant, protect organism from oxidative damage, powerful antioxidants beneficial to human health
	Conditions of use - contains 10% of coffein		
ID	Food or Food constituent	Health Relationship	Proposed wording
2728	Grapefruit (Citrus paradisi Mact. = C. decumana L., C. grandis Osbeck ; Citrus maxima)	Purifying/ detoxifying properties	May help the detoxification process. Possesses antioxidant activity. Can be considered as a detoxifying / purifying agent, due to its antioxidant properties. Provides antioxidant protection.
	Conditions of use - Peel, At least 80 mg of peel per day		
ID	Food or Food constituent	Health Relationship	Proposed wording
2860	Mangosteen (Garcinia mangostana L) fruits and extracts derived from the fruits	Antioxidant	Mangosteen whole fruit juice/concentrate contains antioxidants - [which may neutralise the damaging effects of free radicals in the body] - [which contribute to the total antioxidant capacity within the body] - [which offer protection from oxidative effects/damage within the body

	<p>Conditions of use</p> <p>- Typical adult dosage: 30-100 ml daily of whole fruit juice.</p>		
	<p>No clarification provided by Member States</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
3079	<p>Schwarzer Holunderbeersaft (Sambucus nigra)–CIAA Nr. 711</p> <p><u>Clarification provided</u></p> <p>Elderberry juice (Sambucus nigra)</p>	<p>Antioxidative Wirkung</p> <p><u>Clarification provided</u></p> <p>Antioxidant effect</p>	<p>Schwarzer Holunderbeersaft stärkt die körpereigenen Abwehrkräfte. —Schwarzer Holunderbeersaft schützt die Körperzellen</p> <p><u>Clarification provided</u></p> <p>Elderberry juice boots the body's own defensive mechanism. Elderberry juice protects the body's cells.</p>
	<p>Conditions of use</p> <p>- 400 ml Saft, einmalig</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
3178	xanthohumol enriched hop extract	anti - ageing	The antioxidative properties of Xanthohumol strengthen body cells in fighting oxidation induced aging
	<p>Conditions of use</p> <p>- wellness drink / RDA 10mg</p>		
	<p>No clarification provided by Member States</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
3179	Hop extract containing xanthohumol	anti - ageing	The antioxidative properties of Xanthohumol strengthen body cells in fighting oxidation induced aging
	<p>Conditions of use</p> <p>- wellness drink / RDA 10mg</p>		
	<p>No clarification provided by Member States</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
3180	xanthohumol	anti - ageing	The antioxidative properties of Xanthohumol strengthen body cells in fighting oxidation induced aging
	<p>Conditions of use</p> <p>- wellness drink / RDA 10mg</p>		
	<p>No clarification provided by Member States</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
3181	Hop extract	anti - ageing	The antioxidative properties of Xanthohumol strengthen body cells in fighting

			oxidation induced aging
Conditions of use			
- wellness drink / RDA 10mg			
No clarification provided by Member States			
ID	Food or Food constituent	Health Relationship	Proposed wording
3276	Brassicaceae (Cruciferae) (nazwa powszechnie stosowana: rodzina roślin kapustowatych (krzyżowych)) <u>Clarification provided</u> Brassicaceae (Cruciferae) (nazwa powszechnie stosowana: rodzina roślin kapustowatych (krzyżowych))/ (Brassicaceae (Cruciferae) (Common name: Botanical family that include broccoli, couliflower, cabbage, Bruxelles sprouts etc.)	aktywność antyoksydacyjna <u>Clarification provided</u> aktywność antyoksydacyjna/ Antioxidant activity	Zawiera antyoksydanty (przeciwutleniacze)/ źródło antyoksydantów (przeciwutleniaczy)/ z antyoksydantami (przeciwutleniaczami)/ szczególnie bogate w składniki chroniące komórki oraz DNA przed uszkodzeniem oksydacyjnym/ szczególnie bogate w składniki pomagające w eliminowaniu substancji niekorzystnych z organizmu <u>Clarification provided</u> Contains antioxidants/ source of antioxidants/ with antioxidants/ Are particularly rich in protective compounds that protect cells and DNA from oxidative damage/ are particularly rich in compounds that help our body to eliminate toxic substances.
	Conditions of use		
- roślina/ Konsumowana jako artykuł żywnościowy.>1/2 szklanki (dawki) na dzień = 3-4 dawek na tydzień (zob.: dokument Ada z listy referencyjnej strona 816)			
ID	Food or Food constituent	Health Relationship	Proposed wording
3564	RUTA GRAVEOLENS L.	Can protect cells and tissues against oxidative damage	Increases the physiological resistance of the organism in case of severe ambience conditions.
	Conditions of use		
	- 0.5-1 g of the herb daily or 65 mg of the essential oil; tea: one teaspoon dried leaves and stems in 1 cup of water		
No clarification provided by Member States			
ID	Food or Food constituent	Health Relationship	Proposed wording
3818	SCHISANDRA CHINENSIS BAILL.	Can protect cells and tissues against oxidative damage	Increases the physiological resistance of the organism in case of severe ambience conditions.
	Conditions of use		
- 400-450 mg powdered herb cps three times daily or 1-2 ml of 1:3 EtOH tincture three			

ID	Food or Food constituent	Health Relationship	Proposed wording
			times daily
4220	fruits, cassis, antioxydants	Les antioxydants du cassis (anthocyanines) sont assimilés par l'organisme. Ils sont ensuite excrétés dans les urines	les antioxydants naturels du cassis sont bien assimilés / Le cassis contient des antioxydants assimilables
Conditions of use			
- cassis en baies entières ou en jus : minimum 100g de baies ou 200 ml de jus			
No clarification provided by Member States			
ID	Food or Food constituent	Health Relationship	Proposed wording
4324	Bacopa monnieri WHOLE PLANT	Antioxydant	Contains a high amount of naturally occurring antioxidants. Antioxidants help protect you from radicals which can cause cell damage in the brain. Antioxidants help protect the cells and tissues of your brain from oxidative damage
Conditions of use			
- Powder: 1.0 -0.05g/day; aqueous extract 0.25-0.02 g/day. All over 2 years old: 2-4 years ¼ adult dose, 4-10 years half adult dose			
ID	Food or Food constituent	Health Relationship	Proposed wording
4327	Rose Hip Rosa Canina L	Antioxydant properties	Rose hip is rich in the antioxidants vitamin C and polyphenols
Conditions of use			
- The daily recommended dose can be reached in a single or multiple administrations			
ID	Food or Food constituent	Health Relationship	Proposed wording
4329	Emblica officinalis (common name : Amla)	Healthy ageing	-Helps to promote healthy ageing -Helps to protect from oxidative cell /DNA damage
Conditions of use			
- 500-750 mg of fruit extracts			
ID	Food or Food constituent	Health Relationship	Proposed wording
4351	Amaranthus caudatus- Herba-Amaranth-	Antioxydant Activity	Shows antioxidative effects and help protect the cells against oxidative stress / helps protect you from radicals
Conditions of use			
- Herba / Usual consumption as traditional foodstuff in a normal diet./ The equivalent of 1,8 -3,6 g per day.			
ID	Food or Food constituent	Health Relationship	Proposed wording
4365	Betonica officinalis-herb- Lamiaceae-Crețisor-Wood	Antioxydant Activity	help strenghten the body`s natural defence

	Betony		
	Conditions of use - the equivalent of 4 g herb powder per day		
ID	Food or Food constituent	Health Relationship	Proposed wording
4380	Chelidonium majus-leafs-Papaveraceae-Rostopască-Greater Celandine	Antioxidant Activity	contributes to the total antioxidant capacity of the body
	Conditions of use - the equivalent of 2 g herb powder per day		
ID	Food or Food constituent	Health Relationship	Proposed wording
4390	Cordyceps sinensis-fungus larvae-mycelium	Antioxidant due to polysaccharides content	Free radicals neutralisation actions.
	Conditions of use - 400 – 800 mg / day		
ID	Food or Food constituent	Health Relationship	Proposed wording
4394	Cuscuta chinensis-Chinese dodder-seeds	Antioxidant effect due to flavonoids	Antioxidant effect
	Conditions of use - 50 - 100 mg cuscuta extract / day		
ID	Food or Food constituent	Health Relationship	Proposed wording
4397	Eclipta alba-aerial parts-Trailing eclipta plant, Bhringaraj	Antioxidant Activity	Protect tissue from injuries
	Conditions of use - 4–12 ml leaf tea; 3–6 g powdered herb; 13–36 g for decoction.		
ID	Food or Food constituent	Health Relationship	Proposed wording
4415	Hippophae rhamnoides-berry-oil-Sea buckthorn berry oil	Antioxidant mainly due to phenolic compounds as well as high amounts of carotenoids and vitamins C and E.	Lowers the ageing process.
	Conditions of use - 300 – 1800 mg sea buckthorn oil per day		
ID	Food or Food constituent	Health Relationship	Proposed wording
4416	Hordeum vulgare-Herba – Barley	Antioxidant Activity	Protection of body tissues and cells from oxidative damage.
	Conditions of use - Herba / Usual consumption as traditional foodstuff in a normal diet./ The equivalent of 2,5 – 3 ml per day.		
ID	Food or Food constituent	Health Relationship	Proposed wording
4424	Juglans regia-Buds-Walnut	acting as radical scavengers in the protection of skin cells	Helps maintain healthy skin/epithelial layer
	Conditions of use		

	- Buds / Usual consumption as traditional foodstuff in a normal diet / The equivalent of 120 mg per day.		
ID	Food or Food constituent	Health Relationship	Proposed wording
4455	Origanum vulgare-oregano-leaves	Antioxidant properties due to phenolic compounds, especially rosmarinic acid	Antioxidant
	Conditions of use - 100 - 200 mg/ day, oregano extract		
ID	Food or Food constituent	Health Relationship	Proposed wording
4464	Polygonum cuspidatum-Japanese knotweed rootss and stems	Antioxidant due to stilbene compound resveratrol	Antioxidant / Protects from free radicals
	Conditions of use - 5-60 mg extract standardized at 50% trans-resveratrol /day		
ID	Food or Food constituent	Health Relationship	Proposed wording
4507	Withania somnifera-roots-Ashwagandha, Winter cherry	Antioxidant Activity	Protect tissue from injuries/ Protect the general health by antioxidant activity
	Conditions of use - 3-6 g dry powdered root/day		
ID	Food or Food constituent	Health Relationship	Proposed wording
4527	Camellia sinensis folium, Ginkgo biloba folium, Hibiscus sabdariffa flos, Hippophae rhamnoides fructus, Rosa canina fructus, Theobroma cacao fructus, Mentha piperita herba, Aspalathus linearis folium (tea bush leaves, ginkgo leaves, red sorrel flowers, sea buckthorn fruits, wild dog rose fruits, cacao seed, peppermint herb, rooibos leaves)	Helps to protect from oxidative stress because of polyphenols, catechines, flavanols and vitamin C, constituents present in this plants combination.	helps to protect from oxidative stress / helps to protect the body from free radicals
	Conditions of use - To make an infusion, use 1 teabag (1,5 gr) per cup (200 ml water). Children over 14 years and adults will take 1 cup with tea 3-4 times a day.		
ID	Food or Food constituent	Health Relationship	Proposed wording
4528	Camellia sinensis folium, Ilex paraguariensis folium (tea bush leaves, mate leaves)	Helps to protect from oxidative stress because of polyphenols and catechines, constituents present in the plants combination.	helps to protect from oxidative stress / helps to protect the body from free radicals
	Conditions of use - May be taken 1 capsule (420 mg) 3 times a day		

ID	Food or Food constituent	Health Relationship	Proposed wording
4542	Citrus reticulata pericarpum, Camellia sinensis leaves, Rosa canina fructus, Hibiscus sabdariffa flos (mandarin rind, tea bush leaves, rosehip fruits, red sorrel flowers)	Helps to protect the body from free radicals because of catechins, polyphenols and ascorbic acid, constituents present in plant combination.	helps to protect from oxidative stress / helps to protect the body from free radicals
	Conditions of use - To make an infusion, use 1 teabag (2 gr) per cup (200 ml water). The infusion may be taken 1 cup with tea 3-4 times a day		
ID	Food or Food constituent	Health Relationship	Proposed wording
4611	Q10 with Sea Buckthorn Oil, Q 10, Hippophae oleum, Q 10 , Hippophae oleum	antioxidant properties	Vitaminising / Has antioxidant properties and helps protect you from radicals which cause cell damage / Physical endurance, mental performance / Helps to protect heart health / Supports digestive and hepatic health/ Immune system health / Contributes to the resistance against stress.
	Conditions of use - Capsules / Usual consumption as traditional foodstuff in a normal diet./ The equivalent of 30 – 180 Q10 mg per day.		
ID	Food or Food constituent	Health Relationship	Proposed wording
4629	Taraxacum officinale, folium-Dandelion, leafs 40mg. , Betula pendula, leaves (European white Birch, leafs)50mg. , Viola tricolour, herba , (Johnny Jumpup , herbs) 50mg., Achillea millefolium, herba(Common Yarr) 40 mg-Urtica dioica, folium (Stinging nettle, leafs) 40 mg/cps	Antioxidant Activity	Support for membrane against the destructive actions of free radicals.
	Conditions of use - 6 capsules/day –2 capsules 3 times/day 1320 mg. herbs combination/day, min. 30 days		
ID	Food or Food constituent	Health Relationship	Proposed wording
4659	Bee pollen	Protection of the body against the free radicals damage / oxidative damage	Contains compounds with antioxidative action / Natural source of compounds with antioxidative action that helps maintain the optimum antioxidant status of the body
	Conditions of use - 10 – 30 g / day / about. 7 – 10 g for children /		

ID	Food or Food constituent	Health Relationship	Proposed wording
4694	Pollen-Bee pollen	Antioxidative agent due to vitamins and selenium content	Antioxidant activity.
	Conditions of use - 500 – 2000 mg/day.		
ID	Food or Food constituent	Health Relationship	Proposed wording
4705	Garlic, Onion, Soy Protein Concentrate, Sodium Caseinate, Expanded Corn, Calcium carbonate, Magnesium Oxide, Zinc Oxide	Antioxidant Activity	complex of antioxidants / general stimulant
	Conditions of use - 2-3 servings of 1-2 capsules daily		

GLOSSARY AND ABBREVIATIONS

CAT	Catalase
DNA	Deoxyribonucleotide
FOX	Ferrous oxidation-xylenol orange
FRAP	Ferric reducing ability of plasma
GPx	Glutathione peroxidase
HDL	High-density lipoproteins
LDL	Low-density lipoproteins
MDA	Malondialdehyde
ORAC	Oxygen radical absorbance capacity
ROS	Reactive oxygen species
SOD	superoxide dismutase
TBARS	Thiobarbituric acid-reactive substances
TEAC	Trolox-equivalent antioxidant capacity
TRAP	Total reactive antioxidant potential