

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to *Camellia sinensis* (L.) Kuntze (tea), including catechins from green tea, and contribution to the maintenance or achievement of a normal body weight (ID 1107, 1112, 1544, 2716), increased beta-oxidation of fatty acids leading to a reduction in body fat mass (ID 1123, 1124, 3698), and maintenance of normal blood glucose concentrations (ID 1115, 1545) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

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 *Camellia sinensis* (L.) Kuntze (tea), including catechins from green tea, and contribution to the maintenance or achievement of a normal body weight, increased beta-oxidation of fatty acids leading to a reduction in body fat mass, and maintenance of normal blood glucose concentrations. 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/constituents that are the subjects of the health claims are *Camellia sinensis* Kuntze (tea), catechins present in green tea, epigallo-catechin-3-gallate (EGCG) and green tea extract rich in EGCG. The Panel considers that whereas *Camellia sinensis* (L.) Kuntze (tea) is not sufficiently

¹ On request from the European Commission, Question No EFSA-Q-2008-1846, EFSA-Q-2008-1851, EFSA-Q-2008-1854, EFSA-Q-2008-1862, EFSA-Q-2008-1863, EFSA-Q-2008-2281, EFSA-Q-2008-2282, EFSA-Q-2008-3449, EFSA-Q-2008-4421, adopted on 10 September 2010.

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characterised in relation to the claimed effects, catechins from green tea (including EGCG) are sufficiently characterised.

Contribution to the maintenance or achievement of a normal body weight

The claimed effects are “weight management/metabolism of lipids”, “weight management” and “control of weight”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to an increased oxidation of body fat leading to the loss of fat mass and body weight. The Panel considers that contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the only intervention study from which sufficient information was available for a scientific evaluation found no effect of EGCG consumption on body weight.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of catechins (including EGCG) from green tea (*Camellia sinensis* (L.) Kuntze) and contribution to the maintenance or achievement of a normal body weight.

Increased beta-oxidation of fatty acids leading to a reduction in body fat mass

The claimed effects are “resting metabolic rate and thermogenesis”, “fat metabolism” and “supports metabolism/fat oxidation”. The target population is assumed to be overweight individuals in the general population who wish to reduce their fat mass. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to an increased beta-oxidation of fat and fatty acids, which is a measurable outcome. The Panel considers that an increased beta-oxidation of fatty acids leading to a reduction in body fat mass is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed 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 catechins (including EGCG) from green tea (*Camellia sinensis* (L.) Kuntze) and an increased beta-oxidation of fatty acids leading to a reduction in body fat mass.

Maintenance of normal blood glucose concentrations

The claimed effects are “glucose metabolism” and “blood glucose levels”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal blood glucose concentrations. The Panel considers that long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed 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 catechins (including EGCG) from green tea (*Camellia sinensis* (L.) Kuntze) and the long-term maintenance of normal blood glucose concentrations.

KEY WORDS

Epigallo-catechin-3-gallate (EGCG), *Camellia sinensis*, catechins, green tea, body weight, beta-oxidation, fat mass, blood glucose, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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EFSA DISCLAIMER

See Appendix B

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ 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

1. Characterisation of the food/constituent

The food/constituents that are the subjects of the health claims are *Camellia sinensis* (L.) Kuntze, catechins present in green tea, epigallo-catechin-3-gallate (EGCG) and green tea extract rich in EGCG.

The plant *Camellia sinensis* (L.) Kuntze is an evergreen shrub of the Theaceae family. Tea is an extract of the dried leaves from *Camellia sinensis* (L.) Kuntze and it is usually prepared by infusing the leaves in hot water. The composition of the tea leaves depends on a variety of factors, including climate, season, horticultural practices, and the type and age of the plant. Many kinds of tea are produced, which can be classified into three major types according to the different degrees of fermentation: green (un-fermented), oolong (semi-fermented) and black (fully fermented) (Wang et al., 2000).

The composition of tea beverages greatly depends on the type of leaves used, on the degree of fermentation and on the methods of preparation (Kaszkin et al., 2004; Astill et al., 2001). The degree of fermentation, the production process and the method of preparing the tea infusion have not been described in relation to the claims.

Green tea contains polyphenolic compounds, which include flavanols, flavandiols, flavonoids and phenolic acids. Most of the polyphenols in green tea are catechins. Epigallo-catechin-3-gallate (EGCG) is the most abundant catechin in green tea. In black teas, the most abundant polyphenols are tannins, mainly theaflavin and thearubigin (Mukhtar and Ahmad, 2000). Tea extracts/infusions also contain variable amounts of potentially active food constituents, such as caffeine, theanine or theogallin.

Green tea catechins (including EGCG) can be measured in foods by established methods.

The Panel considers that whereas *Camellia sinensis* (L.) Kuntze (tea) is not sufficiently characterised in relation to the claimed effects, catechins from green tea (including EGCG) are sufficiently characterised.

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>

2. Relevance of the claimed effect to human health

2.1. Contribution to the maintenance or achievement of a normal body weight (ID 1107, 1112, 1544, 2716)

The claimed effects are “weight management/metabolism of lipids”, “weight management” and “control of weight”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to an increased oxidation of body fat leading to the loss of fat mass and body weight.

Weight management can be interpreted as contribution to the maintenance of a normal body weight. In this context a moderate weight loss in overweight subjects without achieving a normal body weight is considered to be a beneficial physiological effect.

The Panel considers that the contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.

2.2. Increased beta-oxidation of fatty acids leading to a reduction in body fat mass (ID 1123, 1124, 3698)

The claimed effects are “resting metabolic rate and thermogenesis”, “fat metabolism” and “supports metabolism/fat oxidation”. The Panel assumes the target population is overweight individuals in the general population who wish to reduce their fat mass.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to an increased beta-oxidation of fat and fatty acids, which is a measurable outcome. An increase in fat oxidation may lead to a decrease in body fat, which might be considered a beneficial physiological effect.

The Panel considers that an increased beta-oxidation of fatty acids leading to a reduction in body fat mass is a beneficial physiological effect.

2.3. Maintenance of normal blood glucose concentrations (ID 1115, 1545)

The claimed effects are “glucose metabolism” and “blood glucose levels”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal blood glucose concentrations.

The Panel considers that long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Contribution to the maintenance or achievement of a normal body weight (ID 1107, 1112, 1544)

A total of 48 references were cited in relation to the claimed effect. Twelve references were reviews on the mechanisms by which green tea catechins (GTCs) could exert the claimed effect, but provided no original data. Three references provided information on technological and quality aspects of green tea. Other references reported on the acute effects of green tea supplements on energy expenditure

and nutrient utilisation but did not report on body weight. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

Nine references provided data from human intervention studies on the effects of green tea catechins on weight management (Chan et al., 2006; Diepvens et al., 2006; Hase et al., 2001; Kovacs et al., 2004; Nagao et al., 2005, 2007; Takashi et al., 2002; Tsuchida et al., 2002; Westerterp-Plangtenga et al., 2005). The papers by Takashi et al. (2002) and Tsuchida et al. (2002) were published in the same Journal and the abstract contained the same information, so apparently referred to the same study.

All of these references with the exception of Takashi et al. (2002) have been considered in a recently published meta-analysis of randomised, double-blind, controlled trials (RCT) which investigated the effects of GTCs with or without caffeine on body weight (Phung et al., 2010).

A total of 15 trials (n=1,243) met the inclusion criteria for the meta-analysis by Phung et al. (2010). Of the 15 trials included, seven trials (n=600) evaluated GTCs with caffeine compared with a caffeine-matched control, six trials (n=524) evaluated GTCs with caffeine compared with a caffeine-free control, and two trials (n=119) evaluated caffeine-free GTCs compared with a caffeine-free control. The Panel notes that studies testing the effects of GTCs plus caffeine compared to a caffeine-free control do not allow conclusions to be drawn on the effects of GTCs alone because an interaction between GTCs and caffeine on the claimed effect cannot be excluded from the data provided. The Panel considers that no conclusions can be drawn from these studies or the meta-analysis by Phung et al. (2010) for the scientific substantiation of the claimed effect.

In a randomised, double-blind, placebo-controlled and parallel study, Takeshita et al. (2008) investigated the effects of GTCs on body weight in 81 healthy Japanese overweight and obese men (BMI \geq 25) who were randomly assigned to consume one bottle of sports drink per day containing decaffeinated green tea extract (548 mg GTC and 0 mg caffeine: catechin group, n=40), or one bottle of sports drink per day (0 mg of both GTCs and caffeine: placebo group, n=41) over 12 weeks. At the end of the study, body weight was significantly lower in the catechin group than in the placebo group. As only the abstract and tables in this publication were in English, and the full text was available in Japanese only, the Panel could not perform a complete evaluation of this study.

In a second randomised, double-blind, placebo-controlled and parallel study, Hill et al. (2007) randomised 42 overweight or obese post-menopausal women to consume either EGCG (300 mg/d) or placebo (lactose) twice daily for 12 weeks. Subjects were excluded if regular tea consumption exceeded three cups per day and/or habitual caffeine intake exceeded 300 mg per day. A total of 38 subjects completed the study (19 per group). Both groups were prescribed moderate physical exercise during the study (i.e. an exercise programme requiring running or walking for 45 minutes, three times per week at a heart rate which corresponded to 75 % of their age predicted maximum). No significant differences between groups were observed with respect to body weight changes (0.08 kg \pm 0.21 vs. -0.45 kg \pm 0.27, in the intervention *versus* the placebo groups, respectively).

In weighing the evidence, the Panel took into account that the only intervention study from which sufficient information was available for a scientific evaluation found no effect of EGCG consumption on body weight.

The Panel concludes that a cause and effect relationship has not been established between the consumption of catechins (including EGCG) from green tea (*Camellia sinensis* (L.) Kuntze) and contribution to the maintenance or achievement of a normal body weight.

3.2. Increased beta-oxidation of fatty acids leading to a reduction in body fat mass (ID 1123, 1124, 3698)

The references provided for the substantiation of this claim included narrative reviews on food constituents other than tea or tea catechins; narrative reviews on the health effects of oolong tea, green tea, and/or EGCG; human intervention studies which assessed the interaction between GTCs and caffeine on different outcomes including fat oxidation, but which did not provide original data; studies on the effects of oolong tea on energy expenditure and fat oxidation but which did not report on the catechin content of the study materials; and studies and reviews on the mechanisms by which tea/EGCG could mediate different effects, including an increase in fat oxidation.

Only one one-arm, open label intervention study in humans was provided which assessed the effects of a green tea extract containing 25 % EGCG on body weight and waist circumference in moderately obese subjects for three months (Chantre and Lairon, 2002). Changes in body fat were not reported. The Panel considers that no conclusions can be drawn from this uncontrolled study for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of catechins (including EGCG) from green tea (*Camellia sinensis* (L.) Kuntze) and an increased beta-oxidation of fatty acids leading to a reduction in body fat mass.

3.3. Maintenance of normal blood glucose concentrations (ID 1115, 1545)

A total of 46 publications were cited in relation to the claimed effect. Some of the references referred to animal and *in vitro* studies, or provided details about the metabolism and pharmacokinetics of catechins, whilst others reported on the association between dietary catechins and disease risk or disease prevention (e.g. type II diabetes, cardiovascular disease, liver disease, atherosclerosis and cancer) in observational (cohort) studies. Other references were reviews dealing with dietary sources of polyphenols and health-promoting properties of green tea unrelated to glucose metabolism. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

Only five of the human studies provided examined the effect of catechins from green tea on blood glucose. However, three of the studies (Fukino et al., 2005, 2008; Hosoda et al., 2003) included insulin-dependent or non-insulin dependent diabetic subjects on either insulin or oral anti-diabetic therapy. The Panel considers that the evidence provided in these studies does not predict the occurrence of an effect of GTCs on the long-term maintenance of normal blood glucose concentrations in the general population. Also, one of the studies investigated the effect of GTCs on post-prandial glycaemic and insulinaemic responses (Tsuneki et al., 2004). The Panel considers that no conclusions can be drawn from these measures in relation to the long-term maintenance of normal blood glucose concentrations.

In the study by Ryu et al. (2006), 55 type II diabetic patients (24 women) who were not regular tea consumers drank 900 mL of water containing 9 g of green tea daily and 900 mL of water alone for four weeks each following a randomised, cross-over design. The Panel notes that whilst it is not stated whether subjects were taking blood glucose lowering medications or not, an exclusion criterion was uncontrolled diabetes. The Panel also notes that green tea was not sufficiently characterised regarding its catechin content, and that fasting blood glucose concentrations are not a reliable marker of long-term blood glucose control. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of catechins (including EGCG) from green tea (*Camellia sinensis* (L.) Kuntze) and the long-term maintenance of normal blood glucose concentrations.

CONCLUSIONS

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

- The food, *Camellia sinensis* (L.) Kuntze (tea), which is the subject of the health claims, is not sufficiently characterised in relation to the claimed effects, whereas catechins from green tea (including EGCG) are sufficiently characterised.

Contribution to the maintenance or achievement of a normal body weight (ID 1107, 1112, 1544, 2716)

- The claimed effects are “weight management/metabolism of lipids”, “weight management” and “control of weight”. The target population is assumed to be the general population. Contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of catechins (including EGCG) from green tea (*Camellia sinensis* (L.) Kuntze) and contribution to the maintenance or achievement of a normal body weight.

Increased beta-oxidation of fatty acids leading to a reduction in body fat mass (ID 1123, 1124, 3698)

- The claimed effects are “resting metabolic rate and thermogenesis”, “fat metabolism” and “supports metabolism/fat oxidation”. The target population is assumed to be overweight individuals in the general population who wish to reduce their fat mass. An increased beta-oxidation of fatty acids leading to a reduction in body fat mass is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of catechins (including EGCG) from green tea (*Camellia sinensis* (L.) Kuntze) and an increased beta-oxidation of fatty acids leading to a reduction in body fat mass.

Maintenance of normal blood glucose concentrations (ID 1115, 1545)

- The claimed effects are “glucose metabolism” and “blood glucose levels”. The target population is assumed to be the general population. Long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of catechins (including EGCG) from green tea (*Camellia sinensis* (L.) Kuntze) and the long-term maintenance of normal blood glucose concentrations.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1846, EFSA-Q-2008-1851, EFSA-Q-2008-1854, EFSA-Q-2008-1862, EFSA-Q-2008-1863, EFSA-Q-2008-2281, EFSA-Q-2008-2282, EFSA-Q-2008-3449, EFSA-Q-2008-4421). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

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

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁶ (hereinafter "the Regulation") entered into force on 19th January 2007.

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

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

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

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

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

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

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

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁷

Foods are commonly involved in many different functions⁸ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

6 OJ L12, 18/01/2007

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

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

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

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

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

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

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

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

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

WORDING OF HEALTH CLAIMS

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

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

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

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

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

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

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

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

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

TERMS OF REFERENCE

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

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

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

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

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

consumed.

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

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

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

APPENDIX B

EFSA DISCLAIMER

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

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

APPENDIX C

Table 1. Main entry health claims related *Camellia sinensis* (L.) Kuntze (tea), including catechins from green tea, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1107	Camelia sinensis (Common Name : Tea)	Weight management/metabolism of lipids	<p>Helps with weight control.</p> <p>Stimulates the lipid degradation.</p> <p>Supports lipid metabolism</p> <p>Support of metabolism and fat oxidation</p> <p>Helps to enhance metabolism</p> <p>Contributes to fat oxidation</p> <p>Helps in weight control</p> <p>Contributes to metabolism, which in turn helps weight control</p> <p>Helps to reduce the appetite</p> <p>support of metabolism and fat oxidation</p>
<p>Conditions of use</p> <ul style="list-style-type: none"> - Amount of consumption: 115 Milligramm (mg)/Tag. Upper limit: 300 Milligramm (mg). - Blätter, Knospen / Äquivalent von mind. 150 mg Coffein, 115-270 mg EGCG und 375 mg Catechinen / Äquivalent von 240 mg Polyphenolen pro Tag - Leaf / Usual consumption as traditional foodstuff in a normal diet / The equivalent of minimum 150 mg caffeine, 115-270 mg EGCG, and 375 mg Catechins / The equivalent of 240 mg of polyphenols per day - Feuille 6x250 mg/jour - Monoprodukt oder Zutat einer Mischung, zur Zubereitung eines Heißaufgusses 			
ID	Food or Food constituent	Health Relationship	Proposed wording
1112	Catechins – Green tea (camellia sinensis)	Weight management	<p>Helps to control fat metabolism</p> <p>Helps to increase energy expenditure</p> <p>Helps to burn the fat</p> <p>Help to increase metabolic rate</p> <p>Helps to maintain healthy BMI</p> <p>Prevent cholesterol absorption</p> <p>Helps to prevent the accumulation of triglycerides</p> <p>Helps to prevent the fat accumulation</p>

	<p>Conditions of use</p> <ul style="list-style-type: none"> - Recommended dosage 400-600 mg catechins. Catechins are active and functional polyphenol components of green tea leaves. One cup (200 mL) of brewed green tea may contain 100-150 mg of catechins.or equivalent of 50-60mg of EGCG. The usual consumption of green tea is about 5-10 cups per day, which is equivalent to 500-1200 mg of catechins or 250-600 mg of EGCG per day. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
1115	Catechins – Green tea (camellia sinensis)	Glucose metabolism	<ul style="list-style-type: none"> - Help to maintain normal blood glucose levels; - Helps in healthy ageing; - Helps to protect insulin producing glands.
	<p>Conditions of use</p> <ul style="list-style-type: none"> - 84 mg/Tag; upper limit 386 mg; Aufgrund von Interventionsstudien kann ein tägl. Verzehr von 84-386 mg EGCG als angemessen für die Glucose - Homöostase angesehen werden. - 400-800 mg bei Herzgesundheit 1600 mg. - Recommended dosage 400-600mg - Catechins are active and functional polyphenol components of green tea leaves. - One cup (200ml) of brewed green tea may contain 100-150 mg of catechins.or equivalent of 50-60mg of EGCG. - The usual consumption of green tea is about 5-10 cups per day, which is equivalent to 500-1200 mg of catechins or 250-600 mg of EGCG per day. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
1123	Camellia sinensis Tea (Green, Oolong and Black Tea)	Resting metabolic rate and thermogenesis	<p>Camellia sinensis supports resting metabolic rate Camellia sinensis supports thermogenesis Camellia sinensis supports energy expenditure and fat oxidation</p>
	<p>Conditions of use</p> <ul style="list-style-type: none"> - The product must contain at least 200 milligrams. Camellia sinensis extract per serving and delivering at least 90 mg EGCG per serving. Claim to be used for foods for active individuals 		
ID	Food or Food constituent	Health Relationship	Proposed wording
1124	Green Tea	Fat metabolism	Green tea inhibits catechol-O-methyltransferase, an enzyme involved in the thermogenesis (burning) of body fat. Supports of metabolism and fat oxidation.
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Leaf/extract Usual consumption as traditional foodstuff in normal diet 		
ID	Food or Food constituent	Health Relationship	Proposed wording
1544	Epigallo-catechin-3-gallate (EGCG) / Green tea extract,	Weight management	Helps to maintain and control weight

	rich in EGCG		<p>Contributes to the reduction of body fat</p> <p>Helps to increase fat oxidation</p> <p>Helps to increase fat oxidation and to reduce body fat</p> <p>When combined with a healthy diet and exercise, can help to control weight</p>
<p>Conditions of use</p> <ul style="list-style-type: none"> - 115-300 mg per day - Number of nutrients/other substances that are essential to claimed effect: 1. Names of nutrient/other substances and Quantity in Average daily serving: 115mg EGCG. Weight of average daily food serving: 115 miligram(s). Daily amount to be consumed to produce claimed effect: 300 miligram(s). Number of food portions this equates to in everyday food portions: 5. Are there factors that could interfere with bioavailability: Yes. Please give reason: Do not store above 25 degrees C. Length of time after consumption for claimed effect to become apparent: indefinitely - 115-300 mg EGCG per day 			
ID	Food or Food constituent	Health Relationship	Proposed wording
1545	Epigallo-catechin-3-gallate (EGCG) / Green tea extract, rich in EGCG	Blood glucose levels	Help to maintain healthy blood glucose levels
<p>Conditions of use</p> <ul style="list-style-type: none"> - Based on intervention studies a daily intake of 84-386 mg EGCG in the field of glucose homeostasis can be regarded as adequate. 			
ID	Food or Food constituent	Health Relationship	Proposed wording
2716	Camellia sinensis - common name: tea	Control of weight	<ul style="list-style-type: none"> - Traditionally used to facilitate the weight loss in addition to dietetic measures; - Used to facilitate the weight loss in addition to dietetic measures; - Helps to loose weight in addition to dietetic measures; - Contributes to loose weight in addition to dietetic measures; - Helps to maintain the weight; - Contributes to maintain the weight; - Stimulates the lipid degradation;

			<ul style="list-style-type: none"> - Supports lipid metabolism; - Support of metabolism and fat oxidation; - Helps to enhance metabolism; - Contributes to fat oxidation; - Helps in weight control; - Contributes to metabolism, which in turn helps weight control.
<p>Conditions of use</p> <ul style="list-style-type: none"> - Traditional use of the leaf / Infusion: 2,5 g in 150 ml water, many times daily / Equivalent quantity in extract. 			
ID	Food or Food constituent	Health Relationship	Proposed wording
3698	Camelia sinensis (green tea)	Supports metabolism /fat oxidation	Natural green tea extract with EGCG helps to enhance metabolism/contributes to fat oxidation
<p>Conditions of use</p> <ul style="list-style-type: none"> - 40 mg leaf. Since green tea is consumed in the diet, the 40 mg is based on the "significant amount" of 15% of what is considered in the bulk of the literature to be 270 mg. The 15% is based on the same logic that the vitamin and mineral claims use that 15% of RDA is enough of the nutrient to make the link between the nutrient and the benefit. - 40 mg. Since green tea is consumed in the diet, the 40 mg is based on the "significant amount" of 15% of what is considered in the bulk of the literature to be 270 mg. The 15% is based on the same logic that the vitamin and mineral claims use that 15% of RDA is enough of the nutrient to make the link between the nutrient and the benefit. 			

GLOSSARY AND ABBREVIATIONS

BMI	Body mass index
EGCG	Epigallo-catechin-3-gallate
GTC	Green tea catechin
RCT	Randomised controlled trial