

## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to coffee, including chlorogenic acids from coffee, and protection of DNA, proteins and lipids from oxidative damage (ID 1099, 3152, 4301), maintenance of normal blood glucose concentrations (ID 1100, 1962), and contribution to the maintenance or achievement of a normal body weight (ID 2031, 4326) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>**

**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>**

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to coffee and protection of DNA, proteins and lipids from oxidative damage, maintenance of normal blood glucose concentrations, and contribution to the maintenance or achievement of a normal body weight. 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 foods/food constituents that are the subject of the health claims are coffee, *Coffea Arabica* L., chlorogenic acids from coffee, and antioxidants in coffee. The Panel considers that whereas coffee and antioxidants in coffee are not sufficiently characterised in relation to the claimed effects, chlorogenic acids from coffee are sufficiently characterised.

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<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-1838, EFSA-Q-2008-1839, EFSA-Q-2008-2695, EFSA-Q-2008-2764, EFSA-Q-2008-3884, EFSA-Q-2010-00254, EFSA-Q-2010-00279, adopted on 28 January 2011.

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

<sup>3</sup> Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Cardiovascular Health/Oxidative Stress: Antti Aro, Marianne Geleijnse, Marina Heinonen, Ambroise Martin, Wilhelm Stahl and Henk van den Berg. The members of the Claims Sub-Working Group on Weight Management/Satiety/ Glucose and Insulin Control/Physical Performance: Kees de Graaf, Joanne Harrold, Mette Hansen, Mette Kristensen, Anders Sjødin and Inge Tetens.

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### **Protection of DNA, proteins and lipids from oxidative damage**

The claimed effects are “protection of body tissues, lipids, cells and DNA from oxidative damage”, “oxidative stress reduction” and “coffee naturally contains antioxidants that may support the body’s natural cell defences”. 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.

The Panel considers that the human studies provided did not use suitable markers to assess oxidative damage *in vivo*. The Panel also notes that in most of the studies provided coffee was not sufficiently characterised in relation to the claimed effect, and that its content of chlorogenic acids was not reported. The Panel considers that evidence provided in *in vitro* studies is not sufficient to predict the occurrence of an effect of coffee consumption on protection of DNA, lipids or proteins from oxidative damage *in vivo* in humans.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of chlorogenic acids from coffee and protection of DNA, lipids or proteins from oxidative damage.

### **Maintenance of normal blood glucose concentrations**

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

The Panel considers that in the studies provided coffee was not sufficiently characterised in relation to the claimed effect, and/or that outcome measures were not appropriate to assess the long-term maintenance of normal blood glucose concentrations.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of chlorogenic acids in coffee and maintenance of normal blood glucose concentrations.

### **Contribution to the maintenance or achievement of a normal body weight**

The claimed effects are “weight loss and weight control in overweight adults/reduces glucose absorption from gut” and “promotes weight-loss and weight-control in overweight healthy adults by reducing glucose uptake in the gastrointestinal system/absorbance from the gut (by regulating glucose homeostasis in the liver, thus promoting the use as fat as a source of energy in the body)”. 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 body weight control. The Panel considers that contribution to the maintenance or achievement of a normal body weight 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 chlorogenic acids from coffee and contribution to the maintenance or achievement of a normal body weight.

**KEY WORDS**

Coffee, oxidative damage, blood glucose, weight management, 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 1924/2006<sup>4</sup> submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out<sup>5</sup>. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The foods/food constituents that are the subjects of the health claims are coffee, *Coffea Arabica* L., chlorogenic acids from coffee, and antioxidants in coffee.

Coffee contains a wide range of “bioactive” compounds including caffeine and other purine derivatives, polyphenolic compounds such as chlorogenic acid derivatives and its degradation product caffeic acid, and specific diterpenes such as kahweol and cafestol. No information is provided on the concentration of such compounds in coffee, but this will likely depend on the coffee variety, on the roasting of the beans and on the brewing process, such as the use of coffee filters. Also, no specifications were provided on the compounds or molecules generically referred to as “antioxidants in coffee”.

The Panel notes that chlorogenic acid from coffee has been specified as the “active” food constituent responsible for the claimed effects considered in this opinion. Chlorogenic acids from coffee are well defined compounds which can be measured in foods by established methods.

The Panel considers that whereas the food/food constituents, coffee and antioxidants in coffee, are not sufficiently characterised in relation to the claimed effects evaluated in this opinion, the food constituent, chlorogenic acids from coffee, is sufficiently characterised.

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

#### 2.1. Protection of DNA, proteins and lipids from oxidative damage (ID 1099, 3152, 4301)

The claimed effects are “protection of body tissues, lipids, cells and DNA from oxidative damage”, “oxidative stress reduction” and “coffee naturally contains antioxidants that may support the body’s natural cell defences”. 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 and pollutants). These reactive intermediates damage molecules such as DNA, proteins

<sup>4</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

<sup>5</sup> 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>

and lipids if they are not intercepted by the antioxidant network which includes radical scavengers like antioxidant nutrients.

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

## **2.2. Maintenance of normal blood glucose concentrations (ID 1100, 1962)**

The claimed effect is “glucose homeostasis”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the long-term maintenance of normal blood glucose concentrations.

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

## **2.3. Contribution to the maintenance or achievement of a normal body weight (ID 2031, 4326)**

The claimed effects are “weight loss and weight control in overweight adults/reduces glucose absorption from gut” and “promotes weight-loss and weight-control in overweight healthy adults by reducing glucose uptake in the gastrointestinal system/absorbance from the gut (by regulating glucose homeostasis in the liver, thus promoting the use as fat as a source of energy in the body)”. 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 body weight control.

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

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

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

### **3.1. Protection of DNA, proteins and lipids from oxidative damage (ID 1099, 3152, 4301)**

Some of the references provided in the consolidated list reported on the association between coffee drinking and disease risk (e.g. hepatocellular carcinoma, liver cirrhosis, breast cancer, colon cancer, and inflammatory and cardiovascular disease) in observational (cohort) studies. Other references were general reviews on claim substantiation, on biomarkers for chronic disease risk, on the chemistry and absorption of chlorogenic acids and other polyphenols from coffee, and on the effects of coffee drinking on liver enzyme activity (a marker of liver damage), and on endothelial and vascular function. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

Some experimental, and generally small-scale, human intervention studies on the effects of coffee consumption, or of individual compounds present in coffee, on markers of antioxidant status (e.g. antioxidant activity/capacity/potential of plasma (Natella et al., 2002)), on the induction of antioxidant enzymes such as super-oxide dismutase (SOD) or glutathione S-transferases (GSTA and

GSTP) and/or on plasma concentrations of glutathione (GSH) (Bichler et al., 2007; Esposito et al., 2003; Grubben et al., 2000; Mursu et al., 2005; Steinkellner et al., 2005), on the formation of malondialdehyde (MDA), on thiobarbituric acid reactive substances (TBARS), and/or on LDL oxidation lag time (Mursu et al., 2005; Yukawa et al., 2004) were provided. The Panel notes that measurements of the total antioxidant activity/potential of plasma are not considered as markers of oxidative damage, and that the formation of TBARS or of MDA assessed by colorimetric assays, as well as the resistance of LDL to oxidation, are not suitable markers to assess lipid peroxidation (Dalle-Donne et al., 2006; Dragsted, 2008; Griffiths et al., 2002; Knasmuller et al., 2008; Mayne, 2003). Also two small intervention studies on the effects of coffee consumption on DNA damage measured *ex vivo* in lymphocytes using single cell gel electrophoresis (Comet assay) after incubation with restriction enzymes and treatment with H<sub>2</sub>O<sub>2</sub> or a heterocyclic compound (Bichler et al., 2007), and on benzo[a]pyrene diol epoxide (BPDE) induced DNA-migration using the Comet assay (Steinkellner et al., 2005), were presented. The Panel notes that these measurements do not provide information about oxidative damage to DNA *in vivo* (Dusinska and Collins, 2008). The Panel also notes that coffee has not been sufficiently characterised in these studies in relation to the claimed effect, and that its content of chlorogenic acids has not been reported. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claimed effect.

In a multiple-dose supplementation trial, 43 healthy non-smoking men consumed daily either no coffee, 3 cups (450 mL) or 6 cups (900 mL) of filtered coffee (7–8 g of grounds per 150 mL cup) for three weeks. *In vivo* LDL oxidation using conjugated dienes, plasma hydroxy fatty acids, activity of antioxidant enzymes, and plasma F<sub>2</sub>-isoprostanes were assessed (Mursu et al., 2005). The Panel notes that coffee has not been sufficiently characterised in this study in relation to the claimed effect, and that its content of chlorogenic acids has not been reported. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claimed effect.

Data from *in vitro* studies on the effect of caffeic acid on LDL resistance to oxidation (lag time), and on glutathione (GSH) depletion (Nardini et al., 1995; 1997; Richelle et al., 2001), and studies on the chemopreventive effects of chlorogenic acids in human cancer cell lines, on transcription factors and biomarkers of cell proliferation (Bandyopadhyay et al., 2004; Feng et al., 2005), and on the effects of kahweol and cafestol on induced DNA damage in cultured NIH3T3 cells (Lee and Jeong, 2007), were submitted. The Panel considers that evidence provided in *in vitro* studies is not sufficient to predict the occurrence of an effect of coffee on protection of DNA, lipids or proteins from oxidative damage *in vivo* in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of chlorogenic acids from coffee and protection of DNA, lipids or proteins from oxidative damage.

### **3.2. Maintenance of normal blood glucose concentrations (ID 1100, 1962)**

Some of the references provided for the substantiation of the claim reported on the association between coffee drinking and disease risk (e.g. type II diabetes, gestational diabetes, metabolic disease, cardiovascular disease) in observational (cohort) studies, and on the effects of chlorogenic acids on various aspects of glucose metabolism (enzymes and transporter proteins). Other references included reviews on the dietary sources of chlorogenic acids, and on magnesium supplementation in diabetes. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

Five references reported on human intervention studies which investigated the effects of coffee consumption on either post-prandial glycaemic and insulinaemic responses (Battram et al., 2006; Feinberg et al., 1968; Johnston et al., 2003; Keijzers et al., 2002), or on plasma C-peptide

concentrations (Wu et al., 2005). The Panel considers that no conclusions can be drawn from these outcome measures in relation to the long-term maintenance of normal blood glucose concentrations.

Two references reported on human intervention studies which addressed the effects of coffee consumption during two to four weeks on fasting glucose and insulin concentrations (Naismith et al., 1970; van Dam et al., 2004). Another reference reported on a cross-sectional study which investigated the association between coffee intake and glucose tolerance and insulin secretion during an oral glucose tolerance test (Bidel et al., 2006). In all of these studies, coffee was not sufficiently characterised in relation to the claimed effect, and outcome measures were not appropriate to assess the long-term maintenance of normal blood glucose concentrations. The Panel considers that no conclusions can be drawn from these studies 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 chlorogenic acids from coffee and maintenance of normal blood glucose concentrations.

### **3.3. Contribution to the maintenance or achievement of a normal body weight (ID 2031, 4326)**

A number of references on the bioavailability of chlorogenic acids, on the effects of coffee and chlorogenic acids on blood glucose control, and on the effects of chlorogenic acids in animal and *in vitro* models with respect to mutagenicity, antioxidant capacity and inhibition of hepatic glucose-6-phosphatase have been provided. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

A randomised, controlled trial investigated the effects of an instant coffee containing a green coffee extract (200 mg of extract per 2200 mg of coffee) with a high content of chlorogenic acids (i.e. 90-100 mg of chlorogenic acids per 200 mg of green coffee extract with equal amounts of the three isomers 5-, 4-, and 3-caffeoylquinic acid) and <2 % caffeine with no cafestol or kahweol *vs.* regular decaffeinated instant coffee containing 30-40 mg of chlorogenic acid per g of coffee on body weight in 30 overweight adults (Thom, 2007). Participants selected were overweight, non-smokers, and not taking medication on a regular basis for the treatment of chronic diseases, and were asked to maintain their usual diet and physical activity or exercise programmes. Subjects consumed 11 g of the test coffee per day (n=15) or 11 g of the control coffee per day (n=15), in both cases as black coffee, for 12 weeks, and were followed up for one and three months after the end of the study. The Panel notes the small sample size of the study, and that the background diet and physical activity at baseline, along with changes during the study, were not assessed and/or reported, for which reason it is unclear whether intervention and control groups were comparable for these variables. The Panel notes the important methodological limitations of the study and considers that no conclusions can be drawn from this study for the scientific substantiation of the claimed effect.

Another randomised, placebo-controlled human intervention study on the effects of a green coffee extract (200 mg of extract per capsule) containing chlorogenic acids (i.e. 90-100 mg per capsule with equal amounts of the three isomers 5-, 4-, and 3-caffeoylquinic acid) and <2 % caffeine with no cafestol and kahweol *vs.* placebo (maltodextrin) on body weight in overweight and obese subjects (males and females aged 19 to 75 years) was provided (Dellalibera et al., 2006). Participants were randomised to consume two capsules daily of the green coffee extract (n=30) or placebo (n=20) with the main meal for 60 days in the context of a “mildly hypocaloric diet”. The Panel notes that, although the authors reported that the intervention and placebo groups were “homogeneous with respect to body weight and fat-free mass to fat mass ratio”, the baseline characteristics of participants in both groups were not provided, and that whether these groups were comparable for other variables (e.g. age and sex distribution) was not reported. The Panel also notes that the background diet and physical activity at baseline and during the intervention were not reported, and that no details were given with

respect to the “mildly hypocaloric diet” prescribed during the study, nor on whether (and how) compliance with dietary advice was checked. The Panel notes the important methodological limitations of the study and 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 chlorogenic acids from coffee and contribution to the maintenance or achievement of a normal body weight.

## CONCLUSIONS

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

- The food/food constituents, coffee and antioxidants in coffee, which are the subjects of the health claims, are not sufficiently characterised in relation to the claimed effects evaluated in this opinion, whereas chlorogenic acids from coffee are sufficiently characterised.

### **Protection of DNA, proteins and lipids from oxidative damage (ID 1099, 3152, 4301)**

- The claimed effects are “protection of body tissues, lipids, cells and DNA from oxidative damage”, “oxidative stress reduction” and “coffee naturally contains antioxidants that may support the body’s natural cell defences”. The target population is assumed to be the general population. 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 chlorogenic acids from coffee and protection of DNA, lipids or proteins from oxidative damage.

### **Maintenance of normal blood glucose concentrations (ID 1100, 1962)**

- The claimed effect is “glucose homeostasis”. 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 chlorogenic acids from coffee and maintenance of normal blood glucose concentrations.

### **Contribution to the maintenance or achievement of a normal body weight (ID 2031, 4326)**

- The claimed effects are “weight loss and weight control in overweight adults/reduces glucose absorption from gut” and “promotes weight-loss and weight-control in overweight healthy adults by reducing glucose uptake in the gastrointestinal system/absorbance from the gut (by regulating glucose homeostasis in the liver, thus promoting the use as fat as a source of energy in the body)”. 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 chlorogenic acids from coffee and contribution to the maintenance or achievement of a normal body weight.

## DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1838, EFSA-Q-2008-1839, EFSA-Q-2008-2695, EFSA-Q-2008-2764, EFSA-Q-2008-3884, EFSA-Q-2010-00254, EFSA-Q-2010-00279). 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 foods<sup>6</sup> (hereinafter "the Regulation") entered into force on 19<sup>th</sup> January 2007.

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

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

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

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

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

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

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

#### ISSUES THAT NEED TO BE CONSIDERED

##### IMPORTANCE AND PERTINENCE OF THE FOOD<sup>7</sup>

Foods are commonly involved in many different functions<sup>8</sup> of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## **TERMS OF REFERENCE**

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

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

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

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

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

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

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

## **APPENDIX B**

### **EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food, a positive assessment of its safety, nor a decision on whether the food 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 coffee, including chlorogenic acids from coffee, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food component	Health Relationship	Proposed wording
1099	Coffee	Protection of body tissues, lipids, cells and DNA from oxidative damage.	Coffee is a major dietary source of antioxidants. Antioxidants from dietary sources:  protect you from free radicals;  protect your cells and tissues from oxidation;  antioxidants help strengthen our body's natural defences against oxidative stress.
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- 1 or 2 cups per day.</li> <li>- A coffee drink made by the filter method and diffusing 7g of ground coffee in 100 mL of water, 8.8 g/125 mL (dose), 35 g/500 mL (daily dose).</li> <li>- The coffee drink contains antioxidants, including 80-100 mg/100 mL of caffeine and approximately 116 mg/100 mL of chlorogenic acids.</li> <li>- 2 Tassen pro Tag.</li> </ul>		
ID	Food or Food component	Health Relationship	Proposed wording
1100	Coffee	Glucose homeostasis.	coffee contributes to healthy blood glucose levels.
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- 4 tassen pro tag.</li> <li>- 3 cups per day.</li> <li>- A coffee drink made by filtering roasted coffee and diffusing 7 g of ground coffee in 100 mL of water, 8.8 g/125 mL (dose), 35 g/500 mL (daily dose).</li> </ul>		
ID	Food or Food component	Health Relationship	Proposed wording
1962	Chlorogenic acids from Coffee	Glucose homeostasis	Chlorogenic acids from coffee extract contributes to keep normal blood glucose levels;  Chlorogenic acids from coffee extract has a beneficial effect on glucose metabolism/ insulin metabolism.
	<b>Conditions of use</b> 400 mg/day coffee extract containing 45 % chlorogenic acids.		
ID	Food or Food constituent	Health Relationship	Proposed wording
2031	CoffeeSLENDER® Tablets made from an extract from	i). Weight loss and weight control in overweight	i). As an aid to weight loss and weight control as part of a calorie

	green coffee beans (Svetol®) the active principle of which is: 5-caffeoylquinic acid or (Chlorogenic acid) =45%, Caffeine = 2%, 3-caffeoylquinic acid =10%	adults. ii). Reduces glucose absorption from gut.	controlled diet. ii). Acts by reducing absorption of sugar (glucose) from the digestive tract.
<b>Conditions of use</b> - Three tablets to be taken daily.			
ID	Food or Food constituent	Health Relationship	Proposed wording
3152	Antioxidants in coffee	Oxidative stress reduction	Antioxidants in coffee helps protect our cells against free radicals.
<b>Conditions of use</b> - 1 - 2 cups/ day			
ID	Food or Food constituent	Health Relationship	Proposed wording
4301	Name of Food product: coffee  Description of food in terms of food legislation categories: food not covered by specific food legislation  Was food on Irish market before 1st July 2007: Yes	Health benefits of food: Coffee naturally contains antioxidants that may support the body's natural cell defences  Do benefits relate to a disease risk factor: No  Target group: All adults aged 18 years and over	Exact wording of claim as it appears on product: Coffee naturally contains antioxidants, that may support the body's natural cell defences.  Examples of any alternative wording that may be used in relation to claim: Coffee is a major dietary source of antioxidants. Antioxidants from dietary sources: protect from free radicals which cause cell damage; protect body tissues, lipids, cells and DNA from oxidative damage; help strengthen the body's natural defences against oxidative stress.  Is claim a picture: Yes  Description of picture: A coffee bean
<b>Conditions of use</b> - Number of nutrients/other substances that are essential to claimed effect: 1. Names of nutrient/other substances and Quantity in Average daily serving: 162mg chlorogenic acids (CGA). Weight of average daily food serving: 162 miligram(s). Daily amount to be consumed to produce claimed effect: 162 miligram(s). Number of food portions this equates to in everyday food portions: 3. Are there factors that could interfere with bioavailability: No. Length of time after consumption for claimed effect to become apparent: There are short-term and long-term effects. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Yes. State the maximum limit in mg/kg body weight/day: 300.00. Potential adverse health effects: It may produce various effects, depending on if a person has caffeine sensitivity. Describe subgroups this limit applies to: pregnant women and people sensitive to caffeine. Other conditions for use: Polyphenols are the most abundant antioxidants in our diets. Coffee beans contain a range of polyphenol			

antioxidants with chlorogenic acids (CGA) being one of the richest dietary sources of CGA.			
ID	Food or Food constituent	Health Relationship	Proposed wording
4326	<p>Decaffeinated green (unroasted) coffee bean extract produced from <i>Coffea canephora robusta</i> (plant:extract ratio between 6:1 to 8:1). The active ingredients contained in the green coffee extract are chlorogenic acids (&gt;45% w/w). The chlorogenic acids mainly comprise the 3 isomers of caffeoylquinic acid, 3-caffeoylquinic acid, 4-caffeoylquinic acid, and 5-caffeoylquinic acid. The green coffee extract also contains dicaffeoylquinic acids (3,4-, 3,5-, and 4,5-dicaffeoylquinic acid) and feruloylquinic acids (3-, 4-, and 5-feruloylquinic acid) at levels of 9.6 and 13.2% of total chlorogenic acids, respectively.</p> <p>Example of Specifications for Decaffeinated Green Coffee Extract.</p> <p>Specification Parameter Specification.</p> <p>Appearance Fine powder</p> <p>Colour Yellow.</p> <p>Flavour Characteristic</p> <p>Identification (UV profile in methanol) Maximum at 325 ± 5 nm.</p> <p>Particle size 60 to 400 mesh.</p> <p>Total polyphenols 50 to 55%.</p> <p>Total chlorogenic acids 45 to 50%.</p> <p>5-Caffeoylquinic acid 10 to 15%</p> <p>5-Caffeoylquinic acid/total chlorogenic acid ratio 0.2 to 0.3.</p> <p>Caffeine Less than 2%.</p>	<p>Promotes weight-loss and weight-control in overweight healthy adults by reducing glucose uptake in the gastrointestinal system/absorbance from the gut (by regulating glucose homeostasis in the liver, thus promoting the use as fat as a source of energy in the body).</p>	<p>As an aid to weight loss and weight control as part of a calorie controlled diet.</p> <p>Acts by reducing absorption of sugar (glucose) from the digestive tract.</p>

	More detailed compositional data is available upon request.		
	<b>Conditions of use</b> <ul style="list-style-type: none"><li>- 400 to 1000 mg per day.</li><li>- The daily recommended dose can be reached in a single or multiple administrations.</li><li>- The product can be taken alone (i.e. in capsules), or integrated to a food matrix (i.e. soluble coffee beverage).</li></ul>		

## GLOSSARY AND ABBREVIATIONS

8-OhdG	8-Hydroxydeoxyguanosine
BPDE	Benzo(a)pyrene diolepoxide
DNA	Deoxyribonucleic acid
GSH	Glutathione
GSTA	A isoform of the glutathione S-transferase
GSTP	P isoform of the glutathione S-transferase
LDL	Low Density Lipoprotein
MDA	Malondialdehyde
ROS	Reactive oxygen species
SOD	Super-oxide dismutase
TBARS	Thiobarbituric acid reactive substances