European Food Safety Authority

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to caffeine and increased fat oxidation leading to a reduction in body fat mass (ID 735, 1484), increased energy expenditure leading to a reduction in body weight (ID 1487), increased alertness (ID 736, 1101, 1187, 1485, 1491, 2063, 2103) and increased attention (ID 736, 1485, 1491, 2375) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

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

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to caffeine and increased fat oxidation leading to a reduction in body fat mass, increased energy expenditure leading to a reduction in body weight, increased alertness, and increased attention. 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 subjects of the health claims are *Coffea arabica* L. (coffee) and other *Coffea* spp., *Paullinia cupana* Kunth (guarana) and caffeine. The Panel considers that, whereas the foods/food constituents *Coffea arabica* L. and *Paullinia cupana* Kunth are not sufficiently characterised in relation to the claimed effects evaluated in this opinion, the food constituent caffeine is sufficiently characterised.

[1] On request from the European Commission, Question No EFSA-Q-2008-1522, EFSA-Q-2008-1523, EFSA-Q-2008-1840, EFSA-Q-2008-1926, EFSA-Q-2008-2221, EFSA-Q-2008-2222, EFSA-Q-2008-2224, EFSA-Q-2008-2228, EFSA-Q-2008-2796, EFSA-Q-2008-2836, EFSA-Q-2008-3108, adopted on 28 January 2011.

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[3] 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 Weight Management/Satiety/Glucose and Insulin Control/Physical Performance: Kees de Graaf, Joanne Harrold, Mette Hansen, Mette Kristensen, Anders Sjödin and Inge Tetens. The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain, and Peter Willatts.

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Increased fat oxidation leading to a reduction in body fat mass

The claimed effect is "fat metabolism/energy expenditure". 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 an increased fat oxidation leading to a reduction in body fat mass. The Panel considers that increased fat oxidation leading to a reduction in body fat mass might be a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of caffeine and an increased fat oxidation leading to a reduction in body fat mass.

Increased energy expenditure leading to a reduction in body weight

The claimed effect is "support of resting metabolic rate and thermogenesis". The target population is assumed to be the general population. The Panel considers that increased energy expenditure leading to a reduction in body weight might be a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of caffeine and increased energy expenditure leading to the reduction of body weight.

Increased alertness

The claimed effects are "cognitive and mental performance", "mental and physical stimulant effect", "mental state and performance", "mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning, as well as resistance to stress)", "mental performance and cognitive function (enhances mental alertness during intense muscular activity)", and "mental performance". The target population is assumed to be the general population. In the context of the proposed wordings and the clarifications provided by Member States, the Panel assumes that the claimed effects refer to alertness. The Panel considers that increased alertness might be a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the evidence provided by consensus opinions/reports, and by the majority of the studies submitted for the scientific substantiation of the claim, showed that there was good consensus on the role of caffeine in increasing alertness, measured as speed of reaction times, in healthy individuals of both sexes, at doses of at least 75 mg.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of caffeine and increased alertness.

The Panel considers that, in order to bear the claim, a product should contain at least 75 mg caffeine per serving. The target population is the general adult population. For children, consumption of a dose of 5 mg/kg body weight could result in transient behavioural changes, such as increased arousal, irritability, nervousness or anxiety. In relation to pregnancy and lactation, moderation of caffeine intake, from whatever source, is advisable.

Increased attention

The claimed effects are "cognitive and mental performance", "mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning, as well as resistance to stress)", "mental performance and cognitive function (enhances mental alertness during intense muscular activity)", and "invigoration of 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 increased attention. The Panel considers that increased attention is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the evidence provided by consensus opinions/reports, and by the majority of the studies submitted for the scientific substantiation of the claim, showed that there was good consensus on the role of caffeine in increasing attention, measured by a range of psychometric tasks, in healthy individuals of both sexes, at doses of at least 75 mg.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of caffeine and increased attention.

The Panel considers that in order to bear the claim, a product should contain at least 75 mg caffeine per serving. The target population is the general adult population. For children, consumption of a dose of 5 mg/kg body weight could result in transient behavioural changes, such as increased arousal, irritability, nervousness or anxiety. In relation to pregnancy and lactation, moderation of caffeine intake, from whatever source, is advisable.

KEY WORDS

Caffeine, fat metabolism, energy expenditure, alertness, attention, health claims.

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EFSA DISCLAIMER

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[4] submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out[5]. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The foods/food constituents that are the subject of the health claims are *Coffea arabica* L. (coffee) and other *Coffea* spp., *Paullinia cupana* Kunth (guarana) and caffeine.

Caffeine is a natural compound present in coffee beans and tea leaves. Other sources include the kola nut, yerba mate, guarana berries and Yaupon Holly. Caffeine is a well characterised substance which can be measured by established methods.

The food/food constituent which is the subject of ID 1101 is "*Coffea arabica* L. and other spp". Coffee contains a wide range of compounds including caffeine and other purine derivatives, polyphenolic compounds such as the degradation product caffeic acid, and specific diterpenes such as kahweol and cafestol. No information was provided on the concentration of such compounds in coffee, but these compounds will likely depend on the coffee variety, on the roasting of the beans and, in relation to human consumption, on the brewing process, such as the use of coffee filters. The Panel notes that "caffeine" has been specified as the "active" food constituent that is responsible for the claimed effects considered in this opinion, but the Panel also notes that coffee contains a wide and variable range of compounds, including caffeine.

The food constituents which are the subjects of IDs 2063, 2103 and 2375 are "guarana", "*Paullinia cupana* (Common Name: guarana)" and "guarana seed; (Paulina cupana fruit)". The varieties *Paullinia cupana* Kunth and *Paullinia cupana* var. *sorbilis* (Mart.) Ducke are native to the Amazon basin. Guarana is derived from both wild and cultivated plants. The seeds typically contain: caffeine 2.5-5 %, tannins 16 %, saponins, theophylline and theobromine (small quantities) (Carlini, 2003; Houghton, 1995; Scholey and Haskell, 2008). The Panel notes that "caffeine" has been specified as the "active" food constituent which is responsible for the claimed effects considered in this opinion, but the Panel also notes that guarana contains a wide and variable range of compounds, including caffeine.

The Panel considers that, whereas the foods/food constituents *Coffea arabica* L. and *Paullinia cupana* Kunth are not sufficiently characterised in relation to the claimed effects evaluated in this opinion, the food constituent caffeine is 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. Increased fat oxidation leading to a reduction in body fat mass (ID 735, 1484)

The claimed effect is "fat metabolism/energy expenditure". 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 an increased fat oxidation leading to a reduction in body fat mass.

The Panel considers that increased fat oxidation leading to a reduction in body fat mass might be a beneficial physiological effect.

2.2. Increased energy expenditure leading to a reduction in body weight (ID 1487)

The claimed effect is "support of resting metabolic rate and thermogenesis". The Panel assumes that the target population is the general population.

Enhancement of resting metabolic rate and thermogenesis is interpreted as an increase in total substrate oxidation (energy expenditure), which is a measurable outcome. An increase in energy expenditure may lead to a decrease in body weight, which is considered a beneficial physiological effect.

The Panel considers that increased energy expenditure leading to a reduction in body weight might be a beneficial physiological effect.

2.3. Increased alertness (ID 736, 1101, 1187, 1485, 1491, 2063, 2103)

The claimed effects are "cognitive and mental performance", "mental and physical stimulant effect", "mental state and performance", "mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning, as well as resistance to stress)", "mental performance and cognitive function (enhances mental alertness during intense muscular activity)", and "mental performance". The Panel assumes that the target population is the general population.

In the context of the proposed wordings and the clarifications provided by Member States, the Panel assumes that the claimed effects refer to alertness. Alertness may relate to either a cognitive (i.e. behavioural) or an affective (i.e. subjective self-rating) construct. Cognitive alertness refers to a state of enhanced arousal and readiness to receive and process information and respond. Alertness is a well defined construct and can be measured by validated psychometric cognitive tests.

The Panel considers that increased alertness might be a beneficial physiological effect.

2.4. Increased attention (ID 736, 1485, 1491, 2375)

The claimed effects are "cognitive and mental performance", "mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning, as well as resistance to stress)", "mental performance and cognitive function (enhances mental alertness during intense muscular activity)", and "invigoration of 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 attention, which means the ability to concentrate while processing information. There are two broad categories

of attention. Selective attention is the ability to concentrate on one task or source of information to the exclusion of others. Sustained attention (vigilance) is the ability to concentrate over a long period of time. Attention is a well defined construct which can be measured by validated psychometric tests.

The Panel considers that increased attention is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Increased fat oxidation leading to a reduction in body fat mass (ID 735, 1484)

Among the references provided for the scientific substantiation of the claim were narrative reviews and human studies which were unrelated to the claimed effect (e.g. performance during prolonged physical exercise, cognitive function and mood) and eight references, which reported on acute, single dose human intervention studies on the effects of caffeine on fat oxidation and/or blood lipids which did not assess changes in body fat mass (Acheson et al., 1980; Arciero et al., 1995; 2000; Dulloo et al., 1999; Hadjicharalambous et al., 2006; McNaughton, 1986; Rumpler et al., 2001; Ryu et al., 2001). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One reference described a longer-term human intervention study on the effects of caffeine plus epigallocatechin on body weight and body composition (Westerterp-Plantenga et al., 2005), and another reference reported the effects of a caffeine-containing vitamin and plant-based supplement administered for eight weeks on body composition compared to placebo (microcrystalline cellulose) (Malek et al., 2006). The Panel considers that no conclusions can be drawn from studies using caffeine in combination with other substances for the scientific substantiation of a claim on caffeine alone.

The Panel concludes that a cause and effect relationship has not been established between the consumption of caffeine and increased fat oxidation leading to a reduction in body fat mass.

3.2. Increased energy expenditure leading to a reduction in body weight (ID 1487)

Among the references provided for the scientific substantiation of the claim were textbooks which did not contain any primary data which could be used for the scientific substantiation of the claim. Eleven human studies investigated acute effects of caffeine intake on energy expenditure (Arciero et al., 1995; 2000; Astrup et al., 1990; Collins et al., 1994; Dulloo et al., 1989; 1999; Engels et al., 1999; Koot and Deurenberg, 1995; MacNaughton et al., 1990; Poehlman et al., 1989; Tagliabue et al., 1994). None of the studies provided assessed the effects of caffeine consumption on body weight or body composition. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of caffeine and increased energy expenditure leading to a reduction in body weight.

3.3. Increased alertness (ID 736, 1101, 1187, 1485, 1491, 2063, 2103)

A number of the references provided addressed endpoints other than the claimed effect, including mood, lipid or carbohydrate metabolism, metabolic rate, physical performance and cardiovascular endpoints, or investigated substances other than caffeine, or caffeine in combination with other substances, or the effect of caffeine withdrawal rather than the effect of caffeine on subjects under normal conditions of use. A meta-analysis (Riby, 2004) addressed the effects of glucose, and a systematic review (Hoyland et al., 2008) reported on macronutrients but not caffeine, which is the

subject of the claim. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Two double-blind, placebo-controlled intervention trials assessed the effect of a commercial standardised guarana extract (containing approximately 12 % caffeine) on measures of alertness (Haskell et al., 2007; Kennedy et al., 2004). The Panel notes that the placebo (capsule containing no guarana extract) used in these two studies did not control for substances other than caffeine. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

A total of 19 randomised, double-blind, placebo-controlled intervention studies assessed the effects of caffeine on reaction time (RT), a measure of alertness as a cognitive construct. The cognitive tests used to measure RTs can be classified into simple reaction time tasks (nine studies), choice reaction time tasks (six studies) and other vigilance tasks measuring speed of reactions (e.g. rapid information processing tasks, visual or auditory vigilance tasks; 10 studies). These studies differed with respect to their design (cross-over, parallel), their sample size (11 to 120 subjects), the baseline characteristics of participants (age range 18-57 years; usual coffee consumption from 0 to 7 cups/day), the doses of caffeine administered (range 12.5 mg to 500 mg in drinks/capsules) and the time between caffeine administration and RT testing (range 20 min to 8 hours). The majority of studies used cross-over designs with relatively small sample sizes (15-25 subjects), involved young regular caffeine consumers (males and females, 18-30 years) who were on caffeine withdrawal for at least 12 hours, and administered caffeine doses ranging from 100 to 300 mg in a single dose, 45-90 min before RT testing.

Of the nine trials which assessed the effect of caffeine on simple reaction time tasks, six reported a significant reduction in RTs following caffeine consumption (dose range 12.5 mg to 320 mg) (Brice and Smith, 2002; Haskell et al., 2005; Robelin and Rogers, 1998; Smit and Rogers, 2000; Smith et al., 1992; 1993), while three studies found no effect (dose range 32 mg to 320 mg) (Hewlett and Smith, 2007; Hogervorst et al., 1999; Lieberman et al., 1987). A significant effect of caffeine on simple reaction time tasks was observed regardless of whether subjects were on caffeine withdrawal (4 trials) (Haskell et al., 2005; Robelin and Rogers, 1998; Smit and Rogers, 2000; Smith et al., 1993) or not (2 trials) (Brice and Smith, 2002; Smith et al., 1992). Most of these studies were conducted in rested subjects. One study which investigated the effect of caffeine on simple reaction time tasks during the day and at night (rested or sleep deprived subjects) reported a significant effect of caffeine in both conditions (Smith et al., 1993). The Panel notes that six of the nine studies which assessed the effects of caffeine consumption on simple RT tests showed a significant reduction in RT following caffeine consumption.

Three studies showed a significant decrease in RTs on choice-reaction time tasks after caffeine consumption (dose range 32 mg to 300 mg) (Lieberman et al., 1987; Lorist et al., 1994a; van Duinen et al., 2005). Lieberman et al. (2002) reported significantly decreased RTs on one choice-reaction time task after caffeine consumption at 200 mg and 300 mg, but not at 100 mg. One study observed a significant effect of caffeine after exercise, but not before (dose range 150 mg to 320 mg) (Hogervorst et al., 1999). One study found no effect (dose of 1 mg caffeine per kg body weight) (Hewlett and Smith, 2007). The Panel notes that five of the six studies which assessed the effects of caffeine consumption on choice-reaction time tasks showed a significant reduction in RT following caffeine consumption.

Of the 10 trials which reported the effect of caffeine on speed of reactions using other vigilance tasks, eight showed a significant decrease in RTs following caffeine consumption (dose range 75 mg to 500 mg), whereas two studies found no effect (dose range 12.5 mg to 250 mg) (Ruijter et al., 2000c; Smit and Rogers, 2000). Again, a significant effect of caffeine on RTs was observed regardless of whether subjects were caffeine deprived (4 trials) (Fine et al., 1994; Hasenfratz and Bättig, 1994;

Rosenthal et al., 1991; Smith et al., 1990) or not (4 trials) (Frewer and Lader, 1991; Lieberman et al., 2002; Smith et al., 1992; Warburton, 1995). Most of these studies were conducted in rested subjects. Two studies tested the effect of caffeine under stress conditions (sleep deprivation and/or exercise), and found a significant effect of caffeine on RTs for visual or auditory vigilance tasks (Lieberman et al., 2002; Rosenthal et al., 1991). The Panel notes that 8 of the 10 studies which assessed the effects of caffeine on other vigilance tasks showed a significant reduction in RT following caffeine consumption.

The Panel notes that the vast majority of the studies which investigated the effects of caffeine consumption on RTs using simple and choice RT tests, and other vigilance tasks, showed a reduction in RTs following caffeine consumption. The Panel also notes that the evidence provided by consensus opinions/reports (ANZFA, 2000; IoM, 2001) shows that there is good consensus on the role of caffeine in increasing speed of reaction time, and in the maintenance of speed of reactions/increased alertness, particularly in low arousal situations (e.g. sleep deprivation and fatigue).

Overall, 12 of the studies provided assessed the effects of different caffeine doses on RTs (Frewer and Lader, 1991; Hasenfratz and Bättig, 1994; Haskell et al., 2005; Hewlett and Smith, 2007; Hogervorst et al., 1999; Lieberman et al., 1987; 2002; Robelin and Rogers, 1998; Rosenthal et al., 1991; Smit and Rogers, 2000; Smith et al., 1993; Warburton, 1995). Two studies investigated dose-response effects. Using doses of 100 mg, 200 mg and 300 mg, Lieberman et al. (2002) found a dose-related effect of caffeine on RTs in a visual vigilance test (no effect on RTs in a 4-choice RT test). Warburton (1995) reported a dose-related effect of 75 mg and 150 mg caffeine in RTs on a rapid visual information processing task. The results from the other studies are heterogeneous (in some studies the effect appeared to increase with increasing caffeine doses, whereas in others the decrease in RTs appeared unrelated to the caffeine dose used). This heterogeneity suggests that the effective dose of caffeine may vary from individual to individual, and may depend on many factors (IoM, 2001). Although some effects have been observed at very low caffeine doses (<75 mg), results were inconsistent (Hewlett and Smith, 2007; Lieberman et al., 1987; Smit and Rogers, 2000). The majority of significant results were obtained when subjects consumed caffeine doses in the range of 75-500 mg. This finding is consistent with consensus opinions reporting on caffeine doses in the range of 100-400 mg (IoM, 2001) and of 60-600 mg (ANZFA, 2000) which have consistently demonstrated reductions in reaction time and enhanced speed of reaction in vigilance tests.

In weighing the evidence, the Panel took into account that the evidence provided by consensus opinions/reports, and by the majority of the studies submitted for the scientific substantiation of the claim, showed that there was good consensus on the role of caffeine in increasing alertness measured as speed of reaction times in healthy individuals of both sexes, at doses of at least 75 mg.

The Panel concludes that a cause and effect relationship has been established between the consumption of caffeine and increased alertness.

3.4. Increased attention (ID 736, 1485, 1491, 2375)

A number of the references provided addressed endpoints other than the claimed effects, including mood, cognitive domains other than attention, lipids or carbohydrate metabolism, metabolic rate, physical performance and cardiovascular endpoints, or investigated substances other than caffeine, caffeine in combination with other substances, the effect of caffeine withdrawal rather than the effect of caffeine on subjects under normal conditions of use, or the effect of caffeine in patients with impaired adrenaline responses. A meta-analysis (Riby, 2004) addressed to glucose, and a systematic review (Hoyland et al., 2008) reported on macronutrients but not caffeine, which is the subject of the claim. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Two double-blind, placebo-controlled intervention trials assessed the effect of a commercial standardised guarana extract (containing approximately 12 % caffeine) on measures of attention (Haskell et al., 2007; Kennedy et al., 2004). The Panel notes that the placebo (capsule containing no guarana extract) used in these two studies did not control for substances other than caffeine. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One study (Brice and Smith, 2002) investigated the effects of caffeine on performance in three attention tests (focused attention task, categoric search task, 5-choice serial RT). Results for the focused attention task were not reported, and although it was stated that measures of RT and accuracy were obtained for the categoric search task, these results were also not reported. The 5-choice serial RT test was administered for too short a period (3 minutes) to adequately assess sustained attention. Another study (Loke, 1990) examined the effects of caffeine on performance in a symbol cancellation task, but did not report the main effects of the intervention. Haskell et al. (2005) observed the effects of caffeine on performance in a rapid visual information processing test and a digit vigilance reaction time test, in both habitual caffeine consumers and non-consumers. Primary analyses of the effects of caffeine on rapid visual information processing were not reported. No description of the digit vigilance reaction time was provided, and whether this is a validated test of sustained attention cannot be determined. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

A total of 22 randomised, double-blind, placebo-controlled intervention studies assessed the effects of caffeine on attention. The studies differed with respect to their design (cross-over, parallel), their sample size (11 to 120 subjects), the baseline characteristics of participants (age range 18-72 years; usual coffee consumption from 0 to 7 cups/day), the doses of caffeine administered (range 12.5 mg to 500 mg in drinks/capsules), and the time between caffeine administration and attention testing (range 20 min to 8 hours). The majority of studies used cross-over designs with relatively small sample sizes (15-25 subjects), involved young regular caffeine consumers (males and females, 18-30 years) who were on caffeine withdrawal for at least 12 hours, and administered caffeine doses ranging from 100 mg to 300 mg in a single dose, 45-90 min before attention testing.

Ten studies examined the effect of caffeine on selective attention by means of a range of psychometric tasks (e.g. visual selective search task, colour selection task, spatial-selection task, Stroop test and categoric search attention task). Six of these studies also examined the effect of caffeine on event-related potentials (ERPs). The ERP is an electrophysiological measure of cortical activity which is time-locked to a specific stimulus event. The ERP is analysed into waves which vary in latency, amplitude and direction (negative and positive polarity). Different components of the ERP are associated with different mental operations. Of relevance to selective attention is the occurrence of the N2b negative wave 200 ms after stimulus onset. This N2b component is related to covert (internal) orienting of attention towards relevant information, and increased selective attention is identified by a greater amplitude in the N2b component.

Lorist et al. (1994b) reported that caffeine (250 mg, n=30 subjects per intervention arm, 18-25 years) significantly reduced RT in a selective attention task ($p<0.02$), but had no effect on performance accuracy. The Panel notes that faster response time, indicated by reduced RT, and with no associated increase in error rate, is evidence for improved attention and efficiency at processing information. In the same study, analysis of the ERP showed that the N2b amplitude was greater in the caffeine than in the placebo condition ($p<0.03$). Lorist et al. (1995) reproduced these findings in a sample of 15 young (18-23 years) and 15 older (60-72 years) subjects, where caffeine (250 mg, n=30 per intervention arm) significantly reduced RT on the same selective attention task ($p=0.001$) with no effects on accuracy. Additionally, the N2b amplitude was significantly increased in the caffeine compared to the placebo condition ($p<0.03$). Lorist et al. (1996) also observed a significant effect of caffeine (3 mg/kg body weight, n=16 subjects per intervention arm, 19-29 years) in the focused attention condition of a visual

selective search task. RT was significantly reduced (p=0.004), and the N2b amplitude was significantly increased (p<0.025). Lorist et al. (1994a) reported similar results in a study on the effects of caffeine on performance in three different tests of selective attention (stimulus degradation, stimulus-response compatibility and time uncertainty tasks). Significant effects of caffeine (250 mg, n=30 per intervention arm) were found in all tasks, with reduced RTs (p<0.004) and fewer errors (p<0.05). ERP measures were also obtained, but data on the N2b component were not reported. Ruijter et al. (2000a) found a significant effect of caffeine (250 mg, n=11 per intervention arm) on RT in a colour selection task (p=0.032) with no associated effects on errors. Ruijter et al. (2000a) also obtained ERP measures, and reported a significantly greater N2b amplitude in the caffeine group (p=0.023). In the same experiment (Ruijter et al., 2000b), no effect of caffeine was found on RT in a spatial selection task, albeit accuracy was significantly improved (p=0.029). The effect of caffeine on the N2b amplitude was not significant. Hogervost et al. (1999) reported a significant effect of caffeine at each of three different doses (150 mg, 225 mg or 320 mg, n=15 per intervention arm) on a Stroop test after strenuous exercise (p<0.05), but not before exercise. Frewer and Lader (1991) studied the effects of caffeine at two doses (250 mg or 500 mg, n=12 per intervention arm) on one- and two-target letter cancellation tasks. Caffeine at 250 mg produced significantly faster completion times compared to placebo on the one-target task (p<0.05), and at 500 mg on the two-target task (p<0.05). Hewlett and Smith (2007) observed no effects of caffeine (1 or 2 mg/kg body weight, n=30 or 60 subjects per intervention arm) on performance in a focused attention choice reaction time task and a categoric search task. Lorist and Snel (1997) failed to observe any significant effect of caffeine (3 mg/kg body weight, n=16 subjects per intervention arm) on performance in a visual selective attention task.

In summary, all 10 of these studies included participants who were habitual caffeine users who had avoided caffeine consumption for a period ranging from 7-24 hours. One study included groups of high- and low-caffeine users (Hewlett and Smith, 2007), but no effects of caffeine were observed in either group. Three of the 10 studies assessed the effects of different caffeine doses on measures of selective attention (Frewer and Lader, 1991; Hewlett and Smith, 2007; Hogervorst et al., 1999). Only Frewer and Lader (1991) reported any dose-related effects. Caffeine at 250 mg produced significantly faster completion times compared to placebo on a one-target letter cancellation task (p<0.05), but the effect of caffeine at 500 mg was not significant. These effects were reversed for a two-target task (250 mg: not significant; 500 mg: p<0.05).

The Panel notes that although there were notable differences in the duration of avoidance of caffeine prior to testing, and in the measures used to assess selective attention, overall a consistent effect of caffeine was observed on a variety of measures of selective attention (15 positive outcomes *vs.* 6 negative outcomes, from 10 trials).

A total of 14 studies examined the effect of caffeine on sustained attention (vigilance). Sustained attention was measured by a variety of psychometric tasks which included digit detection, rapid visual information processing, visual vigilance, continuous performance, 5-choice serial RT, Wilkinson auditory vigilance task and the Bakan vigilance task.

Fine et al. (1994) found that caffeine (200 mg, n=20 subjects per intervention arm) significantly increased the number of correct responses (p<0.0005) and decreased response times (p=0.002) compared to placebo in a visual vigilance task. Hasenfratz and Bättig (1994) reported that caffeine at three different doses (1.5 mg, 3 mg and 6 mg/kg body weight, n=20 per intervention arm) significantly decreased RT (p<0.01), but had no effects on processing rate compared to placebo in the rapid information processing task. No dose-response effect was observed in this study. Rosenthal et al. (1991) reported similar effects for two doses of caffeine (75 mg and 150 mg, n=12 subjects per intervention arm), both of which significantly reduced RT in an auditory vigilance task (p<0.001) with no effects on error rate. No dose-response effect was observed. Smith et al. (1990) showed that caffeine (3 mg/kg body weight, n=32 subjects per intervention arm) significantly improved performance on the Bakan vigilance task with reduced RT and better accuracy compared to placebo

($p<0.05$). The effects were observed both before and after lunch. Smith et al. (1992) replicated these results in a study on the effects of caffeine (4 mg/kg body weight, n=24 subjects per intervention arm) on the Repeated Digits Vigilance Task. Caffeine significantly reduced RT ($p<0.0001$) and increased accuracy ($p<0.0001$), both before and after lunch. Smith et al. (1993) extended these findings to show that caffeine (1.5 or 3 mg/kg body weight, n=24 per intervention arm) significantly increased the number of correct responses on the 5-Choice Serial Response Task ($p<0.005$) at two different doses. These effects were found both during the day and at night. Frewer and Lader (1991) investigated the effects of caffeine (250 mg or 500 mg, n=12 subjects per intervention arm) on two different tests of sustained attention (rapid information processing task and continuous attention task). Accuracy in the rapid information processing task was significantly increased at both caffeine doses ($p<0.02$), but RT was significantly reduced only at the higher 500 mg dose ($p<0.01$). Caffeine at both doses significantly improved accuracy in the continuous attention task ($p<0.05$). Lieberman et al. (1987) investigated the effects of caffeine (32 mg, 64 mg, 128 mg and 256 mg, n=20 subjects per intervention arm) on three different tests of sustained attention (Wilkinson auditory vigilance task, continuous performance task, 4-choice visual RT). Caffeine at all doses significantly improved accuracy on the Wilkinson auditory vigilance task ($p<0.0016$), and significantly reduced RT on the 4-choice visual RT test ($p=0.02$), with no accompanying effects on accuracy. No effects of caffeine were observed on the continuous performance task. Warburton (1995) examined the effects of caffeine (75 mg and 150 mg, n=18 subjects per intervention arm) on the rapid information processing test in participants with minimal caffeine deprivation. There was a significant effect of caffeine on performance accuracy ($p<0.01$), with greater accuracy occurring in the 150 mg condition compared to placebo. A significant reduction in RT was also observed in the caffeine compared to placebo conditions ($p<0.05$), which was also dose related ($p<0.05$). Smit and Rogers (2000) studied the effects of caffeine (12.5 mg, 25 mg, 50 mg and 100 mg; n=23 subjects per intervention arm) on the rapid visual processing task in habitual high- and low-caffeine users. Caffeine at all doses significantly improved performance of high-caffeine users ($p<0.004$), but had no effect on the performance of low-caffeine users, and there were no effects on RT in either group.

Two further studies examined the effects of caffeine on sustained attention in sleep-deprived individuals. Bonnet et al. (1995) studied the effects of either a single dose (400 mg) or repeated doses (150-300 mg every 6 hours for 42 hours) of caffeine on performance in a visual vigilance test in participants with varying durations of sleep deprivation. There were 27 participants in the placebo group, 17 in the 150-300 mg group, and 12 in the 400 mg group. Visual vigilance performance was significantly improved in the caffeine groups, but only up to 24 hours sleep deprivation (group x time interaction $p<0.001$). Lieberman et al. (2002) studied the effects of caffeine (100 mg, 200 mg and 300 mg, n=17 subjects per intervention arm) in participants who underwent 72 hours sleep deprivation as well as physical and environmental stress challenges prior to receiving their caffeine intervention. Performance was measured in two tests of sustained attention (4-choice visual RT test and scanning visual vigilance test). Caffeine produced significant beneficial, dose-related effects including an increase in the number of correct responses ($p=0.0464$) and a decrease in RT ($p=0.0418$) on the scanning visual vigilance test. Significantly more correct responses in the 4-choice visual RT test were shown by both the 200 mg and 300 mg caffeine groups compared to placebo, at one hour after caffeine intake ($p<0.05$).

Two studies found no effects of caffeine on measures of sustained attention. Ruijter et al. (2000c) found no effects of caffeine (250 mg; n=12 subjects per intervention arm) on performance in a sustained attention task (a modified Bourdon test). The authors noted that the attention test used was more cognitively demanding than other sustained attention tests. Hewlett and Smith (2007) observed no effects of caffeine (1 or 2 mg/kg body weight, n=30 or 60 per intervention arm) on performance in a repeated digit detection task administered for five minutes. The Panel notes that the duration of this task may have been insufficient for an adequate assessment of sustained attention.

In summary, nine out of the 14 studies included participants who were habitual caffeine users and who had avoided caffeine consumption for a period ranging from three hours to one week. Four studies compared the effects of caffeine in groups of high- and low-caffeine users (Fine et al., 1994; Hewlett and Smith, 2007; Lieberman et al., 1987; Smit and Rogers, 2000), who had avoided caffeine consumption for 7-12 hours. Two of these studies reported significant effects of caffeine on sustained attention performance and which were the same in both high- and low-caffeine users (Fine et al., 1994; Lieberman et al., 1987). One study (Smit and Rogers, 2000) reported significant effects of caffeine in high-caffeine users, but no effects in low-caffeine users. Hewlett and Smith (2007) found no effects of caffeine in either high- or low-caffeine users, but the duration of the test period may have been insufficient for adequate assessment of sustained attention.

Ten of the 14 studies assessed the effects of different caffeine doses on measures of selective attention (Bonnet et al., 1995; Frewer and Lader, 1991; Hasenfratz and Bättig, 1994; Hewlett and Smith, 2007; Lieberman et al., 1987; 2002; Rosenthal et al., 1991; Smit and Rogers, 2000; Smith et al., 1993; Warburton, 1995). Two studies reported significant dose-related effects. Warburton (1995) found greater rapid information processing test accuracy in both 75 mg and 150 mg caffeine groups compared to placebo, and the effect was greater in the 150 mg group ($p<0.01$). RT was significantly reduced in both caffeine groups ($p<0.05$), and this effect was also dose related ($p<0.05$). Lieberman et al. (2002) examined the effects of three doses of caffeine (100 mg, 200 mg and 300 mg) on visual vigilance test performance, and reported a significant linear increase in accuracy with increasing caffeine intake ($p<0.05$).

The Panel notes that although there were notable differences in the duration of avoidance of caffeine prior to testing and in the measures used to assess sustained attention, overall a consistent effect of caffeine was observed on a variety of measures of sustained attention (35 positive outcomes *vs.* 12 negative outcomes, from 14 trials).

Overall, the Panel notes the consistency of the results of studies on both selective and sustained attention, with a majority showing positive effects of caffeine. Although some effects have been observed at very low caffeine doses (<75 mg), results were inconsistent (Hewlett and Smith, 2007; Lieberman et al., 1987; Smit and Rogers, 2000). The majority of significant results were obtained when subjects consumed caffeine doses in the range of 75-500 mg. This finding is consistent with consensus opinions reporting on caffeine doses in the range of 100-400 mg (IoM, 2001) and of 60-600 mg (ANZFA, 2000) which have consistently demonstrated an effect of caffeine on tests of attention.

In weighing the evidence, the Panel took into account that the evidence provided by consensus opinions/reports and by the majority of the studies submitted for the scientific substantiation of the claim showed that there was good consensus on the role of caffeine in increasing attention, measured by a range of psychometric tasks, in healthy individuals of both sexes, at doses of at least 75 mg.

The Panel concludes that a cause and effect relationship has been established between the consumption of caffeine and increased attention.

4. Panel's comments on the proposed wording

4.1. Increased alertness (ID 736, 1101, 1187, 1485, 1491, 2063, 2103)

The Panel considers that the following wording reflects the scientific evidence: "Caffeine helps to increase alertness".

4.2. Increased attention (ID 736, 1485, 1491, 2375)

The Panel considers that the following wording reflects the scientific evidence: "Caffeine helps to improve concentration".

5. Conditions and possible restrictions of use

The Panel considers that, in order to bear the claim, a product should contain at least 75 mg caffeine per serving. The target population is the general adult population.

For children, consumption of a dose of 5 mg/kg body weight could result in transient behavioural changes, such as increased arousal, irritability, nervousness or anxiety (SCF, 1999). In relation to pregnancy and lactation, moderation of caffeine intake, from whatever source, is advisable. A European Commission Directive lays down rules for the labelling of foodstuffs containing caffeine (Directive 2002/67/EC[6]).

CONCLUSIONS

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

- The foods/food constituents *Coffea arabica* L. and *Paullinia cupana* Kunth, which are the subject of the health claims, are not sufficiently characterised in relation to the claimed effects evaluated in this opinion, whereas the food constituent caffeine is sufficiently characterised.

Increased fat oxidation leading to a reduction in body fat mass (ID 735, 1484)

- The claimed effect is "fat metabolism/energy expenditure". The target population is assumed to be the general population. Increased fat oxidation leading to a reduction in body fat mass might be a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of caffeine and increased fat oxidation leading to a reduction in body fat mass.

Increased energy expenditure leading to a reduction in body weight (ID 1487)

- The claimed effect is "support of resting metabolic rate and thermogenesis". The target population is assumed to be the general population. Increased energy expenditure leading to a reduction in body weight might be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of caffeine and increased energy expenditure leading to the reduction of body weight.

Increased alertness (ID 736, 1101, 1187, 1485, 1491, 2063, 2103)

- The claimed effects are "cognitive and mental performance", "mental and physical stimulant effect", "mental state and performance", "mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning, as well as resistance to stress)", "mental performance and cognitive function (enhances mental alertness during intense muscular activity)", and "mental performance". The target population is assumed to be the general population. Increased alertness might be a beneficial physiological effect.

[6] Commission Directive 2002/67/EC of 18 July 2002 on the labelling of foodstuffs containing quinine, and of foodstuffs containing caffeine, OJ L 191, 19.7.2002, p. 20–21.

- A cause and effect relationship has been established between the consumption of caffeine and increased alertness.
- The following wording reflects the scientific evidence: "Caffeine helps to increase alertness".
- In order to bear the claim, a product should contain at least 75 mg caffeine per serving. The target population is the general adult population. For children consumption of a dose of 5 mg/kg body weight could result in transient behavioural changes, such as increased arousal, irritability, nervousness or anxiety. In relation to pregnancy and lactation, moderation of caffeine intake, from whatever source, is advisable.

Increased attention (ID 736, 1485, 1491, 2375)

- The claimed effects are "cognitive and mental performance", "mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning, as well as resistance to stress)", "mental performance and cognitive function (enhances mental alertness during intense muscular activity)", and "invigoration of the body". The target population is assumed to be the general population. Increased attention is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of caffeine and increased attention.
- The following wording reflects the scientific evidence: "Caffeine helps to improve concentration".
- In order to bear the claim, a product should contain at least 75 mg caffeine per serving. The target population is the general adult population. For children, consumption of a dose of 5 mg/kg body weight could result in transient behavioural changes, such as increased arousal, irritability, nervousness or anxiety. In relation to pregnancy and lactation, moderation of caffeine intake, from whatever source, is advisable.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1522, EFSA-Q-2008-1523, EFSA-Q-2008-1840, EFSA-Q-2008-1926, EFSA-Q-2008-2221, EFSA-Q-2008-2222, EFSA-Q-2008-2224, EFSA-Q-2008-2228, EFSA-Q-2008-2796, EFSA-Q-2008-2836, EFSA-Q-2008-3108). 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 foods[7] (hereinafter "the Regulation") entered into force on 19th January 2007.

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

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

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

a) the role of a nutrient or other substance in growth, development and the functions of the body; or

b) psychological and behavioural functions; or

c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

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

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

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

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[8]

Foods are commonly involved in many different functions[9] 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.

[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).

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

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

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

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

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

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

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

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

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

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

WORDING OF HEALTH CLAIMS

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

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

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

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

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

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

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

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

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

TERMS OF REFERENCE

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

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

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

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

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

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

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

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

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

APPENDIX B

EFSA DISCLAIMER

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

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

APPENDIX C

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

ID	Food or Food constituent	Health Relationship	Proposed wording
735	Caffeine (from tea/coffee/chocolate or added in pure form).	Fat metabolism/Energy expenditure.	Contributes to the mobilisation of fat stores. Contributes ton the stimulation of fat release. Helps to increase fat burning. Contributes to the oxidation of stored fats. Helps generate a negative energy balance. Contributes to increased calorie burning.
	Conditions of use - Minimum of 150 mg per day / 5-15 mg/kg body wt caffeine.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
736	Caffeine (from tea/coffee/chocolate or added in pure form)	Cognitive and mental performance	Contributes to mental performance Helps maintain and improve alertness Aids concentration Helps make you feel more energetic Helps improve how you feel
	Conditions of use - Min. 32 mg per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1101	Coffea arabica L. and other spp (Common Name: Coffee)	Mental and physical stimulant effect Clarification provided Mental and physical stimulant effect Clarification: Coffee improves physical performance. Coffee helps to maintain alert. Coffee helps to maintain	Cognitive and physical performance

		awake.	
	Conditions of use - Coffee drink produced by filtering roasted coffee and with a caffeine content of 90mg/100g, 110mg/125ml (dose), 440mg/500ml (daily dose). - Bean. At least a daily green coffea amount equivalent to 60 mg caffeine.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1187	Coffee drink/caffeine	Mental state and performance	Coffee helps you stay alert. Coffee invigorates
	Conditions of use - Coffee drink produced by filtering roasted coffee and with an average caffeine content of 90mg/100g, 110mg/125 ml (dose), 440mg/500 ml (daily dose).		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1484	Caffeine	Fat metabolism / Energy expenditure	- Contributes to the mobilisation of fat stores; - Contributes ton the stimulation of fat release; - Helps to increase fat burning; - Contributes to the oxidation of stored fats; - Helps generate a negative energy balance; - Contributes to increased calorie burning.
	Conditions of use - Minimum of 150 mg per day / 5-15 mg/kg bodywt caffeine. Beverages must comply with the labelling requirements laid down by Directive 2002/67/EC - Beverage with 27.3 mg/100 mL, 90 mg/serving of epigallocatechin gallate (EGCG) from green tea extract and 30.3 mg/100 mL, 100 mg/serving of caffeine. Catechins (ECGC) from tea and caffeine have been proven to be bioactive in the beverage as consumed, i.e. they have a demonstrated effect on your metabolism. - 75 mg Coffein.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1485	Caffeine (from tea/coffee/chocolate or added in pure form)	Mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning, as well as resistance to stress)	Helps maintain and improve alertness Aids concentration Helps make you feel more energetic Helps keep you alert Contributes to maintain the adequate wakefulness

			Boosts energy & mental focus Enhances mental performance Supports focus and concentration
	Conditions of use - Min. 32 mg per day - Minimum 30 mg/single portion;(the effects are not obviously dose-dependent) - Energy drink: 32mg/100g, 106mg/serving, 320mg/daily - Citrus drink with 12mg/100 g, 60mg/serving. - Pure form: Daily dose >60 mg - The product must contain at least 100 milligrams caffeine per serving or 1-5 mg per kilogram body weight per serving		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1487	Caffeine	Supports resting metabolic rate and thermogenesis	Caffeine can increase resting metabolic rate. Caffeine supports thermogenesis and energy oxidation.
	Conditions of use - Minimum 300 mg caffeine/daily dosis of the product, divided to portions (min. 3 portions). - The product must contain at least 100 milligrams caffeine per serving or 1-5 mg per kilogram body weight per serving Claim to be used for foods for active individuals Beverages must comply with the labelling requirements laid down by Directive 2002/67/EC. - 100 mg par jour / 100 mg per day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1491	Caffeine (with or without carbohydrate)	Mental performance and cognitive function (enhances mental alertness during intense muscular activity)	Enhances mental performance. Enhances focus, alertness and concentration. Enhances reaction time. Stay sharper for longer.
	Conditions of use - Caffeine should be equal to or greater than 32mg per serving		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2063	Guarana	Mental performance	Guarana improves alertness and reduces mental fatigue.
	Conditions of use - equivalent of 10 mg caffeine / individual effect. - Fruit, seed, stem/equivalent of at least 8 mg of caffeine or the equivalent of 75 mg of extract (11-13% of caffeine). - Seed / 1-6 g of powder daily; fluid extract 3% caffeine 1-3 g daily / Equivalent preparations.		

	- Only with at least 50 mg Guarana.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2103	*Paullinia cupana* (Common Name: Guarana)	Mental performance and cognitive function	Supports alertness Helps reduce mental fatigue Helps to strengthen the body Helps to make you feel more energetic Supports energetic alertness Stimulating invigorating, invigoration Contains Guarana
	Conditions of use - Minimum 75 mg extract of *Paullinia cupana* equal to minimum 10 mg caffeine per day (maximum 300 mg caffeine). - Graine 6x300 mg/jour. - Traditional use of the seed / Galenic forms: powder (1-4g); hydroalcoholic extract 0,25 - 1 g/day / Equivalent quantity in extract / Quantity of caffeine per day does not exceed 300 mg. If caffeine > 150 mg, specify "High content in caffeine". - Food supplement with 2000 mg of Guarana seed extract (*Paullinia cupana*) equivalent to 6400 mg of Guarana seeds in the daily dose. - owoc, nasiona, łodyga / owoc, nasiona: zwykle konsumowany jako tradycyjny artykuł żywnościowy w normalnej diecie / równowartość 10 mg kofeiny lub 75 mg zioła. - Sportler–Erwachsene–Coffeingehalt: 0,7 g / Tagesdosis–Tagesdosis Guaranasamen Pulver: 500 mg. - Drink with Guarana extract content of 30 mg/100g, 100 mg/serving, 300 mg/daily serving. A significant number of Guarana's stimulating effects can probably be explained by the caffeine contained in Guarana (about 5%). - Fruit, seed, stem / Usual consumption as traditional foodstuff in a normal diet / The equivalent of 10 mg of caffeine or the equivalent of 75 mg of herb.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2375	Guarana seeed;(Paulina cupana fruit);	Invigoration of the body	Guarana can help maintain normal invigoration of the body and ability to concentrate.
	Conditions of use - Minimum 150 mg guarana extract, containing 10% caffein/portion or seed equivalent with this. - contains 10% of coffein - 1g/jour - Seed / 1-6 g of powder daily ; fluid extract 3% caffeine 1-3 g daily / Equivalent preparations		

GLOSSARY AND ABBREVIATIONS

ERP	Event related potential
RT	Reaction time