

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to caffeine and increase in physical performance during short-term high-intensity exercise (ID 737, 1486, 1489), increase in endurance performance (ID 737, 1486), increase in endurance capacity (ID 1488) and reduction in the rated perceived exertion/effort during exercise (ID 1488, 1490) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

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

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to caffeine and increase in physical performance during short-term high-intensity exercise, increase in endurance performance, increase in endurance capacity and reduction in the rated perceived exertion/effort during exercise. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is caffeine. The Panel considers that caffeine is sufficiently characterised.

Increase in physical performance during short-term high-intensity exercise

The claimed effects are “physical performance (short term and endurance activities)” and “endurance during short term high intensity exercise”. The target population is assumed to be active individuals in the general population. In the context of the proposed wordings, the Panel assumes that the claimed

¹ On request from the European Commission, Question No EFSA-Q-2008-1524, EFSA-Q-2008-2223, EFSA-Q-2008-2225, EFSA-Q-2008-2226, EFSA-Q-2008-2227, adopted on 28 January 2011.

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effects refer to the increase in physical performance during short-term high-intensity exercise. The Panel considers that an increase in physical performance during short-term high-intensity exercise is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the evidence for an effect of caffeine consumption on physical performance during short-term high-intensity exercise is inconsistent, and that one meta-analysis of randomised controlled trials including 8 studies and 22 outcome measures did not show an effect of caffeine consumption on physical performance during short-term high-intensity exercise.

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 increase in physical performance during short-term high-intensity exercise.

Increase in endurance performance

The claimed effect is “physical performance (short term and endurance activities)”. The target population is assumed to be adults performing endurance exercise. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to increase in endurance performance. The Panel considers that an increase in endurance performance is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that most of the human intervention studies provided (including a meta-analysis of five randomised controlled trials and three individual randomised controlled trials) showed an effect of caffeine consumption on endurance performance at doses of at least 3 mg/kg body weight administered at least one hour prior to exercise, and after at least one day of caffeine withdrawal in habitual caffeine consumers.

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 an increase in endurance performance.

The Panel considers that in order to obtain the claimed effect, caffeine should be consumed at doses of 3 mg/kg body weight one hour prior to exercise. The target population is adults performing endurance exercise.

Increase in endurance capacity

The claimed effect is “supports exercise performance (reduction in perceived exertion, improved time to exhaustion and exercise capacity)”. The target population is assumed to be adults performing endurance exercise. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to an increase in endurance capacity. The Panel considers that an increase in endurance capacity is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that most of the human intervention studies provided (including a meta-analysis of 23 randomised controlled trials evaluating 39 outcomes and two individual randomised controlled trials) showed an effect of caffeine consumption on endurance capacity at doses of at least 3 mg/kg body weight administered at least one hour prior to exercise, and after at least 12 hours of caffeine withdrawal in habitual caffeine consumers, and that evidence on a plausible mechanism by which caffeine could exert the claimed effect has been provided.

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 an increase in endurance capacity.

The Panel considers that in order to obtain the claimed effect, caffeine should be consumed at doses of 3 mg/kg body weight one hour prior to exercise. The target population is adults performing endurance exercise.

Reduction in the rated perceived exertion/effort during exercise

The claimed effects are “supports exercise performance (reduction in perceived exertion, improved time to exhaustion and exercise capacity)” and “reduces perception of effort”. The target population is assumed to be adults performing endurance exercise. The Panel considers that a reduction in the rated perceived exertion/effort during exercise is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that most of the human intervention studies provided (including a meta-analysis of 22 randomised controlled trials and one individual randomised controlled trial) showed an effect of caffeine consumption on ratings of perceived exertion during exercise at doses of at least 4 mg/kg body weight administered at least one hour prior to exercise, and after at least 12 hours of caffeine withdrawal in habitual caffeine consumers.

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 a reduction in the rated perceived exertion/effort during exercise.

The Panel considers that in order to obtain the claimed effect, caffeine should be consumed at doses of 4 mg/kg body weight one hour prior to exercise. The target population is adults performing endurance exercise.

KEY WORDS

Caffeine, physical performance, endurance performance, endurance capacity, exertion, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

EFSA DISCLAIMER

See Appendix B

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out⁵. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is caffeine. Caffeine, a natural compound in coffee beans and tea leaves, is a well characterised substance which can be measured by established methods.

The Panel considers that the food constituent, caffeine, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Increase in physical performance during short-term high-intensity exercise (ID 737, 1486, 1489)

The claimed effects are “physical performance (short term and endurance activities)” and “endurance during short term high intensity exercise”. The Panel assumes that the target population is active individuals in the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to increase in physical performance during short-term high-intensity (>80 % maximum O₂ consumption) exercise. Performance relates to the ability of completing a certain task (e.g. running a certain distance) as fast as possible.

The Panel considers that an increase in physical performance during short-term high-intensity exercise is a beneficial physiological effect.

2.2. Increase in endurance performance (ID 737, 1486)

The claimed effect is “physical performance (short term and endurance activities)”. The Panel assumes that the target population is adults performing endurance exercise.

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>

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to increase in endurance performance (i.e. during longer-term exercise generally at intensity <80 % maximum O₂ consumption). Performance relates to the ability of completing a certain task (e.g. running a certain distance) as fast as possible.

The Panel considers that an increase in endurance performance is a beneficial physiological effect.

2.3. Increase in endurance capacity (ID 1488)

The claimed effect is “supports exercise performance (reduction in perceived exertion, improve time to exhaustion and exercise capacity)”. The Panel assumes that the target population is adults performing endurance exercise.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to an increase in endurance capacity. Endurance capacity refers to the exercise time to self-reported fatigue when exercising at a constant workload or speed, generally at intensity <80 % maximum O₂ consumption.

The Panel considers that an increase in endurance capacity is a beneficial physiological effect.

2.4. Reduction in the rated perceived exertion/effort during exercise (ID 1488, 1490)

The claimed effects are “supports exercise performance (reduction in perceived exertion, improve time to exhaustion and exercise capacity)” and “reduces perception of effort”. The Panel assumes that the target population is adults performing endurance exercise.

In the context of the proposed wordings and the clarifications provided by Member States, the Panel assumes that the claimed effects refer to reduction in the rated perceived exertion/effort during exercise.

The Panel considers that a reduction in the rated perceived exertion/effort during exercise is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The combined list of references provided for ID 737, 1486, 1488, 1489 and 1490 was used for the evaluation of the claimed effects reported from section 2.1 to section 2.4. The list of references consisted of 54 articles (excluding duplicates), and included two meta-analyses of randomised controlled trials (RCTs) on the effects of caffeine consumption on exercise testing (Doherty and Smith, 2004), and on the rating of perceived exertion during and after exercise (Doherty and Smith, 2005), respectively, where most of the individual studies submitted in relation to these claims were already considered. The later meta-analysis specifically relates to the evaluation of the health relationship in section 2.4., and is described in section 3.4.

The meta-analysis by Doherty and Smith (2004) was limited to laboratory-based, double-blind, fully randomised (and mostly cross-over), placebo-controlled intervention studies on adult subjects published in peer-reviewed Journals in English after 1975, in which a primary outcome was the effects of a single caffeine dose on whole-body exercise. Studies where caffeine was administered in combination with other substances were not considered. A total of 40 intervention studies including 414 subjects (mean sample size 9.3 ± 2.5 subjects) and 76 outcome measures met the inclusion criteria. Most of the subjects were males (about 90 %) between 20 and 40 years of age, and with an aerobic capacity (VO_{2max}) of 56.0 ± 10.1 mL/kg/min (mostly physically active). The studies considered used three types of exercise protocol: short-term high intensity (ST), graded exercise tests performed to

exhaustion (GXT), and endurance-based efforts (END). In addition, studies with ST and END protocols had used either exercise capacity tests, or time to voluntary exhaustion on a constant exercise intensity (i.e. T_{lim} protocols), or exercise performance tests (e.g. time trials or distance trials (i.e. non- T_{lim} protocols)). Therefore, the effects of caffeine consumption on exercise capacity (T_{lim} protocols) and exercise performance (non- T_{lim} protocols) during short (ST) and long-term (END) exercise could be addressed in the meta-analysis. The meta-analysis also considered how other variables could affect the effects of caffeine consumption on whole-body exercise testing, including usual caffeine consumption, caffeine dose, time of caffeine withdrawal prior to testing, time between caffeine intake and exercise testing, and training of subjects. None of these variables appeared to have an effect on the ergonomic effects of caffeine, although no definitive conclusions could be drawn from the meta-analysis because of the homogeneity of the studies included in relation to these variables.

The effects of caffeine on test outcomes were quantified by calculating effect sizes (ES), as well as the relative change from placebo after caffeine ingestion, ES being a dimensionless measure centred at zero if caffeine had a neutral effect compared to placebo. No publication bias was identified.

The specific effects on various exercise outcomes are presented below for the separate health relationships.

3.1. Increase in physical performance during short-term high-intensity exercise (ID 737, 1486, 1489)

In the meta-analysis by Doherty and Smith (2004), the evaluation of a potential ergogenic effect of caffeine on short-term, high-intensity exercise (ST) included 12 studies evaluating 26 outcomes. Of these, 22 outcome measures addressed non- T_{lim} protocols, and therefore exercise performance (Anderson et al., 2000; Anselme et al., 1992; Bruce et al., 2000; Collomp et al., 2002; Doherty et al., 2004; Greer et al., 1998; Vanakoski et al., 1998; Williams et al., 1988). No significant effect of caffeine consumption on exercise performance was observed ($ES=0.00\pm 0.33$, 95 % CI -0.02 to 0.02). In these studies, subjects were low to moderate caffeine users (in most studies usual caffeine intake was not reported), caffeine was withdrawn 24-168 hours before testing (24-72 h in most studies), and the caffeine dose ranged from 3.5 to 9 mg/kg body weight (5 to 7 mg/kg body weight in most studies) and was administered between 30 and 120 min (mostly between 60 and 120 min) before exercise testing.

Three individual studies which investigated the effect of caffeine consumption on physical performance during short-term exercise tests were provided in the consolidated list (Collomp et al., 1992; Paton et al., 2001; Wiles et al., 2006), one of which had been already considered in the meta-analysis above (Collomp et al., 1992).

In the study by Wiles et al. (2006), eight trained cyclists cycled 1 km in the laboratory after consumption of 5 mg of caffeine per kg body weight, or the same amount of placebo, in a control situation (no intervention) following a randomised, double-blind (for caffeine and placebo) cross-over design. Performance time was significantly reduced (by 3.1 %) after consumption of caffeine compared to the placebo and control tests. This decrease was accompanied by significant increases in mean speed, mean power, and peak power output after caffeine consumption compared to placebo and control. On the other hand, in the study by Paton et al. (2001), physical performance during a repeated sprint test comprising 20-metre sprints repeated 10 times during 100 seconds was not affected in 16 male team-sport athletes, 60 minutes after ingesting caffeine (6 mg/kg body weight) compared to placebo.

In weighing the evidence, the Panel took into account that the evidence for an effect of caffeine consumption on physical performance during short-term high-intensity exercise is inconsistent, and

that one meta-analysis of RCTs including 8 studies and 22 outcome measures did not show an effect of caffeine consumption on physical performance during short-term high-intensity exercise.

The Panel concludes that a cause and effect relationship has not been established between the consumption of caffeine and an increase in physical performance during short-term high-intensity exercise.

3.2. Increase in endurance performance (ID 737, 1486)

In the meta-analysis by Doherty and Smith (2004), the evaluation of a potential ergogenic effect of caffeine on endurance exercise included 23 studies evaluating 39 outcomes. Of these, five studies (with five outcome measures) addressed non- T_{lim} protocols, and therefore endurance performance (Bell and McLellan, 2002; Cole et al., 1996; Conway et al., 2003; Cox et al., 2002; MacIntosh and Wright, 1995). A statistically significant effect of caffeine consumption on endurance performance was observed ($ES=0.28\pm 0.160$, 95 % CI 0.08 to 0.47). In these studies, subjects were low to moderate caffeine users, caffeine was withdrawn 24-48 hours before testing, and the caffeine dose ranged from 4 to 6 mg/kg body weight and was administered between 60 and 150 min before the exercise testing. The Panel notes that the meta-analysis did not address whether the observed positive effects on endurance performance following caffeine intake were due to an ergogenic effect of caffeine intake *per se*, or to a detrimental effect of previous caffeine withdrawal.

A number of individual, randomised, placebo-controlled intervention studies which investigated the effects of caffeine on endurance performance were provided in the consolidated list (Berglund and Hemmingsson, 1982; Bridge and Jones, 2006; Cox et al., 2002; Kovacs et al., 1998; MacIntosh and Wright, 1995). The studies by MacIntosh and Wright (1995) and Cox et al. (2002) were included in the meta-analysis by Doherty and Smith (2004) and are not discussed further.

Berglund and Hemmingsson (1982) found that performance in well trained cross-country skiers during a 21 km time trial was enhanced at sea level and at high altitude after caffeine consumption (6 mg/kg body weight 60 min prior to testing) compared with placebo. Subjects were habitual caffeine consumers and caffeine was withdrawn 12 hours before testing. A 24-sec reduction (-1.2 %) in 8-km running time was found by Bridge et al. (2006) after ingestion of caffeine (3 mg/kg body weight 60 min prior to the race) compared with placebo in 8 trained male distance runners. Subjects were habitual caffeine consumers and caffeine was withdrawn 48 hours before testing. In a study by Kovacs et al. (1998) 15 well-trained men (triathletes and cyclists) were given 1.2 mg, 1.8 mg or 2.56 mg caffeine per kg body weight during a 20-minute cycling warm-up protocol, and an additional 0.9 mg, 1.35 mg or 5.1 mg caffeine/kg body weight during a subsequent one-hour time trial. All doses led to significant improvements in performance compared with placebo.

In weighing the evidence, the Panel took into account that most of the human intervention studies provided (including a meta-analysis of five RCTs and three individual RCTs) showed an effect of caffeine consumption on endurance performance at doses of at least 3 mg/kg body weight administered at least one hour prior to exercise, and after at least one day of caffeine withdrawal in habitual caffeine consumers.

The Panel concludes that a cause and effect relationship has been established between the consumption of caffeine and an increase in endurance performance.

3.3. Increase in endurance capacity (ID 1488)

In the meta-analysis by Doherty and Smith (2004), the evaluation of a potential ergogenic effect of caffeine on endurance exercise included 23 studies evaluating 39 outcomes. Of these, 34 outcome measures addressed T_{lim} protocols, and therefore endurance capacity (Alves et al., 1995; Bell et al.,

1998; Bell and McLellan, 2002, 2003; Butts and Crowell, 1985; Cha et al., 2001; Cole et al., 1996; Conway et al., 2003; Denadai and Denadai, 1998; French et al., 1991; Fulco et al., 1994; Graham and Spriet, 1991, 1995; Graham et al., 1998; Greer et al., 2000; Lindinger et al., 1993; Pasman et al., 1995; Trice and Haymes, 1995; Van Soeren and Graham, 1998). A statistically significant effect of caffeine consumption on endurance capacity was observed ($ES=0.68\pm 0.42$, 95 % CI 0.53 to 0.84). In these studies, subjects were low to moderate caffeine users, caffeine was withdrawn 12-96 hours before testing, and the caffeine dose ranged from 3 to 13 mg/kg (mostly between 5 and 6 mg/kg) body weight and was administered between 60 and 360 min (mostly up to 120 min) before exercise testing. The Panel notes that the meta-analysis did not address whether the observed positive effects on endurance performance following caffeine intake were due to an ergogenic effect of caffeine intake *per se*, or to a detrimental effect of previous caffeine withdrawal.

A number of individual intervention studies which investigated the effects of caffeine on endurance capacity have been provided with the consolidated list, some of which were already included in the meta-analysis by Doherty and Smith (2004) and which will not be discussed further (Bell and McLellan, 2002, 2003; Denadai and Denadai, 1998; French et al., 1991; Graham and Spriet, 1991, 1995; Pasman et al., 1995; Trice and Haymes, 1995; Van Soeren and Graham, 1998). Two additional studies assessed physical capacity during short-term high intensity exercise, and are therefore not pertinent to the claim (Flinn et al., 1990; Greer et al., 2000). Another study addressed the effects of caffeine in combination with glucose, which did not allow any conclusions to be drawn on the effects of caffeine alone (Sasaki et al., 1987).

Three human intervention studies on the effects of caffeine intake on endurance performance were not included in the meta-analysis (Costill et al., 1978; Jackman et al., 1996; Spriet et al., 1992).

In the study by Spriet et al. (1992), eight recreational cyclists (7 males) cycled to exhaustion at 80 % of VO_{2max} on two different days after consuming either caffeine or placebo in a single-blind manner. All subjects consumed placebo in the first test and caffeine in the second. The Panel notes the uncontrolled nature of the study and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

In a double-blind, cross-over, placebo-controlled intervention by Costill et al. (1978), nine competitive cyclists (seven males) consumed either decaffeinated coffee (5 g in 200 mL of hot water) or caffeinated coffee (same amount plus 330 mg caffeine) 60 minutes prior to cycling on a bicycle ergometer at 80 % of VO_{2max} . Total exercise time to exhaustion was significantly increased after consumption of caffeinated coffee ($19.5\% \pm SEM 2.3$; $p < 0.05$). Also in a double-blind, cross-over, placebo-controlled intervention by Jackman et al. (1996), using an intense intermittent exercise protocol (2 min of cycling at an intensity corresponding to maximal VO_2 , interrupted by 6 min rest periods), consumption of caffeine (6 mg/kg body weight) increased time to exhaustion significantly compared to placebo (dextrose) in 14 young adults who were active recreational or university of endurance activity athletes (11 males).

A plausible mechanism by which caffeine could exert the claimed effect is through the reduction of perceived exertion (RPE) during exercise (Doherty and Smith, 2005) (see section 3.4).

In weighing the evidence, the Panel took into account that most of the human intervention studies provided (including a meta-analysis of 23 RCTs evaluating 39 outcomes and two individual RCTs) showed an effect of caffeine consumption on endurance capacity at doses of at least 3 mg/kg body weight administered at least one hour prior to exercise, and after at least 12 hours of caffeine withdrawal in habitual caffeine consumers, and that evidence on a plausible mechanism by which caffeine could exert the claimed effect has been provided.

The Panel concludes that a cause and effect relationship has been established between the consumption of caffeine and an increase in endurance capacity.

3.4. Reduction in the rated perceived exertion/effort during exercise (ID 1488, 1490)

In the meta-analysis by Doherty and Smith (2005) based on 22 laboratory-based, double-blind, fully randomised (and mostly cross-over), placebo-controlled intervention studies, the effects of caffeine ingestion on ratings of perceived exertion (RPE) during exercise were examined, and it was found that caffeine compared to placebo significantly reduced RPE during exercise (in 20 out of the 22 studies) by 5.6 % (95 % CI -4.5 to -6.7), and that RPE could account for 29 % of the variance in the improved exercise performance (based on 16 studies where changes in exercise performance were tested). This analysis comprised studies from 1975 to 2004 representing over 200 subjects (74 % men). The typical subject can be characterised as being 20 to 35 years of age, physically active individuals to extremely well trained elite athletes, and both habitual caffeine users and non-users (half of the studies do not give information on coffee use). The protocols varied, including work intensities from 50 % to 125 % (mean=80 %) of VO_{2max} . The caffeine doses ranged from 4 to 10 mg per kg (median 6 mg/kg) body weight and were typically given one hour before the start of the exercise test, and the caffeine abstinence of the subjects varied from 12 to 240 hours (median = 24 hours).

In a double-blind, cross-over, placebo-controlled intervention study published after the meta-analysis by Doherty and Smith (2005), nine competitive male rugby players ingested either caffeine (6 mg/kg body weight) or placebo (dextrose) 70 min before performing a rugby test consisting of seven circuits in each of two 40-min halves with a 10-min half-time rest (Stuart et al., 2005). The development of fatigue during the test was significantly reduced after caffeine consumption compared to placebo.

In weighing the evidence, the Panel took into account that most of the human intervention studies provided (including a meta-analysis of 22 RCTs and one individual RCT) showed an effect of caffeine consumption on RPE during exercise at doses of at least 4 mg/kg body weight administered at least one hour prior to exercise, and after at least 12 hours of caffeine withdrawal in habitual caffeine consumers.

The Panel concludes that a cause and effect relationship has been established between the consumption of caffeine and a reduction in the rated perceived exertion/effort during exercise.

4. Panel's comments on the proposed wordings

4.1. Increase in endurance performance (ID 737, 1486)

The Panel considers that the following wording reflects the scientific evidence: "Caffeine contributes to an increase in endurance performance".

4.2. Increase in endurance capacity (ID 1488)

The Panel considers that the following wording reflects the scientific evidence: "Caffeine contributes to an increase in endurance capacity".

4.3. Reduction in the rated perceived exertion/effort during exercise (ID 1488, 1490)

The Panel considers that the following wording reflects the scientific evidence: "Caffeine contributes to a reduction in the rated perceived exertion/effort during exercise".

5. Conditions and possible restrictions of use

5.1. Increase in endurance performance (ID 737, 1486)

The Panel considers that in order to obtain the claimed effect, caffeine should be consumed at doses of 3 mg/kg body weight one hour prior to exercise. The target population is adults performing endurance exercise.

5.2. Increase in endurance capacity (ID 1488)

The Panel considers that in order to obtain the claimed effect, caffeine should be consumed at doses of 3 mg/kg body weight one hour prior to exercise. The target population is adults performing endurance exercise.

5.3. Reduction in the rated perceived exertion/effort during exercise (ID 1488, 1490)

The Panel considers that in order to obtain the claimed effect, caffeine should be consumed at doses of 4 mg/kg body weight one hour prior to exercise. The target population is adults performing endurance exercise.

CONCLUSIONS

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

- The food constituent, caffeine, which is the subject of the health claims, is sufficiently characterised.

Increase in physical performance during short-term high-intensity exercise (ID 737, 1486, 1489)

- The claimed effects are “physical performance (short term and endurance activities)” and “endurance during short term high intensity exercise”. The target population is assumed to be active individuals in the general population. In the context of the proposed wordings, it is assumed that the claimed effects refer to increase in physical performance during short-term high-intensity exercise. An increase in physical performance during short-term high-intensity exercise is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of caffeine and an increase in physical performance during short-term high-intensity exercise.

Increase in endurance performance (ID 737, 1486)

- The claimed effect is “physical performance (short term and endurance activities)”. The target population is assumed to be adults performing endurance exercise. In the context of the proposed wordings, it is assumed that the claimed effect refers to increase in endurance performance. An increase in endurance performance is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of caffeine and an increase in endurance performance.
- The following wording reflects the scientific evidence: “Caffeine contributes to an increase in endurance performance”.

- In order to obtain the claimed effect, caffeine should be consumed at doses of 3 mg/kg body weight one hour prior to exercise. The target population is adults performing endurance exercise.

Increase in endurance capacity (ID 1488)

- The claimed effect is “supports exercise performance (reduction in perceived exertion, improve time to exhaustion and exercise capacity)”. The target population is assumed to be adults performing endurance exercise. In the context of the proposed wordings, it is assumed that the claimed effect refers to an increase in endurance capacity. An increase in endurance capacity is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of caffeine and an increase in endurance capacity.
- The following wording reflects the scientific evidence: “Caffeine contributes to an increase in endurance capacity”.
- In order to obtain the claimed effect, caffeine should be consumed at doses of 3 mg/kg body weight one hour prior to exercise. The target population is adults performing endurance exercise.

Reduction in the rated perceived exertion/effort during exercise (ID 1488, 1490)

- The claimed effects are “supports exercise performance (reduction in perceived exertion, improve time to exhaustion and exercise capacity)” and “reduces perception of effort”. The target population is assumed to be adults performing endurance exercise. A reduction in the rated perceived exertion/effort during exercise is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of caffeine and a reduction in the rated perceived exertion/effort during exercise.
- The following wording reflects the scientific evidence: “Caffeine contributes to a reduction in the rated perceived exertion/effort during exercise”.
- In order to obtain the claimed effect, caffeine should be consumed at doses of 4 mg/kg body weight one hour prior to exercise. The target population is adults performing endurance exercise.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1524, EFSA-Q-2008-2223, EFSA-Q-2008-2225, EFSA-Q-2008-2226, EFSA-Q-2008-2227). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

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

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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

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

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

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

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

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

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

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

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁷

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

⁶ OJ L12, 18/01/2007

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

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

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

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

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

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

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

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

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

WORDING OF HEALTH CLAIMS

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

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

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

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

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

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

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

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

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

TERMS OF REFERENCE

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

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

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

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

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

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

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

APPENDIX B

EFSA DISCLAIMER

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

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

APPENDIX C

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

ID	Food or Food constituent	Health Relationship	Proposed wording
737	Caffeine (from tea/coffee/chocolate or added in pure form)	Physical Performance (short term and endurance activities)	Improves physical performance.
	Conditions of use - 1-5mg/kg/day		
ID	Food or Food constituent	Health Relationship	Proposed wording
1486	Caffeine (from tea/coffee/chocolate or added in pure form)	Physical Performance (short term and endurance activities)	Improves physical performance.
	Conditions of use - 1-5mg/kg/day. Beverages must comply with the labelling requirements laid down by Directive 2002/67/EC. Caffeine should be equal to or greater than 1 mg/kg body mass per portion (equivalent to ~160 mg/l).		
ID	Food or Food constituent	Health Relationship	Proposed wording
1488	Caffeine	Supports exercise performance (reduction in perceived exertion, improve time to exhaustion and exercise capacity)	-Caffeine helps prolong exercise time -Caffeine can help increase time to exhaustion allowing you to workout longer -Caffeine supports an increase in performance capacity -Caffeine can improve endurance performance -Caffeine can decrease perceived exertion
	Conditions of use - The product must contain at least 100 milligrams caffeine per serving or 1-5mg 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.		
ID	Food or Food constituent	Health Relationship	Proposed wording
1489	Caffeine	Endurance during short term high intensity exercise	-Enhances physical performance. -Provides a performance edge -Can delay the onset of fatigue -Can increase exercise intensity/work rate

	<p>Conditions of use</p> <ul style="list-style-type: none"> - Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC. Caffeine should be equal to or greater than 1 mg/kg body mass per serve. Beverages must comply with the labelling requirements laid down by Directive 2002/67/EC. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
1490	Caffeine (with or without carbohydrate)	<p>Reduces perception of effort</p> <p><u>Clarification provided</u></p> <p>Effort: Reduces ratings of perceived exertion during exercise</p> <p>[for example as defined by the Borg scale (Psychophysical bases of perceived exertion. Borg G. Med Sci Sports Exerc 14: 377-381, 1982.) or other validated scales of measurement]</p>	Reduces the perception of effort.
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC. Caffeine in doses ranging from 1-13 mg/kg body mass. Beverages must comply with the labelling requirements laid down by Directive 2002/67/EC. 		

GLOSSARY AND ABBREVIATIONS

CI	Confidence interval
END	Endurance based efforts
ES	Effect sizes
GXT	Graded exercise tests performed to exhaustion
RPE	Ratings of perceived exertion
RCT	Randomised controlled trial
ST	Short-term high intensity
VO _{2max}	Maximum O ₂ consumption