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European Food Safety Authority

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to creatine and increase in physical performance during short-term, high intensity, repeated exercise bouts (ID 739, 1520, 1521, 1522, 1523, 1525, 1526, 1531, 1532, 1533, 1534, 1922, 1923, 1924), increase in endurance capacity (ID 1527, 1535), and increase in endurance performance (ID 1521, 1963) 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 creatine and increase in physical performance during short-term, high intensity, repeated exercise bouts, increase in endurance capacity, and increase in endurance performance. 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 creatine. The Panel considers that creatine is sufficiently characterised.

Increase in physical performance during short-term, high intensity, repeated exercise bouts

The claimed effects are "energy metabolism", "muscular effort", "bodily constitution", "increasing strength", "increasing mass", "increasing power", "increasing performance", "muscular

[1] On request from the European Commission, Question No EFSA-Q-2008-1526, EFSA-Q-2008-2257, EFSA-Q-2008-2258, EFSA-Q-2008-2259, EFSA-Q-2008-2260, EFSA-Q-2008-2262, EFSA-Q-2008-2263, EFSA-Q-2008-2264, EFSA-Q-2008-2268, EFSA-Q-2008-2269, EFSA-Q-2008-2270, EFSA-Q-2008-2271, EFSA-Q-2008-2272, EFSA-Q-2008-2655, EFSA-Q-2008-2656, EFSA-Q-2008-2657, EFSA-Q-2008-2696, adopted on 30 June 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.

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effort/recovery", "increasing time to exhaustion" and "increasing lifting volume and performance". The target population is assumed to be adults performing high-intensity exercise. In the context of the proposed wordings and the references provided, the Panel assumes that the claimed effects refer to an increase in physical performance during short-term, high intensity, repeated exercise bouts. The Panel considers that an increase in physical performance during short-term, high intensity, repeated exercise bouts is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that there is good consensus on the role of creatine in increasing physical performance during short-term, high intensity, repeated exercise bouts, and that the meta-analyses and individual intervention studies provided in the consolidated list are consistent with this consensus.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of creatine and an increase in physical performance during short-term, high intensity, repeated exercise bouts.

The Panel considers that in order to obtain the claimed effect, 3 g of creatine should be consumed daily. The target population is adults performing high-intensity exercise.

Increase in endurance capacity

The claimed effect is "increasing workout 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 the three human intervention studies provided from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of creatine supplementation on measures of endurance capacity.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of creatine and an increase in endurance capacity.

Increase in endurance performance

The claimed effects are "muscular effort" and "creatine: energy reserve of muscle tissue". The target population is assumed to be adults performing endurance exercise. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to increase in endurance performance (i.e. during longer-term exercise generally at intensity <80 % of maximum O_2 consumption). The Panel considers that an increase in endurance performance is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that one meta-analysis of 18 human intervention studies, and one additional study, did not show an effect of creatine supplementation on measures of endurance performance.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of creatine and an increase in endurance performance.

KEY WORDS

Creatine, physical performance, endurance capacity, endurance performance, exercise, 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

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EFSA DISCLAIMER

See Appendix B

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[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 food constituent that is the subject of the health claims is creatine.

Creatine is a non-essential nitrogenous organic acid that occurs in vertebrates, and it is also synthesised in the human body from L-arginine, glycine and L-methionine. Approximately 95 % of the creatine pool in the body is located in skeletal muscle. The content of creatine in foods can be measured by established methods.

The Panel considers that the food constituent, creatine, 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, repeated exercise bouts (ID 739, 1520, 1521, 1522, 1523, 1525, 1526, 1531, 1532, 1533, 1534, 1922, 1923, 1924)

The claimed effects are "energy metabolism", "muscular effort", "bodily constitution", "increasing strength", "increasing mass", "increasing power", "increasing performance", "muscular effort/recovery", "increasing time to exhaustion", and "increasing lifting volume and performance". The Panel assumes that the target population is adults performing high-intensity exercise.

In the context of the proposed wordings and the references provided, the Panel assumes that the claimed effects refer to an increase in physical performance during short-term, high intensity, repeated exercise bouts. Physical performance relates to the ability to complete certain tasks with higher intensity, faster, or with a higher power output. Muscle mass and strength are major determinants of physical performance. In repeated exercise bouts, physical performance is also related to the ability of muscle to recover faster from high-intensity exercise.

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

[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] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

2.2. Increase in endurance capacity (ID 1527, 1535)

The claimed effect is "increasing workout 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.

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

2.3. Increase in endurance performance (ID 1521, 1963)

The claimed effects are "muscular effort" and "creatine: energy reserve of muscle tissue". 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 effects refer to an increase in endurance performance (i.e. during longer-term exercise generally at intensity <80 % of maximum O_2 consumption). Endurance performance relates to the ability to complete certain tasks with higher intensity, faster, or with a higher power output when performing long-term exercise.

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

3. Scientific substantiation of the claimed effect

The references provided in the consolidated list in relation to the claims evaluated in this opinion included narrative reviews and book chapters which contained no original data for the scientific substantiation of the claims, and abstracts and conference proceedings reporting on human intervention studies in which the information provided regarding the study design, methodology and statistical analyses was insufficient for a full scientific evaluation. Some of the references reported on human intervention studies in which creatine was administered in combination with other food constituents (e.g. carbohydrates, protein, micronutrients and fatty acids) so that the study design did not allow conclusions to be drawn on the effect of creatine alone. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

The references provided also included statements/consensus opinions from authoritative bodies such as the Agence Française de Sécurité Sanitaire des Aliments (AFSSA, 2000), the Scientific Committee on Food (SCF, 2001), and the American College of Sports Medicine (Terjung et al., 2000). Other consensus opinions were published by the International Society of Sports Nutrition (Buford et al., 2007; Kreider et al., 2010) and the American Dietetic Association (Rodriguez et al., 2009). Two meta-analyses of human intervention studies (Branch, 2003; Nissen and Sharp, 2003) and one "systematic review" (Rawson and Volek, 2003) which addressed the effects of creatine consumption on outcome measures relevant to the claimed effects evaluated in this opinion, considered the vast majority of individual human intervention studies submitted for the scientific substantiation of the claims. In addition, three of the references provided which reported on human intervention studies and which addressed the effects of creatine on outcome measures related to the claimed effects evaluated in this opinion were not included in the meta-analyses described below, and will be considered separately as appropriate (Izquierdo et al., 2002; Ostojic, 2004; Syrotuik et al., 2001).

The purpose of the "systematic review" by Rawson and Volek (2003) was to address the effects of creatine supplementation and concurrent resistance training on muscle strength and weight lifting performance. A total of 22 studies, 14 of which were already included in the meta-analysis by Nissen and Sharp (2003), met the inclusion criteria of Rawson and Volek (2003) and the remaining, except three (Stevenson and Dudley, 2001; Syrotuik et al., 2000; Syrotuik et al., 2001), were considered in

the meta-analysis by Branch (2003). Two of the three references were provided in the consolidated list as individual studies (Stevenson and Dudley, 2001; Syrotuik et al., 2001). The Panel notes that the methodology (e.g. literature search or other strategies used to identify pertinent references, and methodology used to calculate average percent estimates for increases in muscle strength and weight lifting performance) used in this review is poorly described and that all the studies included were already considered in the meta-analyses provided or were submitted separately. The Panel considers that no conclusions can be drawn from this review for the scientific substantiation of the claims evaluated in this opinion.

The meta-analysis by Branch (2003) included 96 publications (published up to December 2000) from 100 randomised, placebo-controlled trials, in which at least subjects were blinded to the intervention. These studies comprised 1,847 subjects. Results were given as means±SEM and 95 % CI. Mean sample size was 19±1 (range 4 to 80). Most of the studies (93 %) were published after 1994, and most (71 % of the studies) were randomised, double-blind, placebo-controlled interventions which addressed the effect of an acute (≤14 days) creatine loading regimen (19.7±0.5 g creatine for an average of 9±1 days) on physical performance in mostly young trained (77 % of the studies) men (68 % of the studies). Only 22 studies investigated the effects of low dose maintenance creatine supplementation (>14 days) following acute creatine loading. Twenty-four studies included men and women as subjects. The effect of creatine supplementation on women was the focus in only 9 studies. The primary objective of the meta-analysis was to quantify the effect of creatine supplementation on body composition (including lean body mass) and exercise performance. Performance tasks were classified as single-bout or repetitive-bout exercises. The first bout of repetitive-bout exercises was classified as a single-bout exercise task. Performance tasks of ≤30 sec, 30 to 150 sec, and >150 sec were also analysed separately. The effect size (ES) of creatine supplementation variable was calculated for each dependent.

The meta-analysis by Nissen and Sharp (2003) assessed the effects of longer-term creatine supplementation on lean body mass and muscle strength during resistance training. Only randomised, placebo-controlled human intervention studies, published in peer reviewed journals between 1967 and 2001, of at least 3 weeks duration and which involved a full-body resistance-training regimen two or more times per week and were conducted in healthy adults who were not under dietary restriction were included. A total of 18 studies using creatine alone as intervention met the inclusion criteria. These studies included a total of 368 subjects (n=180 in the intervention group and n=188 in the control group) with a mean age of 24 years. All studies had a parallel design, and the sample size in individual studies was generally small (mean n=10 per group). All studies included were published between 1997 and 2001. Three studies included men and women, three studies included women only, and the remaining studies were conducted in men only. Five studies were conducted in untrained subjects, and 13 studies in trained individuals. The studies averaged 7.5 weeks (range 3-13 weeks) in duration. The average loading dose of creatine was 19.4 g/day (range 10-21 g/day) for 5.3 days (range 4-7 days), and the average maintenance dose was 6.7 g/day (range 2-10.5 g/day). Changes in lean mass and strength were normalised for inclusion in the meta-analysis by conversion to percentage change per week for both treatment and placebo groups. Effect sizes (ES) of lean mass and strength changes were calculated for each dependent variable. Duration of tasks and task repetition were not considered in the analysis. All the studies included in this meta-analysis except four (Arciero et al., 2001; Bemben et al., 2001; Chrusch et al., 2001; Jowko et al., 2001) were already considered in the meta-analysis by Branch (2003).

These references will be referred to in different sections of the present evaluation as appropriate.

3.1. Increase in physical performance during short-term, high intensity, repeated exercise bouts (ID 739, 1520, 1521, 1522, 1523, 1525, 1526, 1531, 1532, 1533, 1534, 1922, 1923, 1924)

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus on the role of creatine in increasing physical performance during short-term, high intensity, repeated exercise bouts (AFSSA, 2000; Buford et al., 2007; Kreider et al., 2010; Rodriguez et al., 2009; SCF, 2001; Terjung et al., 2000).

Creatine phosphate (CrP) serves as a readily available source of energy in skeletal muscle and other tissues. For most exercise situations, the demand for adenosine triphosphate (ATP) is predominantly provided through oxidative phosphorylation in the mitochondria. However, when aerobic energy production cannot meet the demand for ATP, anaerobic energy production from CrP hydrolysis and glycogenolysis/glycolysis is required to assist in the provision of ATP. Such cases include the transition from rest to exercise, the transition from one power output to a higher power output, and power outputs above 90-100 % maximal oxygen consumption (VO_2max). The rapid re-phosphorylation of adenosine diphosphate (ADP) from CrP via the creatine kinase reaction may buffer changes in ATP during transitions between rest and exercise, and may contribute a substantial fraction of ATP synthesis during short duration, high intensity exercise (AFSSA, 2000; Buford et al., 2007; SCF, 2001; Terjung et al., 2000).

During a bout of high intensity exercise, the relative importance of CrP hydrolysis to ATP synthesis falls off as the exercise duration is increased beyond a few seconds. The greatest improvements in performance following short-term creatine supplementation (5-7 days of ~20 g/day) are found during a series of repetitive, high power output exercise bouts. Exercise performance during the latter bouts of a series (e.g. third, fourth and fifth) can be increased by 5-20 % in very high power output exercise bouts that can be maintained for only a short (seconds) period (e.g. maximal cycling and/or power jumping), and are separated by fairly brief periods of rest (e.g. 20-60 seconds). Therefore, it is likely that creatine supplementation improves exercise performance in sport events which require explosive, high-energy output activities, especially of a repeated nature (AFSSA, 2000; Buford et al., 2007; SCF, 2001; Terjung et al., 2000).

Creatine ingestion increases the total creatine content in human muscle by approximately 15-20 % (mean value), albeit a high inter-individual variability exists. Such increases can be achieved by ingestion of 20 g per day for 4-5 days, but also by ingestion of 3 g per day over a period of one month. The increased creatine content in human muscle is maintained when the ingestion is reduced to 2 g per day after the original loading period. There is a substantial reduction in urine production on the first three days of the loading period and this reduction is coincident with the retention of creatine. The retention of water is thought to be related to an osmotic load caused by creatine retention and to account for the rapid-onset weight gain experienced by many individuals ingesting creatine. Many studies have reported increases in body mass of 1-3 kg following short-term (5-7 days) creatine supplementation (AFSSA, 2000; Buford et al., 2007; SCF, 2001; Terjung et al., 2000).

Longer-term creatine supplementation (e.g. 4 to 12 weeks) in combination with training appears to increase muscle mass and strength as a result of an improved ability to perform high-intensity exercise via increased CrP availability (Buford et al., 2007; SCF, 2001).

The meta-analyses and individual intervention studies provided in the consolidated list are consistent with the above-mentioned consensus. In the meta-analysis by Branch (2003), anaerobic exercise performance capacity during high-intensity, short-duration exercise (≤30 sec) was significantly increased by creatine supplementation (617 performance variables; ES=0.24±0.002, 95 % CI=0.20, 0.28; $p<0.05$), and the majority of the studies considered (45 out of 61) reported an ergonomic effect of creatine. Significantly more repetitions at specific submaximal intensity/workload (21 estimates; ES=0.64±0.18, 95 % CI=0.27, 1.00, $p<0.05$) and greater work capacity (83 estimates; ES=0.21±0.05,

95 % CI=0.11, 0.30, n=83, p<0.05) were performed during consumption of creatine compared to placebo. ES for repetitive-bout exercise was significantly higher than for single-bout exercise, and mean ES for percentage decrement in performance over multiple high-intensity bouts was not significantly different from zero (ES= –0.04±0.06; 95 %CI= –0.16, 0.09), suggesting a resistance to fatigue between exercise bouts associated with creatine supplementation. The effect of creatine on overall exercise performance was still significant, but less evident, for tasks lasting 30 to 150 sec (135 performance estimates; ES=0.19±0.05, 95 % CI=0.10, 0.28; p<0.05), and it was non-significant for tasks lasting more than 150 sec (ES=0.09±0.07; 95 % CI= –0.04, 0.22). On the other hand, the meta-analysis by Nissen and Sharp (2003) supports a positive effect of longer-term (3-13 weeks) creatine supplementation on lean body mass (ES=0.26; 95 % CI=0.17, 0.34, p<0.001) and strength (ES=0.36; CI=0.28, 0.43, p<0.001) during repetitive resistance training, possibly owing to an improved ability to perform high-intensity exercise.

In weighing the evidence, the Panel took into account that there is good consensus on the role of creatine in increasing physical performance during short-term, high intensity, repeated exercise bouts, and that the meta-analyses and individual intervention studies provided in the consolidated list are consistent with this consensus.

The Panel concludes that a cause and effect relationship has been established between the consumption of creatine and an increase in physical performance during short-term, high intensity, repeated exercise bouts.

3.2. Increase in endurance capacity (ID 1527, 1535)

Among the references provided in the consolidated list, three reported on individual human intervention studies which investigated the effect of creatine supplementation on continuous (Zoeller et al., 2007) or intermittent (Izquierdo et al., 2002; Ostojic, 2004) endurance cycling or running capacity. Two of the studies tested the effects of an acute creatine load (Izquierdo et al., 2002; Ostojic, 2004), whereas one study used an acute creatine load followed by a creatine maintenance phase (Zoeller et al., 2007).

Izquierdo et al. (2002) investigated the effects of acute creatine supplementation (20 g/day for five days) on endurance capacity in trained male handball players randomly assigned to either creatine (n=9) or placebo (maltodextrin; n=10). Before and after supplementation, subjects performed a maximal multistage discontinuous incremental running test to exhaustion. No significant differences in endurance capacity were observed between the creatine and placebo groups. Ostojic et al. (2004) examined the effects of a seven-day creatine supplementation (30 g/day) *vs.* placebo (cellulose) on endurance capacity assessed by a maximal multistage 20 m shuttle run test in 20 young soccer players in a randomised parallel study. No significant differences between the creatine and placebo groups were observed. In the study by Zoeller et al. (2007), 55 men (24.5±5.3 years) were randomly assigned to one of the following supplementation groups for four weeks: placebo (34 g glucose/day, n=13), creatine (5.25 g/day creatine monohydrate plus 34 g glucose, n=12), beta-alanine (n=14), or beta-alanine plus creatine (n=16). Prior to and following supplementation, participants performed a graded exercise test on a cycle ergometer to determine time to exhaustion. The initial power output was set at 30 watts and increased 30 watts every two minutes until the subject could not maintain the required power output at a pedaling rate of 70 rpm, or until volitional termination owing to fatigue. No significant differences in time to exhaustion were observed between groups.

The Panel notes that the three human intervention studies provided did not show an effect of creatine supplementation on measures of endurance capacity. The Panel also notes that there is no consensus on the role of creatine in increasing endurance (aerobic) capacity (AFSSA, 2000; Buford et al., 2007; Kreider et al., 2010; SCF, 2001; Terjung et al., 2000).

In weighing the evidence, the Panel took into account that the three human intervention studies provided from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of creatine supplementation on measures of endurance capacity.

The Panel concludes that a cause and effect relationship has not been established between the consumption of creatine and an increase in endurance capacity.

3.3. Increase in endurance performance (ID 1521, 1963)

In the meta-analysis by Branch (2003), half of the studies (nine studies out of 18) which investigated the effect of creatine supplementation on measures of performance during continuous, long-term aerobic exercise (>150 sec) in endurance sports (running and swimming) did not show an effect of creatine supplementation compared to placebo, and the overall effect was not significant (ES=0.09±0.07; 95 % CI= –0.04, 0.22) after exclusion of an outlier with a large ES.

Among the references provided in the consolidated list, one reported on an individual human intervention study which investigated the effect of creatine supplementation on measures of endurance performance (Syrotuik et al., 2001), and was not included in the meta-analysis by Branch (2003).

Syrotuik et al. (2001) randomised 22 rowers to consume either creatine (0.3 g/kg/day for five days followed by a five-week maintenance dose of 0.03 g/kg/day) or placebo together with training (continuous and interval rowing and resistance training 4 and 2 days per week, respectively) for six weeks. No significant differences in repeated power interval performance or 2,000 m rowing times were observed compared to placebo during the five-day creatine loading or the five-week maintenance phases. The Panel notes that this study does not show an effect of creatine supplementation on endurance performance.

The Panel notes that one meta-analysis of 18 human intervention studies, and one additional study, did not show an effect of creatine supplementation on measures of endurance performance. The Panel also notes that there is no consensus on the role of creatine in increasing endurance (aerobic) performance (AFSSA, 2000; Buford et al., 2007; Kreider et al., 2010; SCF, 2001; Terjung et al., 2000).

In weighing the evidence, the Panel took into account that one meta-analysis of 18 human intervention studies, and one additional study, did not show an effect of creatine supplementation on measures of endurance performance.

The Panel concludes that a cause and effect relationship has not been established between the consumption of creatine and an increase in endurance performance.

4. Panel's comments on the proposed wording

4.1. Increase in physical performance during short-term, high intensity, repeated exercise bouts (ID 739, 1520, 1521, 1522, 1523, 1525, 1526, 1531, 1532, 1533, 1534, 1922, 1923, 1924)

The Panel considers that the following wording reflects the scientific evidence: "Consumption of creatine increases physical performance during short-term, high intensity, repeated exercise bouts".

5. Conditions and possible restrictions of use

5.1. Increase in physical performance during short-term, high intensity, repeated exercise bouts (ID 739, 1520, 1521, 1522, 1523, 1525, 1526, 1531, 1532, 1533, 1534, 1922, 1923, 1924)

The Panel considers that in order to obtain the claimed effect, 3 g of creatine should be consumed daily. The target population is adults performing high-intensity exercise.

CONCLUSIONS

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

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

Increase in physical performance during short-term, high intensity, repeated exercise bouts (ID 739, 1520, 1521, 1522, 1523, 1525, 1526, 1531, 1532, 1533, 1534, 1922, 1923, 1924)

- The claimed effects are "energy metabolism", "muscular effort", "bodily constitution", "increasing strength", "increasing mass", "increasing power", "increasing performance", "muscular effort/recovery", "increasing time to exhaustion" and "increasing lifting volume and performance". The target population is assumed to be adults performing high-intensity exercise. In the context of the proposed wordings and the references provided, it is assumed that the claimed effects refer to an increase in physical performance during short-term, high intensity, repeated exercise bouts. An increase in physical performance during short-term, high intensity, repeated exercise bouts is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of creatine and an increase in physical performance during short-term, high intensity, repeated exercise bouts.
- The following wording reflects the scientific evidence: "Consumption of creatine increases physical performance during short-term, high intensity, repeated exercise bouts".
- In order to obtain the claimed effect, 3 g of creatine should be consumed daily. The target population is adults performing high-intensity exercise.

Increase in endurance capacity (ID 1527, 1535)

- The claimed effect is "increasing workout 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 not been established between the consumption of creatine and an increase in endurance capacity.

Increase in endurance performance (ID 1521, 1963)

- The claimed effects are "muscular effort" and "creatine: energy reserve of muscle tissue". The target population is assumed to be adults performing endurance exercise. In the context of the proposed wordings, it is assumed that the claimed effects refer to increase in endurance performance. An increase in endurance performance is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of creatine and an increase in endurance performance.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1526, EFSA-Q-2008-2257, EFSA-Q-2008-2258, EFSA-Q-2008-2259, EFSA-Q-2008-2260, EFSA-Q-2008-2262, EFSA-Q-2008-2263, EFSA-Q-2008-2264, EFSA-Q-2008-2268, EFSA-Q-2008-2269, EFSA-Q-2008-2270, EFSA-Q-2008-2271, EFSA-Q-2008-2272, EFSA-Q-2008-2655, EFSA-Q-2008-2656, EFSA-Q-2008-2657, EFSA-Q-2008-2696). 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[6] (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[7]

Foods are commonly involved in many different functions[8] 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 creatine, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
739	Creatine	Energy metabolism	Support in case of intense physical activity/contributes to increased muscle strength/contributes to increased muscle torque production/contributes to increased training intensity workouts/contributes to increased work capacity/contributes to increased muscle fatigue resistance/helps reduce muscle fatigue during exercise/supplementation increases muscle creatine and phospho creatine levels/supplementation increases muscle energy stores/contributes to increased lean body weight.
	Conditions of use - Max 3 g per day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1520	Creatine	Energy metabolism	Support in case of intense physical activity -contributes to increased muscle strength -contributes to increased muscle torque production -contributes to increased training intensity workouts -contributes to increased work capacity
	Conditions of use - A minimum of 6-20g daily - A minimum of 7.7g per day - Max 3 g per day - Initialdosis: bis 20 g/Tag, während 7 Tagen–Erhaltungsdosis: 2-4 g/Tag - Sportlernahrung–Startphase: 4 Wo. 3g/d, Erhaltungsphase: 2-3g/d - Sportler–Gemeinsam mit viel Flüssigkeit–Tagesdosis Kreatinmonohydrat: 1500 mg - 0,5 g pro Tag		

ID	Food or Food constituent	Health Relationship	Proposed wording
1521	Creatine	Muscular effort	Strengthens /supports /assists human energy reserves Supports the building of muscle Supports the building of muscle improves physical performance
	Conditions of use - Initial phase: 4 Weeks 3g/day, Sustainment: 2-3g/day A minimum of 7.7g per day for claims relating to exercise performance and a minimum of 6g daily for claims relating to body composition		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1522	Creatine	Muscular effort / Recovery	Diminish fatigue after rapid physical activity / For quicker recovery after rapid physical exertion
	Conditions of use - Initial phase: 4 Weeks 3g/day, Sustainment: 2-3g/day A minimum of 7.7g per day for claims relating to exercise performance		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1523	Creatine	Bodily Constitution	supports the creating of lean tissue mass (fat free muscle)
	Conditions of use - Initial phase: 4 Weeks 3g/day, Sustainment: 2-3g/day. A minimum of 6g daily for claims relating to body composition		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1525	Creatine	Increasing Strength	Creatine has been shown to increase strength. Creatine has the ability to enhance muscular strength Ingredient clinically shown to help boost strength Boost muscular strength
	Conditions of use - The product must contain at least 1 gram creatine per serving Claim to be used for foods for active individuals. A minimum of 7.7g per day for claims relating to improvements in strength - Drink with creatine content of 0.05-0.1g/100g, 0.13-0.25g/serving, 0.25-0.5g/daily serving.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1526	Creatine	Increasing Mass	Creatine has been shown to increase lean muscle mass Creatine has the ability to enhance muscle growth With proper diet and exercise, creatine can help support an increase in fat free mass. Ingredient clinically shown to help boost lean body mass

	Conditions of use - The product must contain at least 1 gram creatine per serving Claim to be used for foods for active individuals. A minimum of 6g per day for claims relating to improvements in lean muscle mass		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1527	Creatine	Increasing Workout Capacity	Creatine can help enhance physical working capacity at fatigue threshold
	Conditions of use - The product must contain at least 1 gram creatine per serving. Claim to be used for foods for active individuals. A minimum of 6g per day for claims relating to increasing workout capacity		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1531	EAS Creatine (EAS Phosphagen)	Increasing Strength	Gains in Lean Muscle Mass EAS Creatine (EAS Phosphagen) is clinically shown effective for building muscle mass" NOT "EAS Creatine (formally Phosphagen)
	Conditions of use - The product must contain at least 5 gram creatine monohydrate per serving Claim to be used for foods for active individuals		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1532	EAS Creatine (EAS Phosphagen)	Increasing Mass	EAS Creatine (EAS Phosphagen) is clinically shown to help: Support Gains in Lean Muscle Mass EAS Creatine (formerly Phosphagen) is clinically shown effective for building muscle mass
	Conditions of use - The product must contain at least 5 gram creatine monohydrate per serving. Claim to be used for foods for active individuals		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1533	EAS Creatine (EAS Phosphagen)	Increasing Lifting Volume and Performance	EAS Creatine (EAS Phosphagen) is clinically shown to help increase lifting volume.
	Conditions of use - The product must contain at least 5 gram creatine monohydrate per serving. Claim to be used for foods for active individuals		

ID	Food or Food constituent	Health Relationship	Proposed wording
1534	EAS Creatine (EAS Phosphagen)	Increasing Power	EAS Creatine (EAS Phosphagen) is clinically shown to help: Increase Power EAS Creatine (EAS Phosphagen) is clinically shown effective for improving muscular power
	Conditions of use - The product must contain at least 5 gram creatine monohydrate per serving. Claim to be used for foods for active individuals		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1535	EAS Creatine (EAS Phosphagen)	Increasing Work Capacity	EAS Creatine (EAS Phosphagen) is clinically tested to improve anaerobic work capacity
	Conditions of use - The product must contain at least 5 gram creatine per serving. Claim to be used for foods for active individuals		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1922	Creatine	Increasing Performance	Creatine can help support an increase in peak muscular performance.
	Conditions of use - The product must contain at least 1 gram creatine per serving. Claim to be used for foods for active individuals		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1923	Creatine	Increasing Power	Creatine can help support a muscular environment to enhance explosive movements. Ingredient clinically shown to help boost power. Boost muscular power
	Conditions of use - Claim to be only used for dietetic foods/food supplements for sportpeople under the Dir. 89/398/EEC - 3 g/day - The product must contain at least 1 gram creatine per serving		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1924	EAS Creatine (EAS Phosphagen)	Increasing time to exhaustion	EAS Creatine (EAS Phosphagen) is clinically shown to increase total time to exhaustion in intense repeated exercise bouts
	Conditions of use - The product must contain at least 5 gram creatine monohydrate per serving - Claim to be used for foods for active individuals		

ID	Food or Food constituent	Health Relationship	Proposed wording
1963	Sportfoods Clarification provided Creatine, condition of use: 3g / day (for dietetic foods/food supplements for sportpeople)	Creatine : energy reserve of muscle tissue	Increases muscle power and speed', 'Provide energy to muscle'
	Conditions of use - Claim to be only used for dietetic foods/food supplements for sportpeople under the Dir. 89/398/EEC - 3 g/day		

GLOSSARY AND ABBREVIATIONS

ADP	Adenosine diphosphate
ATP	Adenosine triphosphate
CI	Confidence interval
CrP	Creatine phosphate
ES	Effect size
Rpm	Revolution per minute
SEM	Standard error of the mean
VO_2max	Maximal oxygen consumption