

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to whey protein and increase in satiety leading to a reduction in energy intake (ID 425), contribution to the maintenance or achievement of a normal body weight (ID 1683), growth or maintenance of muscle mass (ID 418, 419, 423, 426, 427, 429, 4307), increase in lean body mass during energy restriction and resistance training (ID 421), reduction of body fat mass during energy restriction and resistance training (ID 420, 421), increase in muscle strength (ID 422, 429), increase in endurance capacity during the subsequent exercise bout after strenuous exercise (ID 428), skeletal muscle tissue repair (ID 428) and faster recovery from muscle fatigue after exercise (ID 423, 428, 431), 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

¹ On request from the European Commission, Question No EFSA-Q-2008-1205, EFSA-Q-2008-1206, EFSA-Q-2008-1207, EFSA-Q-2008-1208, EFSA-Q-2008-1209, EFSA-Q-2008-1210, EFSA-Q-2008-1212, EFSA-Q-2008-1213, EFSA-Q-2008-1214, EFSA-Q-2008-1215, EFSA-Q-2008-1216, EFSA-Q-2008-1218, EFSA-Q-2008-2419, EFSA-Q-2010-00260, adopted on 10 September 2010.

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

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in relation to whey protein and increase in satiety leading to a reduction in energy intake, contribution to the maintenance or achievement of a normal body weight, growth or maintenance of muscle mass, increase in lean body mass during energy restriction and resistance training, reduction of body fat mass during energy restriction and resistance, increase in muscle strength, increase in endurance capacity during the subsequent exercise bout after strenuous exercise, skeletal muscle tissue repair and faster recovery from muscle fatigue after 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 whey protein. The Panel considers that whey protein is sufficiently characterised in relation to the claimed effects.

Increase in satiety leading to a reduction in energy intake

The claimed effect is “increases satiety”. The target population is assumed to be the general population. The Panel considers that an increase in satiety leading to a reduction in energy intake, if sustained, might be a beneficial physiological effect.

None of the studies provided tested the sustainability of an effect of whey protein on measures of satiety and subsequent energy intake (i.e. effects were tested on a single occasion and no information was provided on the repeated consumption of the food constituent).

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein and a sustained increase in satiety leading to a reduction in energy intake.

Contribution to the maintenance or achievement of a normal body weight

The claimed effect is “weight management”. The target population is assumed to be the general population. The Panel considers that contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.

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

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein and contribution to the maintenance or achievement of a normal body weight.

Growth or maintenance of muscle mass

The claimed effects are “promotes protein synthesis when taken after resistance exercise”, “supports an increase in lean body mass when combined with exercise and a hypercaloric diet”, “muscle mass maintenance in the elderly” and “muscle strength and body composition”. The target population is assumed to be the general population. In the context of the proposed wording, the Panel assumes that the claimed effect refers to the growth or maintenance of muscle mass. The Panel considers that growth or maintenance of muscle mass is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that only three small intervention studies in humans were pertinent to the claim, and that these studies reported conflicting results with respect to the effects of whey protein on muscle mass compared to other protein sources (i.e. casein and soy protein).

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein and growth or maintenance of muscle mass over and above the well established role of protein on the claimed effect.

Increase in lean body mass during energy restriction and resistance training

The claimed effect is “supports a gain in lean body mass during periods of energy restriction”. The target population is assumed to be adults on an energy-restricted diet performing resistance training who wish to increase their lean body mass. The Panel considers that an increase in lean body mass during energy restriction and resistance training is a beneficial physiological effect.

From all (but one) of the references provided for the scientific substantiation of this claim no conclusions could be drawn for the scientific substantiation of the claimed effect, and one human randomised controlled intervention study which compared whey protein and casein reported a significantly greater increase in lean body mass in the casein group compared to the whey protein group.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein and an increase in lean body mass during energy restriction and resistance training.

Reduction of body fat mass during energy restriction and resistance training

The claimed effect is “supports a decrease in body fat when combined with exercise and a hypocaloric diet”. The target population is assumed to be adults on an energy-restricted diet performing resistance training who wish to decrease their body fat mass. The Panel considers that a reduction in body fat mass during energy restriction and resistance training is a beneficial physiological effect.

From all (but one) of the references provided for the scientific substantiation of this claim no scientific conclusions could be drawn for the substantiation of the claimed effect, and one human randomised controlled intervention study which compared whey protein and casein reported a significantly greater decrease in body fat mass in the casein group compared to the whey protein group.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein and a reduction of body fat mass during energy restriction and resistance training.

Increase in muscle strength

The claimed effect is “muscle strength”. The target population is assumed to be active individuals who are performing resistance exercise to improve muscle strength. The Panel considers that an increase in muscle strength is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the results from the three small intervention studies in humans that addressed the effects of whey protein versus other protein sources (i.e. casein and soy protein) on muscle strength were conflicting.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein during resistance training and an increase in muscle strength.

Increase in endurance capacity during the subsequent exercise bout after strenuous exercise

The claimed effect is “physical performance”. The target population is assumed to be active individuals. In the context of the proposed wording, the Panel assumes that the claimed effect refers to an increase in endurance capacity during the subsequent exercise bout after strenuous exercise. The Panel considers that an increase in endurance capacity during the subsequent exercise bout after strenuous exercise is a beneficial physiological effect.

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

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between post exercise consumption of whey protein and increase in endurance capacity during the subsequent exercise bout after strenuous exercise.

Skeletal muscle tissue repair

The claimed effect is “physical performance”. The target population is assumed to be active individuals performing resistance exercise. In the context of the proposed wording, the Panel assumes that the claimed effect refers to rebuilding of structural protein within the skeletal muscle tissue after exercise that has caused muscle damage. The Panel considers that skeletal muscle tissue repair is a beneficial physiological effect.

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

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein after resistance exercise and skeletal muscle tissue repair.

Faster recovery from muscle fatigue after exercise

The claimed effects are “muscle fatigue recovery” and “muscle recovery”. The target population is assumed to be active individuals in the general population. The Panel considers that faster recovery from muscle fatigue after exercise is a beneficial physiological effect.

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

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein and faster recovery from muscle fatigue recovery after exercise.

KEY WORDS

Whey protein, satiety, energy intake, body weight, muscle, lean body mass, energy restriction, body fat mass, muscle strength, endurance capacity, exercise, tissue repair, recovery, muscle fatigue, 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 whey protein.

Whey protein is a mixture of globular proteins isolated from whey, a by-product obtained during the manufacturing of cheese from cow's milk. Beta-lactoglobulin (approx. 50 %), alpha-lactalbumin (approx 20 %), bovine serum albumin (approx 10 %) and immunoglobulins are the major protein fractions in whey.

Whey can be treated and processed in different ways depending on the type of whey protein end products to be obtained. Main commercial forms are concentrates (29-89 % protein by weight), isolates (about 90 % protein by weight) and hydrolysates (partially pre-digested). Small differences in composition between different whey protein products may exist depending on the manufacturing processes applied. These products generally have a high content of essential amino acids, especially high proportions of available lysine and cysteine.

A claim on protein and growth or maintenance of muscle mass has been assessed by the Panel with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2010). In this opinion, the Panel will address whether the consumption of whey protein has any effect on growth or maintenance of muscle mass over and above the well established role of protein on the claimed effect.

The Panel considers that the food constituent, whey protein, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effects.

2. Relevance of the claimed effect to human health

2.1. Increase in satiety leading to a reduction in energy intake (ID 425)

The claimed effect is "increases satiety". The Panel assumes that the target population is the general population.

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>

Satiety is the decrease in the motivation to eat after consumption of food. The effect may persist up to several hours, may reduce energy intake either at the next meal or across the day and, if sustained, may lead to a reduction in body weight.

The Panel considers that an increase in satiety leading to a reduction in energy intake, if sustained, might be a beneficial physiological effect.

2.2. Contribution to the maintenance or achievement of a normal body weight (ID 1683)

The claimed effect is “weight management”. The Panel assumes that the target population is the general population.

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

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

2.3. Growth or maintenance of muscle mass (ID 418, 419, 423, 426, 427, 429, 4307)

The claimed effects are “promotes protein synthesis when taken after resistance exercise”, “supports an increase in lean body mass when combined with exercise and a hypercaloric diet”, “muscle mass maintenance in the elderly” and “muscle strength and body composition”. The Panel assumes that the target population is the general population.

In the context of the proposed wording, the Panel assumes that the claimed effect refers to the growth or maintenance of muscle mass. Failure to increase muscle mass during growth and development, and the loss of muscle mass at any age, will reduce muscle strength and power.

The Panel considers that growth or maintenance of muscle mass is a beneficial physiological effect.

2.4. Increase in lean body mass during energy restriction and resistance training (ID 421)

The claimed effect is “supports a gain in lean body mass during periods of energy restriction”. The Panel assumes that the target population is adults on an energy-restricted diet performing resistance training who wish to increase their lean body mass.

The Panel considers that an increase in lean body mass during energy restriction and resistance training is a beneficial physiological effect.

2.5. Reduction of body fat mass during energy restriction and resistance training (ID 420, 421)

The claimed effect is “supports a decrease in body fat when combined with exercise and a hypocaloric diet”. The Panel assumes that the target population is adults on an energy-restricted diet performing resistance training who wish to decrease their body fat mass.

The Panel considers that a reduction in body fat mass during energy restriction and resistance training is a beneficial physiological effect.

2.6. Increase in muscle strength (ID 422, 429)

The claimed effect is “muscle strength”. The Panel assumes that the target population is active individuals who are performing resistance exercise to improve muscle strength.

The Panel considers that an increase in muscle strength is a beneficial physiological effect.

2.7. Increase in endurance capacity during the subsequent exercise bout after strenuous exercise (ID 428)

The claimed effect is “physical performance”. The Panel assumes that the target population is active individuals in the general population.

In the context of the proposed wording, the Panel assumes that the claimed effect refers to an increase in endurance capacity.

The terms endurance performance and endurance capacity are often used as synonyms. However, endurance capacity refers to the exercise time to volitional fatigue when exercising at a constant workload or speed, whereas endurance performance relates to the ability of completing a certain task (e.g. running a certain distance) as fast as possible. In the context of the proposed wording, the Panel assumes that the claimed effect refers to an increase in endurance capacity during the subsequent exercise bout after strenuous exercise.

The Panel considers that an increase in endurance capacity during the subsequent exercise bout after strenuous exercise is a beneficial physiological effect.

2.8. Skeletal muscle tissue repair (ID 428)

The claimed effect is “physical performance”. The Panel assumes that the target population is active individuals performing resistance exercise.

In the context of the proposed wording, the Panel assumes that the claimed effect refers to the rebuilding of structural protein within the skeletal muscle tissue after exercise that has caused muscle damage.

The Panel considers that skeletal muscle tissue repair is a beneficial physiological effect.

2.9. Faster recovery from muscle fatigue after exercise (ID 423, 428, 431)

The claimed effects are “muscle fatigue recovery” and “muscle recovery”. The Panel assumes that the target population is active individuals in the general population.

The Panel assumes that the claimed effects refer to muscle fatigue recovery.

Fatigue can be defined as the loss of peak force or power output. Therefore, muscle fatigue recovery can be defined as the regaining of maximal muscle strength or muscle power after strenuous exercise that has induced muscle fatigue. Regaining muscle strength/power may be beneficial during every day life activities, and is beneficial for athletic performance in disciplines where loss of muscle strength and power reduces performance.

The Panel considers that faster recovery from muscle fatigue after exercise is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Increase in satiety leading to a reduction in energy intake (ID 425)

The references provided include intervention studies and reviews on the effects of dietary protein in general and on whey protein specifically, but on outcomes other than measures of satiety (e.g. protein turnover, muscle synthesis, glucose metabolism and immune effects). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

Among the references submitted, four addressed the effects of whey protein on measures of satiety (in the next 2-3 hours) and subsequent *ad libitum* energy intake when administered as a liquid pre-load on a single occasion, compared to isocaloric, liquid control pre-loads (e.g. glucose, casein, soy protein, gluten), following a randomised cross-over design (Hall et al., 2003; Bowen et al., 2006a, b; Bellissimo et al., 2008).

The Panel notes that none of these studies tested the sustainability of an effect of whey protein on measures of satiety and subsequent energy intake (effects were only tested on a single occasion and no information was provided on the repeated consumption of the food constituent). The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between whey protein consumption and a sustained increase in satiety leading to a reduction in energy intake.

3.2. Contribution to the maintenance or achievement of a normal body weight (ID 1683)

The references provided included intervention studies and reviews on the effects of dietary protein in general, on the effects of dairy products and calcium on adiposity and weight management, and on whey protein specifically, but on outcomes other than measures of body weight (e.g. glucose homeostasis, appetite and food consumption). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein and contribution to the maintenance or achievement of a normal body weight.

3.3. Growth or maintenance of muscle mass (ID 418, 419, 423, 426, 427, 429, 4307)

The majority of the references provided in relation to this claim either assessed the effects of foods or food constituents other than whey protein (e.g. other protein sources, single amino acids, branched-chain amino acids), did not test the specific effect of whey protein (e.g. whey protein in combination with single amino acids, carbohydrates or other protein sources was used as intervention), did not test a specific effect of whey protein as compared to other protein sources (e.g. carbohydrates were used as control), or reported on health outcomes other than muscle growth or maintenance (e.g. acute protein synthesis, protein turnover, and/or body composition without measures of muscle mass). In addition, some of the references provided reported on intervention studies conducted in cancer patients. However, the evidence provided does not establish that results obtained in cancer patients in relation to the claimed effect can be extrapolated to the target population. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

Two human intervention studies compared the effects of isonitrogenous whey protein against casein on surrogate measures of muscle mass (Cribb et al., 2006; Demling and DeSanti, 2000).

In a randomised, double blind, parallel intervention study, Cribb et al. (2006) examined the effects of a whey isolate supplement (n = 6) and of a casein supplement (n = 7) provided in addition to the usual diet on strength and body composition during a 10-week intense resistance training programme in a group of 13 resistance trained subjects. Each supplement provided 1.5 g protein/kg body weight/day. Body composition was assessed by dual-energy x-ray absorptiometry (DXA). Strength assessments consisted of the maximal weight (kg) that could be lifted once (1RM) in three weight training exercises: barbell bench press, squat, and cable pull down. Body fat mass significantly decreased in the whey protein group (-1.5 ± 0.5 kg) compared to casein ($+0.2 \pm 0.3$ kg, $p < 0.01$), whereas lean body mass significantly increased in the whey isolate group (4.99 ± 0.25 kg, $P < 0.01$) compared to the casein group (0.81 ± 0.43 kg). While a significant increase in strength was observed in both groups ($p < 0.05$), such increase was significantly higher in the whey isolate group in all three exercises ($p < 0.05$) compared to the casein group. The Panel notes that, although a direct measure of muscle mass was not performed in this study, an increase in lean body mass associated with an increase in strength supported an increase in skeletal muscle mass, and that such increases were in response to the consumption of whey protein compared to casein.

Demling and DeSanti (2000) conducted a 12-week randomised controlled intervention study where 38 overweight men were randomised to the following groups: 1) no training and hypocaloric diet (80 % of the predicted energy needs, n = 10), 2) resistance training programme, hypocaloric diet and whey hydrolysate (1.5 g/kg per day, n = 11) and 3) resistance training programme, hypocaloric diet and casein hydrolysate (1.5 g/kg per day, n = 11). Body composition was assessed using skinfold thickness and validated equations. Strength for chest, shoulders and legs was assessed as the maximum effort which could be lifted for 8-10 repetitions for a chest press, shoulder press and leg extension. No significant differences in body weight changes between groups were observed. No changes in body fat or lean body mass were observed for the diet-only group, whereas a significant increase in lean body mass and a significant decrease in body fat were observed in the casein and whey groups compared to the diet-only group. The increase in lean body mass and the decrease in body fat were significantly greater in the casein group compared to the whey protein group (4 ± 1.4 kg *versus* 2 ± 0.7 kg, $p < 0.05$ and -7.0 ± 2.1 kg *versus* -4.2 ± 0.9 kg, $p < 0.05$, respectively). Strength for chest, shoulder and legs significantly increased in both the casein and the whey protein groups compared to the diet-only group, and significantly more in the casein group than in the whey protein group ($p < 0.05$). The Panel notes that, although a direct measure of muscle mass was not performed in this study, an increase in lean body mass associated with an increase in strength supported an increase in skeletal muscle mass, and that such increases were in response to the consumption of casein compared to whey protein.

One human intervention study investigated the effects of whey protein compared to another isonitrogenous protein source (i.e. soy protein; Candow et al, 2006). A total of 27 subjects (18 female), who were not participating in resistance training, were randomised to receive 0.3 g/kg body weight/day of sucrose plus 1.2 g/kg body weight/day of either whey protein or soy protein for six weeks in the context of a resistance training programme. Body composition was assessed by DXA. Strength assessments consisted of the maximal weight (kg) that could be lifted once (one-repetition maximum, 1RM) in two weight training exercises: barbell bench press and squat. No significant differences between the whey protein and the soy protein groups were observed with respect to either body composition or muscle strength.

In weighing the evidence the Panel took into account that only three small intervention studies in humans were pertinent to the claim, and that these studies reported conflicting results with respect to the effects of whey protein on muscle mass compared to other protein sources (i.e. casein and soy protein).

The Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein and growth or maintenance of muscle mass over and above the well established role of protein on the claimed effect.

3.4. Increase in lean body mass during energy restriction and resistance training (ID 421)

Most of the references provided for the scientific substantiation of this claim did not address the effects of whey protein specifically (but rather those of protein in general), or did not have lean body mass as an outcome measure. In some of the references provided which assessed the effects of whey protein on lean body mass compared to another isonitrogenous protein source (i.e. casein and soy protein) (Cribb et al. 2006; Candow et al., 2006), or to a non-protein isocaloric control (i.e. carbohydrates) (Cribb et al., 2007; Burke et al., 2001); energy restriction was not part of the intervention. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

One human intervention study (Demling and DeSanti, 2000) addressed the effects of whey protein consumption on lean body mass in humans compared to another isonitrogenous protein source (i.e. casein) in the context of an energy-restricted diet. This study has been described in section 3.3 and reported a significantly greater increase in lean body mass in the casein group compared to the whey protein group.

The Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein and an increase in lean body mass during energy restriction and resistance training.

3.5. Reduction of body fat mass during energy restriction and resistance training (ID 420, 421)

Most of the references provided for the scientific substantiation of this claim did not address the effects of whey protein (but rather of other food constituents or combinations, some including whey protein), and/or did not provide data on body fat changes. In some of the references provided which assessed the effects of whey protein on body fat mass compared to another isonitrogenous protein source (i.e. casein and soy protein), or to a non-protein isocaloric control (i.e. carbohydrates), energy restriction was not part of the intervention (Cribb et al. 2006; Cribb et al., 2007; Burke et al., 2001; Candow et al, 2006). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

One human intervention study (Demling and DeSanti, 2000) addressed the effects of whey protein consumption on lean body mass in humans compared to another isonitrogenous protein source (i.e. casein) in the context of an energy-restricted diet. This study has been described in section 3.3 and reported a significantly greater decrease in body fat mass in the casein group compared to the whey protein group.

The Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein and the reduction of body fat mass during energy restriction and resistance training.

3.6. Increase in muscle strength (ID 422, 429)

A number of references provided for the scientific substantiation of this claim either addressed the effects of foods other than whey protein alone (e.g. whey protein enriched or in combination with certain amino acids, such as cysteine, or branched chain amino acids) and/or reported on health

outcomes other than muscle strength. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Two human intervention studies (Cribb et al. 2006, Demling and DeSanti, 2000) addressed the effects of whey protein consumption on muscle strength in humans compared to another isonitrogenous protein source (i.e. casein). Both have been described in section 3.3. Whereas the study by Cribb et al. (2006) reported a significantly higher increase in muscle strength with the consumption of whey protein supplements compared to casein supplements in the context of a normocaloric diet, conflicting results were obtained in the study by Demling and DeSanti (2000) in the context of an energy-reduced diet. Both studies were performed in male subjects following a resistance training programme.

One human intervention study investigated the effects of whey protein compared to another isonitrogenous protein source (i.e. soy protein) and to isocaloric carbohydrate supplements (Candow et al., 2006). This study has been described in section 3.3. No significant differences in muscle strength were observed between the whey protein and the soy protein groups.

Two human intervention studies compared the effect of whey protein on muscle strength compared to isocaloric carbohydrate supplements (Cribb et al., 2007; Burke et al., 2001). The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claimed effect as they were not controlled for nitrogen intake.

In weighing the evidence, the Panel took into account that the results from the three small intervention studies in humans that addressed the effects of whey protein versus other protein sources (i.e. casein and soy protein) on muscle strength were conflicting.

The Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein during resistance training and an increase in muscle strength.

3.7. Increase in endurance capacity during the subsequent exercise bout after strenuous exercise (ID 428)

Most of the references provided for the scientific substantiation of this claim addressed the effects of protein sources other than whey, used whey protein in combination with other food constituents (e.g. carbohydrates, specific amino acids) or enriched in specific amino acids (e.g. cysteine). Other references addressed the effects of whey protein supplements used as pre-load on endurance capacity and/or performance during exercise, but not at a subsequent exercise bout. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between post exercise consumption of whey protein and an increase in endurance capacity during the subsequent exercise bout after strenuous exercise.

3.8. Skeletal muscle tissue repair (ID 428)

Some of the references provided for the scientific substantiation of this claim addressed the effects of whey protein or of protein other than whey, either alone or in combination with carbohydrates compared to carbohydrates alone or compared to other protein sources, on indirect measures of muscle damage (e.g. concentration of intracellular muscle enzymes in the blood, muscle pain, muscle strength or other performance parameters) which are not necessarily related to improved repair of skeletal muscle structures. The remaining references were narrative reviews that did not provide original data for the substantiation of the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein after resistance exercise and skeletal muscle tissue repair.

3.9. Faster recovery from muscle fatigue after exercise (ID 423, 428, 431)

Some of the references provided for the scientific substantiation of this claim addressed the effects of whey protein on health outcomes unrelated to the claimed effect (e.g. concentration of intracellular muscle enzymes in the blood, muscle pain, muscle strength or other performance parameters) or on the effects of protein hydrolysates in combination with carbohydrates compared to carbohydrates alone given after an initial strenuous exercise bout on performance parameters at a subsequent exercise bout after a recovery period. The Panel notes that, although these latter studies used an appropriate design to test muscle fatigue recovery, the effects of whey protein were not assessed (Ready et al 1999; Romano-Ely et al. 2006; Saunders et al. 2004). The remaining references were narrative reviews which did not provide original data for the substantiation of the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of whey protein and faster recovery from muscle fatigue after exercise.

CONCLUSIONS

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

- The food constituent, whey protein, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effects.

Increase in satiety leading to a reduction in energy intake (ID 425)

- The claimed effect is “increases satiety”. The target population is assumed to be the general population. An increase in satiety leading to a reduction in energy intake, if sustained, might be a beneficial physiological effect.
- A cause and effect relationship has not been established between consumption of whey protein and a sustained increase in satiety leading to a reduction in energy intake.

Contribution to the maintenance or achievement of a normal body weight (ID 1683)

- The claimed effect is “weight management”. The target population is assumed to be the general population. Contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of whey protein and contribution to the maintenance or achievement of a normal body weight.

Growth or maintenance of muscle mass (ID 418, 419, 423, 426, 427, 429, 4307)

- The claimed effects are “promotes protein synthesis when taken after resistance exercise”, “supports an increase in lean body mass when combined with exercise and a hypercaloric diet”, “muscle mass maintenance in the elderly” and “muscle strength and body composition”. The target population is assumed to be the general population. Growth or maintenance of muscle mass is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of whey protein and growth or maintenance of muscle mass over and above the well established role of protein on the claimed effect.

Increase in lean body mass during energy restriction and resistance training (ID 421)

- The claimed effect is “supports a gain in lean body mass during periods of energy restriction”. The target population is assumed to be adults on an energy-restricted diet performing resistance training who wish to increase their lean body mass. An increase in lean body mass during energy restriction and resistance training is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of whey protein and an increase in lean body mass during energy restriction and resistance training.

Reduction of body fat mass during energy restriction and resistance training (ID 420, 421)

- The claimed effect is “supports a decrease in body fat when combined with exercise and a hypocaloric diet”. The target population is assumed to be adults on an energy-restricted diet performing resistance training who wish to decrease their body fat mass. A reduction in body fat mass during energy restriction and resistance training is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of whey protein and a reduction of body fat mass during energy restriction and resistance training.

Increase in muscle strength (ID 422, 429)

- The claimed effect is “muscle strength”. The target population is assumed to be active individuals who are performing resistance exercise to improve muscle strength. An increase in muscle strength is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of whey protein during resistance training and an increase in muscle strength.

Increase in endurance capacity during the subsequent exercise bout after strenuous exercise (ID 428)

- The claimed effect is “physical performance”. The target population is assumed to be active individuals. An increase in endurance capacity during the subsequent exercise bout after strenuous exercise is a beneficial physiological effect.
- A cause and effect relationship has not been established between post exercise consumption of whey protein and an increase in endurance capacity during the subsequent exercise bout after strenuous exercise.

Skeletal muscle tissue repair (ID 428)

- The claimed effect is “physical performance”. The target population is assumed to be active individuals performing resistance exercise. Skeletal muscle tissue repair after exercise is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of whey protein after resistance exercise and skeletal muscle tissue repair.

Faster recovery from muscle fatigue after exercise (ID 423, 428, 431)

- The claimed effects are “muscle fatigue recovery” and “muscle recovery”. The target population is assumed to be active individuals in the general population. Faster recovery from muscle fatigue after exercise is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of whey protein and faster recovery from muscle fatigue after exercise.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1205, EFSA-Q-2008-1206, EFSA-Q-2008-1207, EFSA-Q-2008-1208, EFSA-Q-2008-1209, EFSA-Q-2008-1210, EFSA-Q-2008-1212, EFSA-Q-2008-1213, EFSA-Q-2008-1214, EFSA-Q-2008-1215, EFSA-Q-2008-1216, EFSA-Q-2008-1218, EFSA-Q-2008-2419, EFSA-Q-2010-00260). 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 whey protein, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
418	Whey protein	Promotes protein synthesis when taken after resistance exercise	Taken after resistance exercise, whey protein supports muscle growth
	Conditions of use <ul style="list-style-type: none"> - 20 grams of whey protein after exercise - Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
419	Whey protein	Supports an increase in lean body mass when combined with exercise and a hypercaloric diet	Combined with exercise and a hypercaloric diet, whey protein supports muscle growth
	Conditions of use <ul style="list-style-type: none"> - 0.7 grams of whey protein per kg of bodyweight per day - Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
420	Whey protein	Supports a decrease in body fat when combined with exercise and a hypocaloric diet	Combined with exercise and a hypocaloric diet, whey protein supports your fat loss goals.
	Conditions of use <ul style="list-style-type: none"> - 20 grams per day - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
421	Whey protein	Supports a gain in lean body mass during periods of energy restriction	<ul style="list-style-type: none"> - Whey protein can reduce muscle loss when dieting. - Whey protein offers a nutritional advantage towards achieving a desirable body composition by supporting your fat loss goals and fueling muscle growth during energy restriction.

	<p>Conditions of use</p> <ul style="list-style-type: none"> - 0.7 grams of whey protein per kg of bodyweight per day - Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
422	Whey protein	Supports an increase in strength when combined with resistance exercise	<ul style="list-style-type: none"> - Combined with resistance exercise, whey protein supports an increase in muscular strength. - Whey protein improves exercise performance.
	<p>Conditions of use</p> <ul style="list-style-type: none"> - 1.2 grams of whey protein per kg of bodyweight per day - Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
423	Whey protein.	<p>Is rapidly digested.</p> <p><u>Clarification provided</u></p> <p>Whey protein raises blood amino acid levels more rapidly than casein.</p>	<p>Whey protein provides fast delivery of muscle-building amino acids after training to aid recovery and support muscle growth.</p> <p>Whey protein is a soluble, easy to digest protein and is efficiently absorbed into the body. It's often referred to as a "fast" protein for its ability to quickly provide nourishment to muscles.</p>
	<p>Conditions of use</p> <ul style="list-style-type: none"> - The product must contain at least 10 grams high quality protein per serving. Claim to be used for foods for active individuals. Must meet minimum requirements for use of the claim "Source of protein" as per Annex to Regulation 1924/2006. - Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006. 		

ID	Food or Food constituent	Health Relationship	Proposed wording
425	Whey protein	Increases satiety	<ul style="list-style-type: none"> - Whey protein leaves you feeling fuller for longer, making it easier to control your appetite at the next meal. - Whey protein promotes satiety. - The intake of whey protein & its essential amino acids can promote satiety and aid in the regulation of blood glucose. - Leucine-rich whey protein promotes satiety & weight loss. - Whey protein helps you feel fuller for longer, increasing the sense of satiety.
			<p>Conditions of use</p> <ul style="list-style-type: none"> - 48 grams of whey protein per serving - Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.
ID	Food or Food constituent	Health Relationship	Proposed wording
426	Whey protein	Muscle mass maintenance in the elderly	<ul style="list-style-type: none"> - Whey protein essential amino acids aid muscle maintenance in the elderly and at risk persons. - Whey protein essential amino acids reduce lean tissue loss in the elderly and at risk persons.
			<p>Conditions of use</p> <ul style="list-style-type: none"> • Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.
ID	Food or Food constituent	Health Relationship	Proposed wording
427	Whey protein	Maintenance and growth of muscle	Whey protein essential amino acids aid muscle maintenance and growth.
			<p>Conditions of use</p> <ul style="list-style-type: none"> - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.

ID	Food or Food constituent	Health Relationship	Proposed wording
428	Whey protein	Physical Performance	<ul style="list-style-type: none"> - Whey protein essential amino acids aid muscle fatigue recovery. - Whey protein supports muscle repair following resistance training. - Whey protein accelerates recovery from exercise. - Whey protein, consumed post each exercise bout, prolongs endurance perform
			<p>Conditions of use</p> <ul style="list-style-type: none"> • 10-30 g Protein pro Stunde unmittelbar, vor, während und sofort nach sportlicher Belastung. • Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.
ID	Food or Food constituent	Health Relationship	Proposed wording
429	Whey Prot*omegaein	Muscle strength and body composition.	Consumption of whey in conjunction with resistance exercise supports an increase in lean body mass and strength.
			<p>Conditions of use</p> <ul style="list-style-type: none"> • The product must contain at least 10 grams high quality protein per serving. • Claim to be used for foods for active individuals.
ID	Food or Food constituent	Health Relationship	Proposed wording
431	Whey protein Hydrolysate	Muscle Recovery	<p>Whey protein hydrolysate enhances muscle recovery.</p> <p>Glutamine-rich whey protein enhances muscle recovery.</p>
			<p>Conditions of use</p> <ul style="list-style-type: none"> • Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.
ID	Food or Food constituent	Health Relationship	Proposed wording
1683	Whey Protein Milk Mineral Complex	Weight management	<ul style="list-style-type: none"> - Whey protein milk mineral complex helps promote fat loss. - Whey protein milk mineral complex helps maintain lean body mass. - Whey protein milk mineral complex helps maintain lean body mass whilst reducing body fat. - Whey protein milk mineral complex promotes satiety.

			- Whey protein milk mineral complex contains ACE inhibitory peptides which influence fat metabolism. Whey protein milk mineral complex helps maintain bone mineral density.
	<p>Conditions of use</p> <ul style="list-style-type: none"> - -Number of nutrients/other substances that are essential to claimed effect: 2, Quantity in Average daily serving: 22.5 grams whey mineral complex, 4 grams partially hydrolysed whey protein, -Daily amount to be consumed to produce claimed effect: 26.5 grams, -Length of time after consumption for claimed effect to become apparent: It is apparent after a period of regular use. -Number of days: 84, -Other conditions for use: To be consumed as part of a calorie controlled/restricted diet. - -Number of nutrients/other substances that are essential to claimed effect: 1, Quantity in Average daily serving: 22.5 g Whey protein milk mineral complex, -Daily amount to be consumed to produce claimed effect: 20 gram(s), -Length of time after consumption for claimed effect to become apparent: 90 mins, -Other conditions for use: To be consumed as part of a calorie controlled/ restricted diet. - -Number of nutrients/other substances that are essential to claimed effect: 2, -Names of nutrient/other substances and Quantity in Average daily serving: 22.92 g Partially Hydrolysed whey protein, 1.48 g Whey Mineral Complex, -Daily amount to be consumed to produce claimed effect: 24.4 gram(s), -Length of time after consumption for claimed effect to become apparent: It is apparent after a period of regular use. -Number of days: 84 -Other conditions for use: To be consumed as part of a calorie restricted diet. - Suggest intake of 24 g/day ; To be consumed as part of a calorie controlled diet. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
4307	Whey protein isolate (Lacprodan DI-9212)	Increase muscle synthesis	Increases muscle synthesis
	<p>Conditions of use</p> <ul style="list-style-type: none"> - 0.25 g/kg BW Lacprodan?DI-9212. Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006. 		

GLOSSARY AND ABBREVIATIONS

DXA Dual-energy x-ray absorptiometry

1RM One-repetition maximum