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Draft guidance on the scientific requirements for health claims related to muscle function and physical performance

(Revision 1)

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Abstract

The European Food Safety Authority (EFSA) has asked the Panel on Dietetic Products, Nutrition and Allergies (NDA) to revise the guidance on the scientific requirements for health claims related to physical performance published in 2012. Since then, the NDA Panel has completed the evaluation of Article 13.1 claims (except for claims put on hold by the European Commission) and has evaluated additional health claim applications submitted pursuant to Article 13(5) in the area covered by this guidance. In addition, the NDA Panel has developed the general scientific guidance for stakeholders for health claims applications which addresses general issues that are common to all health claims. To further assist applicants, EFSA launched in 2014 a grant which aimed at gathering information in relation to claimed effects, outcome variables and methods of measurement in the context of the scientific substantiation of health claims. This update takes into account the experience gained by the NDA Panel with the evaluation of additional health claim applications, changes introduced to the general scientific guidance for stakeholders, and information collected from a grant. The guidance is intended to assist applicants in preparing applications for the authorisation of health claims related to muscle function and physical performance. The draft guidance was discussed and endorsed by the NDA Panel on 28 June 2018 for release for public consultation.

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Summary

The European Food Safety Authority (EFSA) has asked the Panel on Dietetic Products, Nutrition and Allergies (NDA) to revise the guidance on the scientific requirements for health claims related to physical performance published in 2012.

Since then, the NDA Panel has completed the evaluation of Article 13.1 claims (except for claims put on hold by the European Commission) and has evaluated additional health claim applications submitted pursuant to Article 13(5) in the area covered by this guidance. In addition, the NDA Panel has developed the general scientific guidance for stakeholders for health claims applications which addresses general issues that are common to all health claims. To further assist applicants, EFSA launched in 2014 a grant which aimed at gathering information in relation to claimed effects, outcome variables and methods of measurement in the context of the scientific substantiation of health claims. The information collected helped to inform the NDA Panel in updating the present guidance.

This guidance is intended to assist applicants in preparing applications for the authorisation of health claims related to muscle function and physical performance. It focuses on key issues, particularly:

- claimed effects which are considered to be beneficial physiological effects, and
- characteristics of the human intervention studies which can provide evidence for the scientific substantiation of specific claims addressed in this guidance (e.g. appropriate outcome variables and methods of measurement, suitable study group(s), suitable controls).

This guidance does not intend to provide an exhaustive list of beneficial physiological effects, or of studies/outcome variables/methods of measurement which could be acceptable for claim substantiation, or address potential health relationships and related outcome variables/methods of measurement which have not yet been considered by the Panel in the context of a particular application.

The guidance is released for public consultation (from 16 July to 2 September 2018) to gather views from scientific communities and stakeholders before finalisation. This guidance supersedes the guidance on the scientific requirements for health claims related to physical performance published in 2012. It is intended that the guidance will be further updated as appropriate in the light of experience gained from the evaluation of health claims in this area.

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Background and Terms of Reference as provided by EFSA

Background

Regulation (EC) No 1924/2006[1] harmonises the provisions related to nutrition and health claims and establishes rules governing the Community authorisation of health claims made on foods. According to the Regulation, health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard to be carried out by EFSA.

Owing to the scientific and technical complexity of health claims, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) has placed considerable effort into developing scientific criteria for the substantiation of health claims, and has published guidance on the scientific substantiation of health claims since 2007[2].

In the last years, the NDA Panel has gained considerable experience in the evaluation of health claim applications. To further assist applicants seeking approval of health claims, EFSA launched in 2014 a grant (GP/EFSA/NUTRI/2014/01) which aimed at gathering information in relation to claimed effects, outcome variables and methods of measurement in the context of the scientific substantiation of health claims. The information collected[3] was to help inform the NDA Panel and serve as a basis for further guidance to applicants.

In this context, note is taken of the need to adapt the existing guidance on the scientific requirements for health claims[4] to the new scientific and technical developments in specific areas, taking into account lessons learned from the evaluation of health claim applications and the information collected from the grant.

To this end, the NDA Panel is asked to update the existing guidance on the scientific requirements for health claims related to physical performance published in 2012[5].

Terms of reference

The NDA Panel is requested by EFSA to update the existing guidance on the scientific requirements for health claims related to physical performance.

The guidance document shall clarify and address the scientific and technical developments in this area, taking into account the experience gained by the NDA Panel with the evaluation of health claims and the information collected from the grant.

The draft guidance shall be released for public consultation prior to finalisation, and shall be revised taking into account the comments received during the public consultation before adoption by the NDA Panel. A technical report on the outcome of the public consultation shall be published.

1. Introduction

The Guidance on the scientific requirements for health claims related to physical performance published in 2012(EFSA NDA Panel, 2012c) laid down recommendations on specific issues that need to be addressed in applications submitted for the substantiation of health claims in this area. Since then, the NDA Panel has evaluated additional health claim applications related to muscle function and physical performance.

Among the health claim applications submitted to EFSA as of 8/02/2018 (n=490), 12 were relevant to this guidance: five were withdrawn during the evaluation, and seven were evaluated/finalised by the NDA Panel. Among those finalised, three were evaluated by the NDA Panel with a favourable opinion and all three referred to claims other than those based on the essentiality on nutrients: two were on muscle function and one on physical performance (Appendix A).

Examples of health claims evaluated by the NDA Panel with a favourable opinion (under Article 13(1) and applications under Article 13(5)) will be used to provide guidance to applicants on the scientific

[1] 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.
[2] https://www.efsa.europa.eu/en/applications/nutrition/regulationsandguidance
[3] https://www.efsa.europa.eu/en/supporting/pub/1272e
[4] https://www.efsa.europa.eu/en/applications/nutrition/regulationsandguidance
[5] https://www.efsa.europa.eu/en/efsajournal/pub/2817

requirements for the substantiation of health claims in specific areas, whereas examples of claims evaluated by the NDA Panel with an unfavourable opinion will be used to illustrate the shortcomings that prevented the substantiation of these claims.

To further assist applicants, the information collected from the grant (GP/EFSA/NUTRI/2014/01)[6] launched by EFSA in 2014, which aimed at gathering information in relation to claimed effects, outcome variables and methods of measurement in the context of the scientific substantiation of health claims, was considered by the NDA Panel for updating this guidance.

2. Objectives and scope

This guidance is intended to assist applicants in preparing applications for the scientific substantiation of health claims related to physical performance and muscle function. The document focuses on key issues, particularly:

- claimed effects which are considered to be beneficial physiological effects;
- definition of the target population for which the claim is intended;
- characteristics of human intervention studies which can provide evidence for the scientific substantiation of specific claims addressed in this guidance (e.g. appropriate outcome variables and methods of measurement, suitable study group(s), suitable controls).

Issues related to scientific substantiation that are common to all health claims (e.g. principles applied for claims based on the essentiality of nutrients vs. claims other than those based on the essentiality of nutrients, aspects related to the characterisation of the food/constituent and to the characterisation of the claimed effect, examples of the evidence required for the substantiation of claims, criteria for the identification of pertinent human studies) are addressed in the General scientific guidance for stakeholders on health claims applications (EFSA NDA Panel, 2016a) and will not be reiterated in this document.

This guidance does not intend to provide an exhaustive list of beneficial physiological effects or of studies/outcome variables/methods of measurement which have not yet been considered by the NDA Panel in the context of a particular application. This guidance will be kept under review and will be amended and updated in the light of experiences gained from the evaluation of additional health claim applications in this area.

This guidance should be read in conjunction with the General scientific guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016a), the Scientific and technical guidance for the preparation and presentation of a health claim application (EFSA NDA Panel, 2017), Regulation (EC) No 1924/2006 on nutrition and health claims made on foods,[7] the Guidance on the implementation of Regulation (EC) No 1924/2006 (Standing Committee on the Food Chain and Animal Health, 2007), Commission Regulation (EC) No 353/2008,[8] the Commission Implementing Decision of 24 January 2013,[9] and future guidelines and regulations, as applicable.

3. Definition of terms

During the scientific evaluation of health claims in the area of physical performance over the last 10 years, and in preparation for the update of this guidance document, the Panel has noticed the lack of consensus with respect to the terminology used in sport science (and practice) to describe different types of "physical activities" or "exercises" with respect to their duration, "intensity", and the effort required to perform them, and with respect to the methods and units of measurement of such effort.

[6] https://www.efsa.europa.eu/en/supporting/pub/1272e

[7] 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. Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1924:20100302:en:PDF

[8] Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council (Text with EEA relevance) (OJ L 109, 19.4.2008, p. 11): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2008R0353:20091221:EN:PDF

[9] Commission Implementing Decision of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council. OJ L 22, 25.1.2013, p. 25–28. Available at http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32013D006

Whereas a number of publications have addressed this aspect in the last years and have proposed ways to standardise both nomenclature and "exercise" classification depending on the type, "intensity", duration, and predominant metabolic pathways contributing to energy supply, they contradict each other in several ways (Caspersen et al., 1985; Howley, 2001; Chodzko-Zajko et al., 2009; Norton et al., 2010; Garber et al., 2011; Fisher and Smith, 2012; Chamari and Padulo, 2015; Winter et al., 2016).

Several terms have been used by the Panel in the context of specific evaluations (Art 13(1) claims and Art 13(5) applications) for which there is no consensual definition. These terms have rather been defined for the purpose of the specific assessment and to establish conditions of use for the claim (e.g. endurance capacity, strenuous exercise, short-term high-intensity exercise). In other instances, terms have not been defined assuming that they had a precise meaning and were well understood in the research field, which may not be so (e.g. muscle fatigue).

For the purpose of this guidance, and within the context of the scientific evaluation of health claims in the area of muscle function and physical performance, the Panel provides a common definition of terms to help communication between applicants, EFSA and risk managers, but also indicates the information that should be provided in future applications to characterise the claimed effect, the target population and the conditions of use for the claim whenever common terms used in the scientific literature may lead to misinterpretation.

For the purpose of this guidance, and having regard of the scientific references cited above:

Physical activity is defined as any bodily movement produced by skeletal muscles which requires energy expenditure. Physical activity broadly encompasses physical exercise, sports, and physical activities done as part of daily living, occupation, leisure, and active transportation.

Physical fitness is a set of attributes that people have or achieve that relates to the ability to perform physical activity (e.g. cardiorespiratory endurance, muscular endurance, muscular strength, body composition, flexibility, agility, balance, coordination, speed, power, reaction time). The degree to which people have these attributes can be measured with specific tests.

Physical exercise is defined as a subset of physical activity that is planned and structured, and has as a final or an intermediate objective the improvement or maintenance of one or more components of physical fitness.

Resistance exercise (training) is a specific type of physical exercise designed to increase muscular strength, power, and/or endurance. It can vary in the resistance, speed, the number of times the resistance is moved in a single group (set) of exercise, the number of sets done, and the rest interval provided between sets.

Intensity/load, frequency, duration, and mode/type are used to describe the characteristics of an exercise to bring about a particular response. Their combination affects the volume of the exercise and the predominant metabolic pathways and substrates that are involved.

Intensity/load refers to the effort required by an individual to complete a given physical activity or exercise. Objective measures of exercise intensity are usually expressed as relative values (e.g. $\%HR_{max}$, %HRR[10], $\%VO_{2max}$, $\%VO_2R$[11]). Exercise intensity has also been classified using subjective measures, i.e. relative to the subject's perception of effort, using the Borg's Rating of Perceived Exertion (RPE) scale. For resistance training, "intensity" refers to the amount of resistance (load). The one repetition maximum (1RM), which is the greatest weight that can be lifted or displaced one time in good form, is relevant for dynamic measurements, whereas the maximal voluntary contraction (MVC) is relevant for isometric measurements. Objective measures of load are usually expressed as relative values (e.g. %1RM, %MVC).

Frequency in training programs is described as the number of activity sessions per day, week, or month.

[10] HRR = HR_{max} – resting HR
[11] VO_2R = VO_{2max} – resting VO_2

Duration refers to the number of minutes of activity in each exercise session (and to the duration of each interval within a session for interval training).

The mode/type refers to the type of exercise performed (e.g. cycling, running, swimming, weight-lifting, etc) and to whether this is intermittent (e.g. repeated bouts, sprints, interval training) or continuous.

Whereas several classifications of physical exercise have been proposed with respect to their intensity and duration, the main metabolic pathways involved and/or the type of physical fitness targeted (e.g. endurance, cardiorespiratory, flexibility, and neuromuscular exercise; "aerobic and "anaerobic" exercise; sedentary, light, moderate, vigorous and high-intensity exercise; all-out (maximal) efforts: "explosive", "high intensity", "endurance intensive efforts"), the Panel notes that the nomenclature in this field is not harmonised. Therefore, in the context of claims substantiation, the claimed effect (e.g. the testing conditions under which the food/constituent may affect performance) must be described (characterised) in terms of mode/type of exercise, intensity/load (using objective measures and expressed as relative values), and duration (in minutes). The characterisation of training programs which may be part of the conditions of use for the claim (e.g. if the efficacy of food/constituent on performance is only observed when its consumption is coupled to a training program) requires also information on frequency. The characterisation of physical exercises for the substantiation of health claims on physical capacity and physical performance is addressed in section 4.2.2.

Muscle contraction is the activation of tension-generating sites within muscle fibres and can be concentric or eccentric.

Muscle strength refers to the (maximum) amount of external force that a skeletal muscle (or muscle group) can exert. It may be expressed as MVC for isometric measurements and as the 1RM for dynamic measurements.

Endurance is the ability to sustain a physical activity or exercise over a period of time.

Muscle endurance refers to the ability of muscle groups to exert and maintain an external force for a number of repetitions or successive exertions against a constant resistance.

Muscle fatigue is defined as any exercise-induced reduction in the maximal capacity to generate force or power output, or in the capacity to maintain a pre-defined force or power output.

Exercise-induced **muscle soreness** is an aching sensation following muscular exertion that can be acute (i.e. the immediate ache perceived by the athlete while or immediately after exercise) or delayed. Delayed-onset muscle soreness (DOMS) generally occurs following unaccustomed muscular exertion and is mainly related to eccentric muscular efforts. Muscle soreness can vary from mild discomfort to incapacitating pain depending on the intensity, volume and novelty of the exercise.

Exercise-induced **muscle damage** refers to the disruption of muscle fibres during exercise which may be associated to a reduction of muscle function. Muscle damage may lead to pain and soreness, but these may also occur in the absence of muscle damage.

Mechanical work is the amount of energy transferred by a force acting over a certain distance.

Power relates to the rate at which mechanical work can be performed.

Physical performance is the ability to complete certain physical tasks. An increase in physical performance refers to completion of a given physical task with higher intensity, and therefore faster or with a higher power output.

Physical capacity is the ability to continue a physical activity despite increasing physical or psychological stress, and refers to the exercise time to fatigue when exercising at predefined conditions (e.g. a given load, intensity or speed).

Appropriate outcome variables to assess physical capacity and physical performance in human intervention studies are discussed in section 4.2.2.

The terms **endurance capacity and endurance performance** have been used by the Panel in previous guidance documents and scientific opinions to denote physical capacity and performance assessed during physical exercises of "moderate" intensity (generally <80 % VO_{2max}). These terms will only be used in the present guidance to describe examples of previous evaluations for illustration purposes.

4. Assessment

4.1. Function claims based on the essentiality of nutrients

Several health claims related to essential nutrients have been scientifically substantiated based on the principle of the essentiality of these nutrients[12]: i) the nutrient is required for normal human body function(s), i.e. it has an essential mechanistic role in a metabolic function and/or it has the ability to reverse clinical signs and symptoms of its deficiency; ii) the nutrient cannot be synthesised by the body or cannot be synthesised in amounts which are adequate to maintain normal body function(s) and iii) the nutrient must be obtained from a dietary source. For these claims (described below in this sections), the Panel did not review the primary scientific studies submitted and it did not weigh the evidence.

4.1.1. Claims on muscle function

The improvement, maintenance or reduced loss of **muscle function (contraction)** is considered a beneficial physiological effect. Failure to increase **muscle mass** during growth and development, and the loss of muscle mass at any age, will impair muscle function (e.g. **muscle strength** and power). Faster recovery of normal muscle function after exercise is also considered a beneficial physiological effect.

Claims on the well-established role of some minerals such as sodium (EFSA NDA Panel, 2011g), potassium (EFSA NDA Panel, 2010h), magnesium (EFSA NDA Panel, 2009c) and calcium (EFSA NDA Panel, 2009a) on the maintenance of **normal muscle function (contraction)** have been evaluated by the Panel with a favourable outcome. The target population for these claims was the general healthy population. Conditions of use were established on the basis that any significant amount of the essential nutrient in the diet will contribute to the claimed effect (i.e. conditions of use were linked to nutrition claims).

A claim on dietary protein and **growth or maintenance of muscle mass** was also evaluated by the Panel with a favourable outcome (EFSA NDA Panel, 2010a). The Panel considered that the role of dietary protein in the growth (during development) and maintenance (after adolescence) of whole body lean body mass, including muscle mass, was well-established. Maintenance of lean body mass can be achieved if (protein) nitrogen intake is equal to or above (protein) nitrogen losses over a period of time. It is well documented that protein intake (indispensable aminoacids) is necessary to maintain nitrogen (protein) balance as nitrogen is lost from the body primarily via the urine, but also in small amounts via faeces, sweat, skin, hair and nails. Similarly, maintenance of muscle mass is typically achieved if mean muscle protein synthesis rate is equal to mean muscle protein breakdown rate over a period of time. Protein intakes within the Dietary Reference Values (DRVs) allow for the growth and maintenance of lean body mass, including muscle mass, for normal protein turnover, and for muscle recovery after physical exercise. The target population for this claim was the general healthy population. Conditions of use were established on the basis that any significant amount of protein in the diet will contribute to the claimed effect (i.e. conditions of use were linked to nutrition claims).

For the scientific substantiation of health claims related to specific protein sources or protein components on measures of muscle function (i.e. muscle mass and muscle strength), see section 4.2.1.

[12] See General scientific guidance for stakeholders on health claim applications, Section 6.1.

4.2. Function claims other than those based on the essentiality of nutrients

4.2.1. Claims on muscle function

Function claims other than those based on the essentiality of nutrients have been submitted on muscle strength, rather than on muscle function. Noting that **muscle strength** is a specific aspect of muscle function, claims may refer to muscle strength specifically, rather than to muscle function in general. In this context, outcome variables that are appropriate to assess muscle strength in human studies include one repetition maximum (1-RM) and isometric strength tests (e.g. 1-RM weight lifting (bench press), 1-RM leg press, 1-RM knee extension, 1-RM biceps curl, isometric handgrip strength, isokinetic knee extension torque). Owing to these single outcome variables of muscle strength generally assessing specific muscle groups, the evaluation of general muscle strength requires the use of multiple outcome variables in combination (e.g. assessing muscle strength in the upper and lower body). Outcome variables related to motor functional performance (e.g. gait speed, timed-get-up-and-go test, stair climbing) are not direct measures of muscle strength. The use of these outcome variables in the scientific substantiation of claims on physical performance is discussed in section 4.2.2.1.

Outcome variables related to **body composition** (e.g. whole-body lean body mass, muscle mass) or **muscle structure** (e.g. muscle shape, number and type of muscle fibres, muscle damage, muscle tissue repair) are not direct measures of muscle function. However, since changes in one or more of these outcome variables may contribute to the improvement, maintenance or reduced loss of muscle function, they could be used as supportive evidence for the scientific substantiation of claims on muscle function/strength. Invasive (e.g. muscle biopsy) and non-invasive (e.g. high-frequency ultrasound, magnetic resonance imaging) techniques can be used to assess different components of muscle structure. Claims related to changes in body composition have been addressed in the "Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations" (EFSA NDA Panel, 2012d).

The scientific evaluation of health claims on **muscle strength** requires sufficient characterisation of the target population for which the claim is made and of the conditions of use for the claim. The target population for the claim should be sufficiently defined regarding physical fitness and/or age of the subjects (e.g. athletes, elderly subjects). The conditions of use for the claim should clearly indicate all aspects related to the consumption of the food constituent (e.g. the amount, the frequency of consumption, the timing of consumption in relation to the physical exercise) and to the concomitant intervention(s) (e.g. type/intensity/frequency/duration of concomitant training) that are important/needed to achieve the claimed effect, as appropriate.

A claim on creatine in combination with resistance training and improvement in muscle strength was evaluated by the Panel with a favourable outcome (EFSA NDA Panel, 2016b). The target population for the claim was adults > 55 years of age who are engaged in regular resistance training. The scientific assessment was based on the results of 10 human intervention studies provided by the applicant and on evidence for a mechanism by which creatine could exert the claimed effect. The human intervention studies investigated multiple outcome variables of muscle strength (e.g. 1-RM weight lifting (bench press), 1-RM chest press, 1-RM knee extension, 1-RM biceps curl, 1-RM leg press, and 1-RM leg extension) in different combinations in order to assess upper and lower body muscle strength using different protocols. Overall, the human intervention studies submitted provided evidence for an effect of creatine consumed at doses of at least 3 g/day in combination with regular resistance training (three times per week for several weeks) of moderate intensity on muscle strength in adults 55 years of age and older, while no such effect was observed when similar weekly doses of creatine were given on training days only (three times per week). The Panel also took into account the plausible mechanism by which daily consumption of creatine in combination with resistance training could improve muscle strength.

The recovery or restoration of muscle function (e.g. muscle strength, contraction) after exercise is considered a beneficial physiological effect. Human intervention studies investigating the effect of a food/constituent given after an initial strenuous exercise bout on performance parameters at a subsequent exercise bout after a recovery period are appropriate to assess the effect of the food/constituent on the recovery of muscle function after exercise (e.g. repetitions-to-fatigue test re-

test). Subjective measures of (perceived) muscle fatigue/exertion or muscle soreness (e.g. validated questionnaires[13]) may be used as supportive evidence in this context. Measures of skeletal muscle glycogen stores and some measures of muscle structure (e.g. muscle damage, muscle tissue repair) can provide support for a mechanism by which the food/constituent could exert the claimed effect.

A health claim related to glycaemic carbohydrates and **recovery of normal muscle function (contraction) after strenuous exercise** was evaluated by the Panel with a favourable outcome (EFSA NDA Panel, 2013). The scientific substantiation of this claim relied on consensus opinions from authoritative bodies, which were based on a wealth of human intervention (efficacy) studies, human studies on methods used for measuring muscle glycogen stores, and mechanistic *in vitro* and animal studies. As for the mode of action, the Panel took into account that it is well-established that glucose, which is mainly provided to body cells from glycaemic carbohydrates, can be stored as glycogen in the liver and in the skeletal muscles, and that muscle glycogen, which is used primarily as a source of energy within the muscles, can only be stored in a limited amount in skeletal muscles. It is also well-established that strenuous exercise depletes skeletal muscle glycogen stores, that low glycogen stores limit energy production in muscles and thereby limit skeletal muscle contraction, and that glycaemic carbohydrates, consumed especially in the first hours following strenuous exercise, stimulate glycogen re-synthesis in muscle and contribute to the replenishment of skeletal muscle glycogen stores to a greater extent than other energy-containing macronutrient. This leads to the recovery of normal skeletal muscle function (contraction). The target population for this claim was individuals performing strenuous exercise. The conditions of use for this claim were rather based on the amount of carbohydrates and consumption time relative to the exercise which could increase glycogen re-synthesis in muscle and restore skeletal muscle glycogen stores.

A number of claims on the effects of specific protein sources (e.g. bovine colostrum, casein protein hydrolysates, whey protein), specific amino acids which are incorporated into proteins (e.g. BCAA, L-glutamine), or specific constituents derived from protein amino acids (L-carnitine, L-carnosine) on the growth or maintenance of muscle mass, the maintenance of normal muscle function, faster recovery of muscle function/strength/glycogen stores after exercise, faster recovery from muscle fatigue after exercise, and skeletal muscle tissue repair have been evaluated by the Panel with an unfavourable opinion (Appendix A).

For the scientific substantiation of claims on the effects of specific protein sources/constituents on outcome variables related to **muscle mass and muscle function (e.g. muscle strength)**, human intervention studies assessing the effect of a specific protein source/constituent against another isonitrogenous protein source/constituent were considered as pertinent to the claim, whereas studies controlling for energy only (e.g. using isocaloric carbohydrate sources as placebo) could not be used for the scientific substantiation of these claims. Measures of whole body lean mass in combination with measures of muscle strength were considered appropriate to assess changes in muscle mass. For well-characterised protein sources/constituents, the Panel concluded that a cause and effect relationship had not been established between the consumption of specific protein sources/constituents and growth or maintenance of muscle mass over and above the well-established role of protein on the claimed effect (i.e. beyond what could be expected from the consumption of mixed dietary protein within the DRV when energy and other nutrient requirements are met; (EFSA NDA Panel, 2012a); see also section 4.1.1).

Two applications on citrulline malate and **faster recovery from muscle fatigue after exercise** were evaluated by the Panel with an unfavourable opinion (EFSA NDA Panel, 2012b, 2014a). The human intervention studies provided for the scientific substantiation of the claim assessed subjective measures of muscle soreness after strenuous exercise, blood lactate concentrations during exercise, and/or perceived fatigue during exercise. Performance parameters were not assessed in those studies. The Panel considered that, while there is consensus on the contribution of training in reducing blood lactate concentrations during and after exercise and on delaying muscle fatigue during exercise, no evidence was provided that lowering blood lactate through a dietary intervention can prevent or alleviate loss of muscle function during exercise or can lead to a faster recovery from muscle fatigue

[13] See the General scientific guidance EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016a. General scientific guidance for stakeholders on health claim applications EFSA Journal 2016;14(1):4367, 38 pp. doi:10.2903/j.efsa.2016.4367., i.e. Annex C-Considerations on the validation of questionnaires and their use as outcome variables for the scientific substantiation of health claims.

by contributing to the restoration of muscle function after exercise. The Panel also noted that there is no consensus on the role of lactate in the recovery from muscle fatigue.

4.2.2. Claims on physical performance and physical capacity

Physical performance is the ability to complete certain physical tasks. An increase in physical performance refers to completion of a given physical task with higher intensity, and therefore faster or with a higher power output. Measures of physical performance are obtained in the context of task-limited (e.g. time spent to run/row/swim or cycle a pre-defined distance), or time-limited (e.g. maximum distance cycled in a pre-defined time) physical activities. Improvement, maintenance or reduced loss of physical performance is a beneficial physiological effect for individuals performing physical exercise for different reasons (e.g. athletes preparing for a competition or during a competition, and individuals engaged in physical work or recreational activities), but also for individuals performing common (non-exercise related) physical tasks.

Physical capacity, on the other hand, refers to the exercise time to fatigue when exercising at pre-defined conditions (e.g. a given workload, intensity or speed). Exercise time to fatigue is an appropriate measure of physical capacity. An increased physical capacity is a beneficial physiological effect for individuals performing physical exercise which is not limited by time or task (e.g. recreational running, walking, swimming, cycling and fitness training).

Although an increase in physical capacity (e.g. the time that an individual can exercise to fatigue at a given workload, intensity or speed) may lead to an improvement in physical performance, measures of physical capacity are not appropriate outcome variables for the scientific substantiation of claims on physical performance and *vice versa*. An increase in physical capacity, however, could be associated to an increase in physical performance and therefore measures of physical capacity could be used to support an effect of the food/constituent on performance.

Claims on specific physiological effects (e.g. reduction in rated perceived exertion/effort during exercise, enhancement of water absorption during exercise) which may lead to an improvement in physical capacity and/or performance have been proposed and evaluated by the Panel in the context of claims pursuant to Art. 13(1) of Regulation (EC) No 1924/2006. A claim related to carbohydrate-electrolyte solutions and enhancement of water absorption during exercise (EFSA NDA Panel, 2011h), and a claim related to caffeine (EFSA NDA Panel, 2011j) and the reduction in the rated perceived exertion/effort during exercise, have been evaluated by the Panel with a favourable outcome. For both food/constituents, a claim on increase/maintenance of endurance performance (carbohydrate-electrolyte solutions and caffeine) and/or a claim on increased endurance capacity (caffeine) were also evaluated by the Panel with a favourable outcome within the same scientific opinion (Appendix A). The Panel considers that specific physiological effects such as the reduction in the rated perceived exertion/effort during exercise or an enhancement of water absorption during exercise could be the mechanisms by which a food/constituent could exert an effect on physical capacity or performance. However, evidence that the food/constituent has an effect on direct measures of physical capacity or physical performance should also be provided.

4.2.2.1. Claims on physical performance

The scientific evaluation of health claims on physical performance requires sufficient characterisation of the exercise or physical activity under evaluation, of the target population for which the claim is made, and of the conditions of use for the claim. These aspects may be tightly linked to knowledge (or hypotheses) on the mechanisms by which the food/constituent could exert the claimed effect.

The exercise or physical activity under evaluation (e.g. the testing conditions under which the food/constituent may affect performance) needs to be characterised by:

a) **the mode/type of exercise or physical activity.** The type of exercise (e.g. cycling, running, swimming, weight-lifting) or physical activity (e.g. walking), and whether it is intermittent (e.g. repeated bouts, sprints, repetitions maximum) or continuous (e.g. running at constant speed, cycling at a given cadence) needs to be indicated.

b) **the intensity/load** expressed in relative terms using objective measures (e.g. %HRmax, %HRR , %VO2max, %VO2R; %1RM, %MVC);

c) **duration**, as minutes of activity in each exercise session. For intermittent exercises, the number and duration of exercise sets/intervals, and the number and duration of rest periods within a session, should also be indicated.

Owing to the vast variety of exercise protocols that are being used to test physical performance in humans, additional information may be required for their characterisation. For example, test trials (e.g. a time-limited, self-paced maximal cycling ride) may be preceded by other trials of fixed intensity and duration to increase harmonisation of the pre-test conditions (EFSA NDA Panel, 2018). If that is the case, the pre-test physical exercise should also be described in terms of mode/type, intensity and duration as accurately as possible. Duration and intensity of the exercise should be expressed quantitatively (e.g. duration in minutes, intensity as $\%VO_{2max}$) rather than qualitatively (e.g. short duration, high intensity).

The target population for the claim should be sufficiently defined regarding fitness status and/or age (e.g. young athletes, untrained elderly subjects, individuals on resistance training).

Outcome variables/methods of measurement of physical performance which may be appropriate for the assessment of the claimed effect in humans in the context of a particular type of exercise or physical activity should be indicated (e.g. time spent to run a certain distance, distance cycled during a time-trial).

As for the conditions of use, when the food/constituent should be consumed relative to the physical performance test (e.g. before and/or during exercise), the duration of the intervention, and the need of concomitant training, are important aspects to consider. In this context, training programs should also be characterised in relation to the mode/type (e.g. resistance training; swimming), the intensity/load (where appropriate), the duration of each session, and the frequency (e.g. number of activity sessions per day, week, or month).

Cycling, running, swimming or rowing time-trial tests (e.g. a sort of race where individuals try to cover a pre-defined distance as fast as possible) are **task-limited physical activities** that can be used to assess physical performance both in the general population and in athletes practising such sports. The time spent to cover a certain distance, either alone or in combination with the total/mean work/power output developed during the time-trial test, is an appropriate outcome measure of physical performance. The time spent to cover a certain distance depends on individual conditional capacities, like resistance, speed, muscular power and strength, which can be modified (improved) by training. Jumping height is critical for a successful performance in many sport activities, like basketball or volleyball, and can be used as a measure of physical performance in the general population. Throwing distance in javelin throw or shot put are also appropriate task-limited measures of physical performance. However, since these are highly technical field disciplines, the use of these outcomes is limited to the evaluation of physical performance in javelin throwers or shot putter athletes. Conversely, task (distance/work)-limited walking speed tests are appropriate for the substantiation of health claims on reduced loss of physical performance in the elderly, whereas their use to assess changes in physical performance in other population subgroups (e.g. physically competent children and adults, athletes) is limited.

Physical performance can also be assessed in the context of **time-limited physical activities** as the maximal distance covered by e.g. cycling, running, swimming or rowing within a predefined time, either alone or in combination with the total/mean work/power output developed during the test.

The use of other task-limited or time-limited tests of physical performance, such as walking speed or the number of chair-stands in a certain time, are more appropriate for the substantiation of health claims on the improvement (i.e. reduced loss) of physical performance in the elderly.

Some of the outcome variables proposed for the substantiation of claims on physical performance (e.g. changes in VO_{2max}, increase muscle glycogen stores, changes in substrate oxidation, blood lactate concentrations, muscle carnosine stores) are not direct measures of performance, but could be used in support of a mechanism by which the food/constituent could exert the claimed effect.

A claim on creatine and increase in physical performance during short-term, high intensity, repeated exercise bouts has been evaluated by the Panel with a positive outcome (EFSA NDA Panel, 2011k). The scientific substantiation of the claim was based on a wealth of human intervention studies which investigated the effects of different creatine doses, patterns of consumption and duration of the

supplementation on physical performance during continuous and intermittent physical activities of variable intensity and duration in various population subgroups (men and women of different ages and levels of training); on the results of two meta-analysis summarising the results of the above-mentioned human studies; and on the well-established mechanism by which creatine could exert the claimed effect. The conditions of use for the claim were established based on the results of the human intervention studies (i.e. minimum effective daily dose). The target population was adults performing high-intensity exercise. Conversely, the human studies provided did not show an effect of creatine supplementation on measures of endurance capacity or endurance performance, and there was no consensus on the role of creatine in increasing endurance capacity or performance.

A claim on beta-alanine and increase in physical performance during short-duration, high intensity exercise has been evaluated by the Panel with an unfavourable outcome (EFSA NDA Panel, 2014b). Human intervention studies on the effects of beta-alanine on measures of physical capacity (e.g. time to exhaustion and/or total work done and/or physical working capacity at fatigue threshold) in the context of time unlimited physical activities which did not report on any measures of physical performance were excluded from the assessment. The main outcomes investigated in the remaining studies were the time spent to complete a certain task (run, row, swim or cycle a pre-defined distance) and power output in time-limited (all-out or maximal effort) tasks lasting seconds. Overall, no effect of beta-alanine supplementation on measures of physical performance was found.

A claim on carbohydrate solutions and increase in physical performance during a high-intensity and long-lasting physical exercise has been evaluated by the Panel with a favourable outcome (EFSA NDA Panel, 2018). The applicant defined high-intensity and long-lasting physical exercises as those being performed at least at 65% of the VO_{2max}, at maximal effort, or during a time trial test for at least 60 min. The scientific substantiation of the claim was based on the results of four human intervention studies conducted in non-fasting conditions after a standard meal, which were supported by the results of four intervention studies conducted after an overnight fast and the results of two intervention studies conducted under poorly specified nutritional conditions (e.g. at least a 4-h fast). In these studies, trained participants underwent one or more exercise trials of fixed intensity (generally ≥65% of the VO_{2max} or 70-80% of HR_{max}) and duration (overall lasting > 60 min), followed by an all-out test in which performance was measured. Different types of exercise (e.g. cycling, running) were used for the pre-test and the test trials, which were either continuous, intermittent, or a combination of these (e.g. a cycling trial before and during the test; four cycling trials of eight intermittent bouts followed by an all-out maximal ride). Carbohydrate solutions (containing glucose, mixtures of glucose and fructose, sucrose and/or maltodextrins) were consumed before and/or during the exercise session. The target population for the claim was defined as healthy trained adults performing high-intensity (at least at 65% of the VO_{2max}) and long-lasting (at least 60 min) physical exercise.

A claim on caffeine and an increase in endurance performance has been evaluated by the Panel with a positive outcome (EFSA NDA Panel, 2011j). The Panel took into account that most of the human intervention studies provided using time- or task-limited exercise protocols lasting 60 min or more (including a meta-analysis of five RCTs and three individual RCTs) showed an effect of caffeine consumption on endurance performance at doses of at least 3 mg/kg body weight administered at least one hour prior to exercise, and after at least one day of caffeine withdrawal, in habitual caffeine consumers.

4.2.2.2. Claims on physical capacity

The scientific evaluation of health claims on physical capacity requires sufficient characterisation of the claimed effect and of the target population for which the claim is made.

Physical capacity can be assessed in human intervention studies using several exercise protocols as long as they are not task- or time-limited overall, so that subjects can exercise to fatigue. The particular mode/type of exercise (e.g. cycling, running and swimming; single bout vs. repeated bouts) and the conditions in which physical capacity is tested (e.g. intensity of the exercise, speed, power output) should be specified. The exercise time to fatigue under defined conditions can be assessed by using objective (e.g. cycling cadence, running speed) or self-reported (e.g. with a validated questionnaire) measurements of physical fatigue. As for claims on physical performance, the target population for the claim should be sufficiently defined regarding fitness status and/or age. The

amount and the time of consumption of the food/constituent relative to the exercise test (e.g. before and/or during exercise) is an important aspect to consider when establishing conditions of use.

A claim on caffeine and an increase in endurance capacity has been evaluated by the Panel with a positive outcome (EFSA NDA Panel, 2011j). The Panel took into account that most of the human intervention studies provided using no time-limited exercise protocols (including a meta-analysis of 23 RCTs evaluating 39 outcomes and two individual RCTs) showed an effect of caffeine consumption on endurance capacity at doses of at least 3 mg/kg body weight administered at least one hour prior to exercise, and after at least 12 hours of caffeine withdrawal, in habitual caffeine consumers. The Panel also considered that a plausible mechanism by which caffeine could exert the claimed effect is through the reduction of perceived exertion during exercise, a claim which was evaluated in the same scientific opinion with a positive outcome.

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792 # Glossary and Abbreviations

1-RM	One repetition maximum
BCAA	Branched-chain amino acids
DOMS	Delayed-onset muscle soreness
DRV	Dietary Reference Values
HRmax	Maximum heart rate
HRR	Heart rate reserve
MVC	Maximum voluntary contraction
RCTs	Randomised controlled trials
RPE	Rating of perceived exertion
VO2max	Maximum oxygen consumption

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Appendix A – Health claims on muscle function and physical performance evaluated by the EFSA NDA Panel

Food constituent	Claimed effect	Outcome	Based on the essentiality of nutrients	Scope	References
ATP	Maintenance of normal muscle function	Unfavourable	-	Art. 13(1)	(EFSA NDA Panel, 2011i)
B-alanine	Increase in physical performance during short-term high-intensity exercise	Unfavourable	-	Art. 13(1)	(EFSA NDA Panel, 2010d)
	Increase in time to exhaustion	Unfavourable	-		
	Increase in physical performance during short-duration, high-intensity exercise	Unfavourable	-	Art. 13(5)	(EFSA NDA Panel, 2014b)
Bovine colostrum	Improvement in exercise performance when combined with regular training	Unfavourable	-	Art. 13(1)	(EFSA NDA Panel, 2011l)
	Increase in lean body mass when combined with resistance exercise	Unfavourable	-		
	Recovery following intense exercise	Unfavourable	-		
BCAA	Growth or maintenance of muscle mass	Unfavourable	-	Art. 13(1)	(EFSA NDA Panel, 2010g)
	Attenuation of the decline in muscle power following exercise at high altitude	Unfavourable	-		
	Faster recovery from muscle fatigue after exercise	Unfavourable	-		
	Improvement of cognitive function after exercise	Unfavourable	-		
	Reduction in perceived exertion during exercise	Unfavourable	-		
Beta-alanine	Increase in physical performance during short-duration, high intensity exercise	Unfavourable	-	Art. 13(5)	(EFSA NDA Panel, 2010d)
B-hydroxy B-methylbutyrate monohydrate (HBM) alone or in combination with α-ketoisocaproic acid (KIC)	Reduction of muscle tissue damage during exercise	Unfavourable	-	Art. 13(1)	(EFSA NDA Panel, 2011m)
	Increase in lean body mass	Unfavourable	-		
	Increase in muscle strength	Unfavourable	-		
	Increase in endurance performance	Unfavourable	-		
	Skeletal muscle tissue repair	Unfavourable	-		
	Faster recovery from muscle fatigue after exercise	Unfavourable	-		

Food constituent	Claimed effect	Outcome	Based on the essentiality of nutrients	Scope	References
Caffeine	Increase in physical performance during short-term high-intensity exercise	Unfavourable	-	Art. 13(1)	(EFSA NDA Panel, 2011j)
	Increase in endurance capacity	Favourable	NO		
	Increase in endurance performance	Favourable	NO		
	Reduction in the rated perceived exertion/effort during exercise	Favourable	NO		
Calcium	Maintenance of normal muscle function (contraction)	Favourable	YES	Art.13(1)	(EFSA NDA Panel, 2009a)
Carbohydrate solutions	Maintenance of physical performance during endurance exercise	Unfavourable	-	Art. 13(5)	(EFSA NDA Panel, 2014c)
	Improvement of physical performance during a high-intensity and long-lasting physical exercise	Favourable	NO	Art. 13(5)	(EFSA NDA Panel, 2018)
Carbohydrate-electrolyte solutions	Reduction in rated perceived exertion/effort during exercise	Unfavourable	-	Art. 13(1)	(EFSA NDA Panel, 2011h)
	Enhancement of water absorption during exercise	Favourable	NO		
	Maintenance of endurance performance	Favourable	NO		
Casein protein hydrolysates	Growth or maintenance of muscle mass	Unfavourable	-	Art. 13(1)	(EFSA NDA Panel, 2011n)
	Increase in endurance performance	Unfavourable	-		
	Faster recovery from muscle fatigue after exercise	Unfavourable	-		
Citruline malate	Faster recovery from muscle fatigue after exercise	Unfavourable	-	Art. 13(5)	(EFSA NDA Panel, 2012b, 2014a)
Coenzyme Q10	Contribution to normal energy-yielding metabolism	Unfavourable	-	Art. 13(1)	(EFSA NDA Panel, 2010f)
	Increase in endurance capacity and/or endurance performance	Unfavourable	-		
Creatine	Increase in physical performance during short-term, high intensity, repeated exercise bouts	Favourable	NO	Art. 13(1)	(EFSA NDA Panel, 2011k)
	Increase in endurance capacity	Unfavourable	-		
	Increase in endurance performance	Unfavourable	-		

Food constituent	Claimed effect	Outcome	Based on the essentiality of nutrients	Scope	References
	Improvement in muscle strength (in combination with resistance training)	Favourable	NO	Art. 13(5)	(EFSA NDA Panel, 2016b)
L-carnitine	Faster recovery from muscle fatigue after exercise	Unfavourable	-	Art.13(1)	(EFSA NDA Panel, 2011a)
	Skeletal muscle tissue repair	Unfavourable	-		
	Increase in endurance capacity	Unfavourable	-		
L-carnosine	Increase in muscle power	Unfavourable	-	Art.13(1)	(EFSA NDA Panel, 2011b)
	Increase in endurance capacity	Unfavourable	-		
Glycaemic carbohydrates	Recovery of normal muscle function (contraction) after strenuous exercise	Favourable	YES	Art.13(5)	(EFSA NDA Panel, 2013)
L-glutamine	Growth or maintenance of muscle mass	Unfavourable	-	Art.13(1)	(EFSA NDA Panel, 2011c)
	Faster restoration of muscle glycogen stores after strenuous exercise	Unfavourable	-		
	Skeletal muscle tissue repair	Unfavourable	-		
Magnesium	Maintenance of normal muscle function (contraction)	Favourable	YES	Art.13(1)	(EFSA NDA Panel, 2009c)
Potassium	Maintenance of normal muscle function (contraction)	Favourable	YES	Art.13(1)	(EFSA NDA Panel, 2010h)
Protein	Growth or maintenance of muscle mass	Favourable	YES	Art.13(1)	(EFSA NDA Panel, 2010a)
Ribose	Faster recovery from muscle fatigue after exercise	Unfavourable	-	Art.13(1)	(EFSA NDA Panel, 2011d)
Sodium	Maintenance of normal muscle function (contraction)	Favourable	YES	Art.13(1)	(EFSA NDA Panel, 2011g)
Sodium phosphate	Increase in endurance performance	Unfavourable	-	Art.13(1)	(EFSA NDA Panel, 2011f)
	Increase in endurance capacity	Unfavourable	-		
Soy phosphatidyl choline	Faster recovery from muscle fatigue after exercise	Unfavourable	-	Art.13(1)	(EFSA NDA Panel, 2010e)
	Improvement of neuromuscular function	Unfavourable	-		
	Contribution to normal fat metabolism	Unfavourable	-		
Superoxide dismutase (SOD)	Reduction of muscle fatigue during exercise	Unfavourable	-	Art.13(1)	(EFSA NDA Panel, 2010b)
Taurine	Maintenance of normal cardiac function	Unfavourable	-	Art.13(1)	(EFSA NDA
	Maintenance of normal muscle function	Unfavourable	-		

Food constituent	Claimed effect	Outcome	Based on the essentiality of nutrients	Scope	References
	Delay in the onset of physical fatigue during exercise	Unfavourable	-		Panel, 2009b, 2011e)
Whey protein	Growth or maintenance of muscle mass	Unfavourable	-	Art.13(1)	(EFSA NDA Panel, 2010c)
	Increase in lean body mass during energy restriction and resistance training	Unfavourable	-		
	Reduction of body fat mass during energy restriction and resistance training	Unfavourable	-		
	Increase in muscle strength	Unfavourable	-		
	Increase in endurance capacity during the subsequent exercise bout after strenuous exercise	Unfavourable	-		
	Skeletal muscle tissue repair	Unfavourable	-		
	Faster recovery from muscle fatigue after exercise	Unfavourable	-		