TECHNICAL REPORT

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# Outcome of a public consultation on the draft guidance on the scientific requirements for health claims related to muscle function and physical performance

## (Revision 1)

European Food Safety Authority (EFSA)

## Abstract

The European Food Safety Authority (EFSA) carried out a public consultation to receive input from the scientific community and all interested parties on a draft guidance on the scientific requirements for health claims related to muscle function and physical performance, prepared by the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA), supported by the Working Group on Claims. The draft guidance was endorsed by the Panel for public consultation at its plenary meeting on 28 June 2018. The written public consultation was open from 16 July to 2 September 2018. EFSA received comments from three interested parties. EFSA and its NDA Panel wish to thank all stakeholders for their contributions. The present report summarises the outcome of the public consultation, and includes a summary of the comments received and how they were addressed. In particular, the report describes the revisions of the draft guidance that have been applied in light of the comments received. The guidance was discussed and adopted at the NDA Plenary meeting on 27 September 2018, and is published in the EFSA Journal.



**Key words:** guidance, health claims, scientific requirements, muscle function, physical performance, public consultation

**Requestor:** EFSA

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# 1. Introduction

## 1.1. 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 be only 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)[2] has placed considerable focus on developing scientific criteria for substantiation of health claims and has published guidance on scientific substantiation of health claims since 2007[3].

Over the last number of 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[4] 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[5] 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[6].

## 1.2. 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.

## 1.3. Consideration

Following a request from EFSA to the NDA Panel to update the existing guidance document on the scientific requirements for the substantiation of health claims related to physical performance published in 2012 (EFSA NDA Panel, 2012), the NDA Panel developed a guidance on the scientific requirements for health claims related to muscle function and physical performance (hereafter 'guidance').

In the meantime, the NDA Panel has updated the general guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016) to address general issues that are common to all health claims.

In this context, the NDA Panel has revised the guidance taking into account that:

[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] As from 1 July 2018, the NDA Panel has been renamed as EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA).
[3] http://www.efsa.europa.eu/en/applications/nutrition
[4] https://www.efsa.europa.eu/en/supporting/pub/1272e
[5] https://www.efsa.europa.eu/en/applications/nutrition/regulationsandguidance
[6] https://www.efsa.europa.eu/en/efsajournal/pub/2817

- Issues related to the scientific substantiation that are common to all claims are addressed in the general scientific guidance for stakeholders (EFSA NDA Panel, 2016) (hereafter 'general guidance') and will not be reiterated in this guidance;
- Examples of claims evaluated favourably by the Panel can be used to provide guidance to applicants on the scientific requirements for the substantiation of health claims in specific areas, whereas examples of claims evaluated unfavourably by the Panel can be used to illustrate the shortcomings that prevented the substantiation of these claims;
- The guidance cannot provide advice on health claims which have not been evaluated by the Panel yet, nor set out an exhaustive list of beneficial physiological effects and studies/outcome variables which could be acceptable. This is because defining the conditions under which health relationships and outcome variables for claimed effects may be acceptable is possible only in the context of specific applications, which are often unique and technically complex (e.g. health relationships and outcome variables which may be acceptable in the context of a particular application may not be so in the context of another application with, for example, a different target population).

In line with EFSA's policy on openness and transparency, and in order for EFSA to receive comments on its work from the scientific community and stakeholders, EFSA engages in public consultations on key issues. Accordingly, the draft guidance was released for public consultation (from 16 July to 2 September 2018) (see Appendix A).

The revised guidance was discussed and adopted at the NDA Plenary meeting on 27 September 2018, and is published in the EFSA Journal (EFSA NDA Panel, 2018). EFSA is committed to publishing the comments received during the public consultation, as well as a short report on the outcome of the consultation.

# 2. Assessment of the comments received

EFSA received comments from three interested parties, including food business operators and industry associations. A total of eight comments were submitted by means of the electronic form on the EFSA website (Appendix B).

**Table 1:** List of organisations submitting comments

| Organisation | Country |
|---|---|
| Food Supplements Europe | Belgium |
| Nutraveris / European Specialist Sports Nutrition Alliance (ESSNA) | France |
| Dominus Nutrition | Finland |

A summary of the comments received is given below. All written comments are listed in Appendix B.

## 2.1. Comments related to the scope of the draft guidance

*Comments received*

Two comments were related to the completeness and nature of the draft guidance document. It was considered that the draft was not a comprehensive review of the available scientific evidence, and that some beneficial physiological effects or mechanisms of action in relation to muscle function were not addressed.

*Panel's consideration of the comments received*

The purpose of the guidance document is not to systematically address or review all the available scientific evidence in the area of sports nutrition, but rather to assist applicants in the preparation of applications for authorisation of health claims in the areas of muscle function and physical performance. In this context, and as further clarified in section 2 (objectives and scope) of the revised guidance, the document has been developed based on previously published scientific opinions of the NDA Panel on health claims related to muscle function and physical performance. Thus, it represents

the views of the NDA Panel based on the experience gained from the evaluation of health claims in these areas. It is **not** intended that the document should:

a) include an exhaustive list of beneficial effects and studies/outcome variables which are acceptable for claims substantiation or,

b) address potential health relationships and related outcome variables/methods of measurement which have not been considered by the Panel yet in the context of a particular application.

This is because defining the conditions under which health relationships and outcome variables/methods of measurement may be acceptable is only possible in the context of specific applications, which are often unique and technically complex. For example, health relationships and outcome variables which may be acceptable in the context of a particular application may not be so in the context of another application with, for example, a different target population. The guidance rather presents examples drawn from evaluations already carried out to illustrate the approach of the Panel.

*Comment received*

There was a question on whether target populations such as the elderly or "medical patients" were under the scope of this guidance.

*Panel's consideration of the comment received*

EFSA wishes to clarify that, as stated in section 2 (Objectives and scope), this guidance should be read in conjunction with the General scientific guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016), the Scientific and technical guidance for the preparation and presentation of a health claim application (EFSA NDA Panel, 2017), and Regulation (EC) No 1924/2006 on nutrition and health claims made on foods[7], among others.

In this context, the **target population** is the population group(s) for which health claims are intended, and a **suitable study group** means a study group which is representative of the target population for the claim or a study group from which extrapolation of the results to the target population is biologically appropriate.

Regulation (EU) No 1169/2011[8] indicates that, for the purpose of communicating the health properties of a food/constituent to consumers, subjects with a disease cannot be the target population for health claims made on food. Thus, in principle, the target population for health claims made on food should be the general (healthy) population or specific subgroups thereof, e.g. healthy subjects selected on the basis of a genetic (e.g. sex, ethnicity), demographic (e.g. age: children, adults, elderly), physiological (e.g. pregnancy, menopause) or lifestyle (e.g. level of physical activity, diet) characteristic (EFSA NDA Panel, 2016). These are only examples, not an exhaustive list. Therefore elderly subjects are under the scope of this guidance as a possible target population for claims on muscle function and physical performance, whereas diseased subjects under medical care are not. However, the Panel wishes to clarify that diseased subjects could be a suitable study group for the scientific substantiation of health claims as long as extrapolation of the results to the target population is biologically appropriate. It is the responsibility of the applicant to provide a scientific rationale for such extrapolation. Biological plausibility will be considered by the NDA Panel on a case-by-case basis in the context of specific applications (see section 7.6 of the General scientific guidance for stakeholders on health claim applications, EFSA NDA Panel 2016).

No changes were introduced in the guidance on the basis of this comment.

[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] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. J L 304, 22.11.2011, p. 18–63. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R1169

## 2.2. Comments related to the definition of terms

*Comments received*

There was a request to include in section 3 (definition of terms), in addition to the terminology used to describe different types of physical activities, a definition of terms related to the characterisation of the target population regarding physical fitness and age (e.g. athletes, recreationally active subjects, elite athletes, adolescents, elderly). It was also requested to clarify the difference between athletes and recreationally active subjects, and to define physical work and recreational activities.

*Panel's consideration of the comments received*

The Panel notes that there is no consensus on the definition of terms commonly used to describe the level of physical fitness and/or the level of training of individuals (athletes, recreationally active subjects, elite athletes), or to define age groups (adolescents, elderly). However, the Panel considers that any definitions that could be given in the context of this guidance regarding age and levels of physical fitness (or levels of training) for the purpose of characterising the target population for a claim could be too prescriptive and unlikely to accommodate the diversity of individual applications.

For this reason, one paragraph has been added at the end of section 3 (definition of term), as follows:

*"The target population for the claim should be characterised in terms of age and level of physical fitness (or level of training) if: a) these characteristics are thought to affect the relationship between the intake of the food/constituent and the claimed effect, and/or b) if the studies provided for the substantiation of the claim have been conducted in specific study groups (e.g. elderly male subjects) and the extrapolation of the results to the general (healthy) population cannot be justified. The Panel notes, however, that there is no consensus on the definition of terms like "moderately active individuals", "recreationally active individuals", "athletes" or "elite athletes". Similarly, common terms used to define age groups (e.g. adolescents, elderly subjects) may correspond to different age ranges. Therefore, for the purpose of characterising the target population in the area of health claims related to muscle function and physical performance, age and/or level of physical fitness (or training) should be indicated as precisely as possible whenever these characteristics are important to establish conditions of use for the claim. For example, the level of physical fitness (or level of training) of the target population would be better described by characteristics such as the intensity/load, frequency, duration, and mode/type of the physical exercise being performed on regular basis, while years (or age ranges) would be more appropriate to describe age".*

Whereas the characterisation of the target population as described above is needed to allow the scientific evaluation of the claim by the Panel (i.e. to conclude on the scientific substantiation, provide a wording that reflects the scientific evidence, and set conditions of use where appropriate), applicants could propose alternative descriptions of the target population within the wording of a claim for consumer communication during the authorisation procedure (see section 7.8 of the General scientific guidance for stakeholders on health claim applications, EFSA NDA Panel 2016).

The Panel also wishes to clarify that the sentence in section 4.2.2 reading "*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 recreational activities), but also for individuals performing common (non-exercise related) physical tasks*", in which some of the terms for which clarification has been requested appear, is intended to merely indicate that the target population for such claims could be anyone in the general population performing physical tasks, regardless of the purpose.

## 2.3. Comments related to claims on muscle function

*Comment received*

It was noted that the reference to indispensable amino acids in the context of the maintenance of nitrogen balance in line 267 of the draft guidance was unclear, since all amino acids should be considered for the maintenance of nitrogen balance.

*Panel's consideration of the comment received*

The Panel agrees with the comment. The reference to indispensable amino acids in the context of the maintenance of nitrogen balance has been deleted in the revised version of the guidance.

*Comments received*

It was noted that an increase in muscle protein synthesis (or a decrease in muscle protein breakdown) rate is not mentioned in the guidance as a beneficial physiological effect or pertinent outcome measure neither in relation to an increase in muscle mass and strength nor in relation to the recovery or restoration of muscle function (e.g. muscle strength, contraction) after exercise. It was also mentioned that only measures of skeletal muscle glycogen stores appeared to be important in relation to claims on the recovery or restoration of muscle function (e.g. muscle strength, contraction) after exercise, and that the chapter should be re-written to take into account all known components of recovery, including post-exercise skeletal muscle protein synthesis.

*Panel's consideration of the comments received*

The Panel wishes to clarify that, as mentioned in section 2 of the guidance, the document has been developed based on previously published scientific opinions of the NDA Panel on health claims related to muscle function and physical performance. It is not intended that the document should include: a) an exhaustive list of beneficial effects and studies/outcome measures which are acceptable for claims substantiation, or b) address potential health relationships and related outcome measures which have not been considered by the Panel yet in the context of a particular application. In other words, other beneficial physiological effects and outcome variables for their measurement could be acceptable for claims substantiation if adequately justified in the context of specific applications. For this reason, the 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.

Measures of muscle protein turnover (rates of muscle protein synthesis and breakdown) have been added in support to the mechanisms by which a food/constituent could exert an effect on muscle mass and strength, and on the recovery or restoration of muscle function (e.g. muscle strength, contraction) after exercise in the revised guidance document (section 4.2.1). However, measures of muscle protein turnover (and their related methods of measurement) were not among the outcome measures proposed in applications related to an increase in muscle strength. The only health claim submitted in relation to a faster recovery of normal muscle function (contraction) after strenuous exercise referred to glycaemic carbohydrates (EFSA NDA Panel, 2013) and was therefore used by the Panel to illustrate its experience in the scientific evaluation of such claims. The example, however, has been simplified in the revised version of the guidance to avoid misinterpretations.

*Comment received*

A comment referred to the fact that the claim on recovery or restoration of muscle function after exercise appeared to be limited to food/ingredients consumed after a strenuous exercise, whereas food/ingredients consumed before the exercise, either acutely or chronically, could also have an impact on the claimed effect.

*Panel's consideration of the comment received*

As mentioned in relation to the previous comments, it is not intended that the guidance contains an exhaustive list of all possible claims that could be submitted to EFSA for substantiation in the area of muscle function and physical performance. However, the Panel agrees that food/constituents could have an effect on recovery or restoration of muscle function after exercise whether consumed before (either acutely or chronically), during and/or after an initial strenuous exercise bout. For clarity, the guidance (section 4.2.1) has been updated accordingly as follows:

"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 *consumed before (either acutely or chronically), during and/or 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) may be used as supportive

evidence in this context. Measures of skeletal muscle glycogen stores, *measures of muscle protein turnover (rates of muscle protein synthesis and breakdown)*, 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".

*Comment received*

It was highlighted that, in the previous EFSA guidance (EFSA NDA Panel, 2012), changes in muscle damage contributing to the improvement, maintenance or reduced loss of muscle function, as well as faster recovery from muscle damage after exercise, could be considered as beneficial physiological effects, whereas in the present guidance muscle damage is considered only as supportive for the substantiation of a mechanism of action. There was a request for EFSA to clarify this change and to indicate appropriate outcome measures to assess muscle damage (e.g. creatinine kinase, lactate dehydrogenase, myoglobin).

*Panel's consideration of the comment received*

The Panel wishes to clarify that, even if expressed in a different way, a reduction in muscle damage was not considered as a beneficial physiological effect *per se*, neither in the previous (EFSA NDA Panel, 2012) nor in the present guidance. In 2012, changes in muscle damage were considered as beneficial provided that such changes contributed to the improvement, maintenance or reduced loss of muscle function, or to a faster recovery from muscle damage after exercise. To assess that, measures of muscle function (e.g. muscle strength) were needed for the substantiation of such claims. The present guidance clarifies that measures of muscle damage are not direct measures of muscle function, but can provide support for a mechanism by which the food/constituent could exert the claimed effect. No outcome variables are discussed in the guidance in relation to muscle damage because the Panel has not evaluated this outcome in the context of a specific application yet.

No changes were introduced in the guidance on the basis of this comment.

## 2.4. Comments related to claims on physical performance

*Comment received*

In reference to the text in line 515 "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", it was mentioned that the definition of endurance exercise was rather limited to $VO_{2max}$, heart rate, and endurance tests of ≥60 minutes in combination with an all-out test. It was suggested to broaden this definition and to include examples of relevant and validated (all-out) tests.

*Panel's consideration of the comment received*

The text mentioned above (in line 515 of the draft guidance) refers to the evaluation of a specific health claim application on carbohydrate solutions and increase in physical performance during a high-intensity and long-lasting physical exercise, which has been evaluated by the Panel with a favourable outcome (EFSA NDA Panel, 2018) and is used as an example for illustration purposes. It describes the conditions of use set for the claim on the basis of data provided for substantiation. It is not intended to define endurance exercise or provide a complete list of validated all-out (maximal effort) tests. Examples of such tests can be found in the scientific opinion, but other valid tests may be available or developed in the future.

Indeed, the guidance clarifies in section 3 (definition of terms) that 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 exercises of "moderate" intensity (generally <80 % $VO_{2max}$), and that these terms are only used in the present guidance to describe examples of previous evaluations for illustration purposes. The reason for this change is that, as described in the same section, the nomenclature to classify the intensity and duration of physical exercise is not harmonised. As explained in section 4.2.2.1 (claims on physical performance) the exercise or physical activity under evaluation needs to be characterised by the mode/type of exercise, the intensity/load, and the duration. In this context, there is no need to give a general definition of endurance exercise in the guidance.

No changes were introduced in the guidance on the basis of this comment.

*Comment received*

It was suggested that, in case where elderly subjects and "medical patients" are included among the target population for claims, relevant physical fitness and physical performance tests for these populations (e.g. sit-to-stand test, functional walking tests, etc.) should be included in the guidance.

*Panel's consideration of the comment received*

As outlined above, the target population for health claims includes elderly subjects but excludes individuals with a disease. In this context, the guidance already foresees in section 4.2.2.1 (claims on physical performance) that 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. Similarly, it is mentioned that 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, is more appropriate for the substantiation of health claims on the improvement (i.e. reduced loss) of physical performance in the elderly. These are meant only as examples.

No changes were introduced in the guidance on the basis of this comment.

EFSA and its NDA Panel wish to thank all stakeholders for their comments and contributions.

## References

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# Glossary and Abbreviations

| | |
|---|---|
| $HR_{max}$ | Maximum heart rate |
| $VO_{2max}$ | Maximum oxygen consumption |

# Appendix A – Explanatory text for the public consultation on a draft guidance on the scientific requirements for health claims related to muscle function and physical performance

EFSA has launched an open consultation on its draft guidance for the scientific requirements for health claims related to muscle function and physical performance (revision 1).

This document 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.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from the scientific community and stakeholders, EFSA has launched a public consultation on the draft document developed by the NDA Panel of EFSA.

Please use the electronic template provided to submit comments and refer to the line and page numbers of the respective document. In case you encounter technical issues while filling-in the public consultation form, please make sure you first clean the browser's history or switch browser. If you would like to submit data-sets or files to support your comments, you can either upload them via the form or send them by email.

Please note that comments will not be considered if they:

- are submitted after the closing date of the public consultation;
- are not related to the contents of the document;
- contain complaints against institutions, personal accusations, irrelevant or offensive statements or material;
- are related to policy or risk management aspects, which are out of the scope of EFSA's activity.

EFSA will assess all comments from interested parties which are submitted in line with the criteria above. The comments will be further considered by the relevant EFSA Panel and taken into consideration if found to be relevant.

Persons or entities participating in the EFSA Public Consultation are responsible for ensuring that they hold all the rights necessary for their submissions and consequent publication by EFSA. Comments should inter alia be copyright cleared taking into account EFSA's transparency policy and practise to publish all submissions. In case your submission reproduces third party content in the form of charts, graphs or images, please ensure that the required prior permissions of the right holder have been obtained.

All comments submitted will be published. Comments submitted by individuals in a personal capacity will be presented anonymously. Comments submitted formally on behalf of an organisation will appear with the name of the organisation.

## Appendix B – Full list of comments submitted by means of the electronic form on the EFSA website

| Organisation | Chapter | Comment |
|---|---|---|
| Nutraveris / ESSNA (European Specialist Sports Nutrition Alliance) | 3. Definition of terms | The definition of athletes and recreationally active subjects and their ages should be added. |
| Dominus Nutrition | 4.1.1 Claims on muscle function | I would like to thank the European Food Safety Authority (EFSA) for the opportunity to comment on their publication "Draft guidance on the scientific requirements for health claims related to muscle function and physical performance (Revision 1)" (hereinafter referred to as "the Draft").<br><br>I have peer-reviewed some +200 manuscripts related to sports nutrition, sports supplements and ergogenic aids, and I never seen so poorly written paper by academic authors. The Draft is a superficial and poorly written opinion paper rather than a comprehensive review of the available scientific evidence. Althought there are numerous shortcoming and omissions, this comment will focus on "The recovery or restoration of muscle function (e.g. muscle strength, contraction) after exercise" (L329). The Draft rely on "old-school" view that post-exercise glycogen re-synthesis is all that matters. In reality, nothing could be farther from the truth. Thus, this section should be completely re-written to take account all know components of recovery/restoration of muscle function after exercise, including post-exercise skeletal muscle protein synthesis. |
| Nutraveris / ESSNA (European Specialist Sports Nutrition Alliance) | 4.1.1 Claims on muscle function | Line 267: the mention of indispensable amino acids for the maintenance of nitrogen balance is unclear. All amino acids should be consider for the maintenance of nitrogen balance. |
| Nutraveris / ESSNA (European Specialist Sports Nutrition Alliance) | 4.2.1. Claims on muscle function | An increase in muscle protein synthesis (MPS) rate is not mentioned as a beneficial physiological effect, nor as a relevant outcome measure. This while an increased MPS (or decreased MPB) is the underlying physiological mechanism of increasing muscle mass and muscle strength. In many studies on the relation between protein intake and muscle growth and maintenance, MPS is the main outcome measure. We suggest to include MPS as a relevant outcome measure and as a beneficial physiological effect in order to increase muscle mass and muscle strength.<br><br>Claims on muscle damage: in its previous guidance (EFSA, 2012 [2817]), EFSA recognized that changes in muscle damage contributing to the improvement, maintenance or reduced loss of muscle function can be considered as a beneficial physiological effect. Moreover, faster recovery from muscle damage after exercise contributing to the restoration of muscle function can be considered as a beneficial physiological effect. |

| Organisation | Chapter | Comment |
|---|---|---|
| | | In this updated guidance, muscle damage is considered only as a support for the substantiation of a mechanism of action. Can EFSA clarify whether changes in muscle damage are no longer considered as beneficial physiological effects (as described above)? Muscle damage is a major problem for sportspeople. Reduction in muscle damage and faster recovery from muscle damage should be considered as beneficial physiological effects.<br><br>Finally, EFSA does not indicate how muscle damage should be assessed. Creatine kinase is the most common marker of muscle damage. Lactate dehydrogenase and myoglobin are also widely used for the assessment of muscle integrity. Are these markers considered as pertinent by EFSA?<br><br>Reference: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Guidance on the scientific requirements for health claims related to physical performance. EFSA Journal 2012;10(7):2817.<br><br>Line 331: the claim on recovery or restoration of muscle function is limited to ingredients consumed after a strenuous exercise. However, food/ingredients can be consumed before the exercise bout. Moreover, EFSA position suggest that health claim on recovery/restoration of muscle effects are limited to an acute effect of the food/ingredient. We suggest to modify the paragraph to include 1) the possibility to submit health claim on the effects of chronic intake of a food/ingredient on recovery of muscle function, and 2) the possibility to demonstrate the effects of a food/ingredient consumed before the exercise session. |
| Nutraveris / ESSNA (European Specialist Sports Nutrition Alliance) | 4.2.2 Claims on physical performance and physical capacity | Line 395: as mentioned above for definition of terms, we suggest the definition of physical work and recreational activities to be added. |
| Nutraveris / ESSNA (European Specialist Sports Nutrition Alliance) | 4.2.2.1 Claims on physical performance | Line 447: as mentioned above for definition of terms, we suggest the definition of target population (fitness status) to be added.<br><br>Line 515: "In these studies, trained participants underwent one or more exercise trials of fixed intensity (generally ≥65% of the VO2max or 70-80% of HRmax) and duration (overall lasting > 60 min), followed by an all-out test in which performance was measured". The definition of endurance exercise is rather limited to VO2 max and heart rate and endurance tests of ≥60 minutes in combination with an all-out test. We would suggest to broaden this definition and to include examples of relevant and validated (all-out) tests. |

| Organisation | Chapter | Comment |
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| Nutraveris / ESSNA (European Specialist Sports Nutrition Alliance) | Other comments | Nutraveris and ESSNA (European Specialist Sports Nutrition Alliance) would like to thank EFSA for updating the guidance on scientific requirements for health claims related to muscle function and physical performance, and offering the possibility for consultation.<br><br>Line 108: EFSA requires the definition of the target population for which the claim is intended. For claims related to muscle function and physical activity, claims may be intended for athletes, recreationally active subjects, or healthy subjects not involved in physical training.<br><br>As already done in part 3 Definition of terms to clarify the terminology used to describe different types of physical activities, we suggest to complete this guidance with clarification on the various (athletes, trained, recreationally active, elite,…) populations. The difference between athletes and recreationally active subjects has notably to be clarified. Similarly, a large number of clinical trials have assessed the effects of compounds/ingredients in elderly or adolescent subjects. The definition (age) of such subjects should be clarified.<br><br>In addition, the scope of this guidance (health claim related to muscle function and physical performance) is also relevant for populations such as elderly and medical nutrition. It is unclear to us whether these populations are taken into account in this guidance. If elderly and medical patients are also within the scope, then we suggest to include examples of relevant physical fitness and physical performance tests for these populations (e.g. sit-to-stand test, functional walking tests, etc.). |
| Food Supplements Europe | Other comments | Food Supplements Europe welcomes the revision of these guidelines and thanks EFSA for the opportunity to comment. These guidelines are clear and provide useful information. We do not have specific comments. |