DRAFT SCIENTIFIC OPINION

Guidance on the scientific requirements for health claims related to physical performance[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

The Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked by the European Food Safety Authority (EFSA) to draft guidance on scientific requirements for health claims related to physical performance. This draft guidance has been drawn from scientific opinions of the NDA Panel on such health claims. Thus, this guidance document represents the views of the NDA Panel based on the experience gained to date with the evaluation of health claims in this area. It is not intended that the document should include an exhaustive list of beneficial effects and studies/outcome measures which are acceptable. Rather, it presents examples drawn from evaluations already carried out in order to illustrate the approach of the Panel, as well as some examples which are currently under consideration within ongoing evaluations. This draft guidance document was endorsed by the NDA Panel on 24 November 2011, and is released for public consultation from 19 December 2011 to 09 March 2012.

KEY WORDS

Health claims, scientific requirements, physical performance.

[1] On request from EFSA, Question No EFSA-Q-2010-01186, endorsed for public consultation on 24 November 2011.

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BACKGROUND AS PROVIDED BY EFSA

Regulation (EC) No 1924/2006[4] harmonises the provisions that relate 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 has been carried out by EFSA.

EFSA and its NDA Panel have been engaging in consultation with stakeholders and have published guidance on scientific substantiation of health claims since 2007[5]. Most recently, a briefing document on scientific evaluation of health claims was published for consultation in April 2010, followed by a technical meeting with experts from the food industry, Member States and the European Commission in Parma, in June 2010[6].

Based on experiences gained with the evaluation of health claims, and to further assist applicants in preparing and submitting their applications for the authorisation of health claims, the NDA Panel is asked to develop guidance documents on the scientific requirements for the substantiation of health claims in selected areas, in addition to the guidance for the scientific substantiation of health claims related to gut and immune function (EFSA-Q-2010-01139).

TERMS OF REFERENCE AS PROVIDED BY EFSA

The NDA Panel is requested by EFSA to develop guidance documents on the scientific requirements for health claims in the following areas:

- Post-prandial blood glucose responses/blood glucose control
- Weight management, energy intake and satiety
- Protection against oxidative damage
- Cardiovascular health
- Bone, joints, and oral health
- Neurological and psychological functions
- Physical performance

Specific issues to be addressed in these guidance documents include:

- which claimed effects are considered to be beneficial physiological effects?
- which studies/outcome measures are appropriate for the substantiation of function claims and disease risk reduction claims?

Each guidance document should be subject to public consultation, and may be followed up as appropriate by scientific meetings with experts in the field.

Before the adoption of each guidance document by the NDA Panel the draft guidance shall be revised, taking into account the comments received during the public consultation. A report on the outcome of the public consultation shall be published for each guidance document. All guidance documents should be finalised by July 2012.

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.
[5] http://www.efsa.europa.eu/en/nda/ndaclaims.htm
[6] http://www.efsa.europa.eu/en/ndameetings/docs/nda100601-ax01.pdf

ASSESSMENT

1. Introduction

To assist applicants in preparing and submitting their applications for the authorisation of health claims, EFSA and in particular its Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) has ongoing consultations with stakeholders, and has published guidance on the scientific substantiation of health claims since 2007[7]. In April 2010, a draft briefing document on the scientific evaluation of health claims was published for consultation, and was followed by a technical meeting with experts from the food industry, Member States and the European Commission in Parma, in June 2010. The draft briefing document has been transformed into a Panel output, taking into account the questions/comments received. This document constitutes the general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims, and outlines the approach of the NDA Panel to the evaluation of health claims in general. In response to requests from industry, EFSA is engaged in further consultation with stakeholders, and is developing additional guidance on specific types of claims.

The objective of the present public consultation is to discuss with scientific experts in the field the scientific requirements for the substantiation of health claims related to physical performance. This consultation document will be revised to take into account the comments received, in order to provide additional guidance to applicants for the substantiation of health claims in this area.

The consultation document focuses on two key issues regarding the substantiation of health claims related to physical performance:

- claimed effects which are considered to be beneficial physiological effects.
- studies/outcome measures which are considered to be appropriate for the substantiation of health claims.

Issues which are related to substantiation and are common to health claims in general (e.g. characterisation of the food/constituent) are addressed in the general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims [8].

This document has been drawn from scientific opinions of the NDA Panel on health claims related to physical performance. Thus, it represents the views of the NDA Panel based on the experience gained to date with the evaluation of health claims in this area. The document should be read in conjunction with the general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims.

It is not intended that the document should include an exhaustive list of beneficial effects and studies/outcome measures which are acceptable. Rather, it presents examples drawn from evaluations already carried out in order to illustrate the approach of the Panel, as well as some examples which are currently under consideration within ongoing evaluations.

[7] http://www.efsa.europa.eu/en/ndaclaims/ndaguidelines.htm

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

2. General considerations

2.1. Beneficial physiological effects

According to Regulation (EC) No 1924/2006, the use of health claims shall only be permitted if the food/constituent, for which the claim is made, has been shown to have a beneficial physiological effect. In assessing each claim, the NDA Panel makes a scientific judgement on whether the claimed effect is considered to be a beneficial physiological effect in the context of the specific claim, as described in the information provided and taking into account the population group for whom the claim is intended. For function claims, a beneficial effect may relate to the maintenance or improvement of a function.

The NDA Panel considers that the population group for which health claims are intended is the general (healthy) population or specific subgroups thereof, for example, elderly people, physically active subjects, or pregnant women. Applications for claims which specify target groups other than the general (healthy) population are the subject of ongoing discussions with the Commission and Member States with regard to their admissibility.

The NDA Panel also considers whether the claimed effect is sufficiently defined to establish that the studies identified for substantiation of the claim were performed with (an) appropriate outcome measure(s) of that claimed effect. Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim.

2.2. Studies/outcome measures appropriate for substantiation of claims

As human studies are central for the substantiation of health claims, this document focuses in particular on such studies. In considering whether the studies provided are pertinent (i.e. studies from which conclusions can be drawn for the scientific substantiation of the claim), the NDA Panel addresses a number of questions, including:

- Whether the studies have been carried out with the food/constituent for which the claim is made. This requirement means that there should be sufficient definition of the food/constituent for which the claim is made, and of the food/constituent which has been investigated in the studies which have been provided for substantiation of the claim. The evaluation also considers how the conditions under which the human studies were performed relate to the conditions of use (e.g. quantity and pattern of consumption of the food/constituent) proposed for the claim.

- Whether the design and quality of the studies allow conclusions to be drawn for the scientific substantiation of the claim. The evaluation takes into account the hierarchy of evidence as described in the scientific and technical guidance of the EFSA NDA Panel[9], for example, intervention studies generally provide stronger evidence than observational studies. Intervention studies should be appropriately conducted so as to minimise bias. In observational studies adequate control for factors other than the food/constituent known to have an impact on the claimed effect is important. Each health claim is assessed separately and there is no pre-established formula as to how many or what type of studies are needed to substantiate a claim. In this regard, the reproducibility of the effect of the food/constituent as indicated by consistency between studies is an important consideration.

[9] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (revision 1). EFSA Journal,9(5):2170, 36 pp.

- Whether the studies have been carried out in a study group representative of the population group for which the claim is intended. Can the results obtained in the studied population be extrapolated to the target population? For studies in groups (e.g. subjects with a disease) other than the target group for a claim (e.g. the general population), the NDA Panel considers on a case-by-case basis the extent to which it is established that extrapolation from the study group to the target group is biologically plausible.

- Whether the studies used (an) appropriate outcome measure(s) of the claimed effect. For this, the NDA Panel considers what is generally accepted in the relevant research fields (e.g. guidelines published by scientific societies based on rigorous methodological approaches), and consults experts from various disciplines, as appropriate.

3. Claims on physical performance

Physical performance relates to the ability to complete certain physical tasks with higher intensity, faster, or with a higher power output. An improved physical performance may be a beneficial physiological effect for individuals performing physical exercise for different reasons (e.g. athletes preparing for a competition or during a competition, individuals engaged in physical work or recreational activities). Claims should refer to the direct effects of the food on performance.

Information on the characteristics (e.g. type, duration and intensity) of the exercise for which the claim is made may be important for the definition of the claimed effect (e.g. physical performance during short-term, high intensity exercise *vs*. longer-term, endurance performance; single exercise bout *vs*. repetitive bouts) and of the target population for the claim. Outcome measures 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 should be indicated (e.g. time spent to run a certain distance, distance cycled during a time-trial, throwing distance in javelin or shot put, one repetition maximum weight lifted, jumping height). Some of the outcomes proposed (e.g. muscle glycogen stores, maximum oxygen consumption (VO_2max), muscle fatigue, muscle damage and muscle repair) 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 on physical performance.

The studies provided for the scientific substantiation of the claim should reflect the conditions of use for the claim. For example, the moment when the food/constituent is consumed relative to the physical performance may be of importance (e.g. before or during exercise).

4. Claims on endurance capacity

Endurance capacity refers to the exercise time to self reported fatigue when exercising at a constant workload or speed, generally at intensity <80 % VO_2max. An increased endurance capacity may be a beneficial physiological effect for individuals performing physical exercise which is not limited by time (e.g. recreational running, walking, swimming or cycling, fitness training). Claims should refer to the direct effects of the food on endurance capacity.

The particular type of exercise (e.g. cycling, running, swimming) and the conditions (e.g. distance, power output, single *vs.* repeated bouts) in which endurance capacity is tested should be specified. Endurance capacity is measured as the exercise time to self reported fatigue under defined conditions. Some of the outcomes proposed (e.g. muscle glycogen stores, muscle fatigue, muscle damage and muscle repair) are not direct measures of endurance capacity but could be used in support of a mechanism by which the food/constituent could exert the claimed effect.

5. Claims on physiological effects which may lead to an improvement in physical performance or endurance capacity

Claims on specific physiological effects which may lead to an improvement in physical performance have been proposed. These include, for example, reduction in perceived exertion/effort during exercise, increase in muscle strength, or enhancement of water absorption during exercise. Such effects may be considered beneficial depending on the context of the claim, and on the target population for which the claim is intended. Claims should refer to the direct effects of the food.

Outcome measures which may be appropriate for the assessment of the claimed effects in humans should be indicated. For example, validated questionnaires could be used for the assessment of perceived exertion/effort during exercise. For self-reported outcome measures, adequate blinding of subjects is particularly important. Appropriate outcome measures for claims on muscle strength include, for example, one repetition maximum weight lifted, isokinetic knee extension torque and isometric handgrip strength. Some of the outcomes proposed (e.g. lean body mass, muscle mass, muscle fatigue, muscle damage and muscle repair) are not direct measures of muscle strength but could be used in support of a mechanism by which the food/constituent could exert an effect on muscle strength.

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 concentration"[10].

CONCLUSIONS

The draft guidance document focuses on two key issues regarding the substantiation of health claims related to physical performance:

- claimed effects which are considered to be beneficial physiological effects.
- studies/outcome measures which are considered to be appropriate for the substantiation of health claims.

The document has been drawn from scientific opinions of the NDA Panel on health claims related to physical performance. Thus, it represents the views of the NDA Panel based on the experience gained to date with the evaluation of health claims in this area.

[10] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Draft guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations released for public consultation.

GLOSSARY AND ABBREVIATIONS

VO_2max	Maximum oxygen consumption