



EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to beta-alanine and increase in physical performance during short-duration, high-intensity exercise pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to beta-alanine and increase in physical performance during short-duration, high-intensity exercise pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Natural Alternative International, Inc. (NAI), submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of the United Kingdom, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to beta-alanine and increase in physical performance during short-duration, high-intensity exercise. The food constituent that is the subject of the claim is beta-alanine, which is sufficiently characterised. The Panel considers that an increase in physical performance during short-duration, high-intensity exercise is a beneficial physiological effect. In weighing the evidence the Panel took into account that only one out of 11 pertinent human intervention studies (including 14 pertinent outcomes) from which conclusions could be drawn showed an effect of beta-alanine on physical performance during short-duration, high intensity exercise. The Panel concludes that a cause and effect relationship has not been established between the consumption of beta-alanine and an increase in physical performance during short-duration, high intensity exercise.

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KEY WORDS

beta-alanine, carnosine, physical performance, health claims

¹ On request from the Competent Authority of the United Kingdom following an application by Natural Alternative International, Inc. (NAI), Question No EFSA-Q-2013-00974, adopted on 25 June 2014.

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SUMMARY

Following an application from Natural Alternative International, Inc. (NAI), submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of the United Kingdom, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to beta-alanine and increase in physical performance during short-duration, high-intensity exercise.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application includes a request for the protection of proprietary data.

The food constituent that is the subject of the health claim is beta-alanine. The Panel considers that beta-alanine is sufficiently characterised.

The claimed effect proposed by the applicant is “increases performance during short-duration high intensity exercise”. The target population proposed by the applicant is “healthy adults between 19 and 71 years of age involved in intense muscular activity”. The Panel considers that an increase in physical performance during short-duration, high-intensity exercise is a beneficial physiological effect.

The applicant identified four human intervention studies which investigated the effect of beta-alanine on physical performance during short-duration, high-intensity exercise and which also reported on muscle carnosine as being pertinent to the claim. EFSA informed the applicant that all available studies on the effects of beta-alanine on physical performance (claimed effect) which did and did not report on muscle carnosine stores (proposed mechanism for the effect) will be used in the scientific evaluation of the claim. Therefore, 13 additional human studies which claimed to investigate the effect of beta-alanine on physical performance during short-duration, high-intensity exercise were used by EFSA. The Panel notes that eight of these studies assessed measures of physical capacity (e.g. time to exhaustion, and/or total work done during trials with no time limitation and/or physical working capacity at fatigue threshold) and did not include any measures of physical performance. The Panel considers that these eight studies were not pertinent for the scientific substantiation of the claim on physical performance.

The remaining nine publications reported on the results of 11 human intervention studies and included 14 outcomes which were relevant to the claim. Six studies with eight outcomes assessed the effect of beta-alanine on the time spent to run, row, swim or cycle a pre-defined distance. The Panel notes that none of these studies showed an effect of beta-alanine on the time spent to perform different pre-defined physical tasks. Five studies with six outcomes were related to the effect of beta-alanine on power output during a pre-defined time. The Panel notes that beta-alanine did not have a significant effect on mean power output in five out of the six tests which were assessed in these studies. The applicant also provided a meta-analysis which included the four studies which assessed different outcomes related to physical exercise together with muscle carnosine content and which were submitted in the original application for the scientific substantiation of the claim. The Panel notes that the analysis considered only a selection of the studies which were pertinent for the scientific substantiation of the claim. The Panel also notes that outcome measures which were not appropriate for the assessment of a claim on physical performance were included in the analysis. The Panel therefore considers that no conclusions can be drawn from this meta-analysis for the scientific substantiation of the claim.

In weighing the evidence, the Panel took into account that beta-alanine did not have an effect on 13 out of the 14 outcomes (assessed in 11 human intervention studies) from which conclusions could be drawn for the scientific substantiation of a claim on physical performance during short-duration high-intensity exercise.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of beta-alanine and increase in physical performance during short-duration high-intensity exercise.

TABLE OF CONTENTS

Abstract	1
Summary	2
Table of contents	4
Background	5
Terms of reference.....	5
EFSA Disclaimer.....	5
Information provided by the applicant	7
Assessment	7
1. Characterisation of the food constituent.....	7
2. Relevance of the claimed effect to human health.....	7
3. Scientific substantiation of the claimed effect.....	8
3.1. Human intervention studies measuring time	9
3.2. Human intervention studies measuring power output	9
3.3. Pooled analysis	9
Conclusions	10
Documentation provided to EFSA	10
References	10

BACKGROUND

Regulation (EC) No 1924/2006⁴ harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 18/12/2013.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- The scientific evaluation procedure started on 08/01/2014.
- On 06/03/2014, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application, and the clock was stopped on 18/03/2014, in compliance with Art. 18(3) of Regulation (EC) No 1924/2006.
- On 02/04/2014, EFSA received the requested information as submitted by the applicant and the clock was restarted.
- During its meeting on 25/06/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to beta-alanine and increase in physical performance during short-duration high-intensity exercise.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to beta-alanine and increase in physical performance during short-duration high-intensity exercise.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of beta-alanine, a positive assessment of its safety, nor a decision on whether beta-alanine is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

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.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Natural Alternatives International, 1185 Linda Vista Drive, San Marcos, CA 92078, USA.

The application contains a request for the protection of proprietary data for the pooled analysis of four human intervention studies in accordance with Article 21 of Regulation (EC) No 1924/2006.

Food/constituent as stated by the applicant

According to the applicant, the food constituent for which this health claim is made is beta-alanine.

Health relationship as claimed by the applicant

According to the applicant, beta-alanine supplementation increases muscle carnosine stores and the most recent scientific literature indicates at least three plausible mechanisms through which elevations in muscle carnosine could reduce muscle fatigue. In summary these are (i) increasing physico-chemical buffering, (ii) improving calcium sensitivity and/or excitation contraction coupling and (iii) acting as a redox buffer and/or protecting against oxidative damage. The elevation in muscle carnosine could improve muscle contractile performance by simultaneously exerting beneficial effects via all these mechanisms.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wordings for the health claim: "beta-alanine increases performance during short-duration high intensity exercise".

Specific conditions of use as proposed by the applicant

The applicant has proposed a minimum intake of 3.2–5.9 g of beta-alanine per day. The target population proposed is healthy adults between 19 and 71 years of age involved in intense muscular activity.

ASSESSMENT

1. Characterisation of the food constituent

The applicant stated that the food constituent that is the subject of the health claim is beta-alanine, which is a naturally occurring non-essential amino acid in which the amino group is at the β -position from the carboxyl group (with chemical formula $C_3H_7NO_2$). Beta-alanine can be measured in food by established methods.

Information about manufacturing process, stability and batch-to-batch variability has been provided.

The Panel considers that the food constituent, beta-alanine, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is "increases performance during short-duration high-intensity exercise". The target population proposed by the applicant is "healthy adults between 19 and 71 years of age involved in intense muscular activity".

The Panel notes that the claimed effect refers to the increase in physical performance during short-duration, high-intensity exercise.

Physical performance relates to the ability to complete certain physical tasks faster, with higher intensity or higher power output. Measures of physical performance are obtained in the context of

time-limited or task-limited physical activities (e.g. time spent to run a certain distance, maximum distance cycled during a specified time resulting in a higher average power output) (EFSA NDA Panel, 2012).

Physical capacity, on the other hand, refers to the exercise time to fatigue when exercising at a given workload, intensity or speed. Measures of physical capacity (e.g. exercise time to fatigue) are not appropriate outcome measures for the scientific substantiation of claims on physical performance (EFSA NDA Panel, 2012).

The applicant proposed that beta-alanine is a precursor of carnosine, which increases muscle carnosine stores, and that this is the mechanism by which the food constituent may exert the claimed effect.

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

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in Medline, using the search terms “beta-alanine”, “supplementation” and “exercise”. This search revealed a total of 48 publications. A manual selection among those references was then performed to exclude studies in which beta-alanine either was not used as an intervention or was given in combination with other substances, training studies and studies which did not assess muscle carnosine as well as physical performance.

As a result, the applicant identified four human intervention studies which investigated the effect of beta-alanine on physical performance during short-term, high intensity exercise and also reported on muscle carnosine concentrations as being pertinent to the claim (Derave et al., 2007; Hill et al., 2007; Baguet et al., 2010; Del Favero et al., 2012). EFSA informed the applicant that all available scientific evidence is used by EFSA in the scientific evaluation of the claim and therefore all studies on the effects of beta-alanine on physical performance (claimed effect) which did and did not report on muscle carnosine stores (proposed mechanism for the effect) will be used. Therefore, 13 additional human studies which claimed to investigate the effect of beta-alanine on physical performance during short-duration, high-intensity exercise were used by EFSA (Stout et al., 2006, 2007; Zoeller et al., 2006; Hoffman et al., 2008; Van Thienen et al., 2009; Sweeney et al., 2010; Kern and Robinson, 2011; Sale et al., 2011; Smith et al., 2011; Bellinger et al., 2012; Chung et al., 2012; Saunders et al., 2012; Smith-Ryan et al., 2012).

The Panel notes that eight of these studies (Stout et al., 2006, 2007; Zoeller et al., 2006; Hill et al., 2007; Salle et al., 2011; Smith et al., 2011; Del Favero et al., 2012; Smith-Ryan et al., 2012) assessed 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 and did not include any measures of physical performance. The Panel considers that the outcomes from these studies were not appropriate for the scientific substantiation of a claim on physical performance.

The remaining nine publications reported on the results of 11 studies (two publications included two different populations which were randomised and analysed separately) and 16 outcomes. The Panel considers that two of the outcomes evaluated in those studies were not pertinent to the claimed effect (time to exhaustion measured in an isometric test of the static endurance of the knee extensors and during flexed-arm hang at 90°).

A total of 11 randomised, double-blind, placebo-controlled studies (in nine publications) reporting on 14 pertinent outcomes which assessed the effect of beta-alanine on physical performance during short-duration, high-intensity exercise were provided (Derave et al., 2007; Hoffman et al., 2008; Van Thienen et al., 2009; Baguet et al., 2010; Sweeney et al., 2010; Kern and Robinson, 2011; Bellinger et al., 2012; Chung et al., 2012; Saunders et al., 2012). It is unclear whether one study (Saunders et al.,

2012) was blinded. In two studies (Sweeney et al., 2010; Saunders et al., 2012), the description of the randomisation process was unclear.

All studies pertinent to the claimed effect were performed in young adult subjects, and only two studies included females. Studies differed with respect to the number of subjects per study arm (7 to 20 subjects), the type of participants (young subjects in training programmes, non-elite athletes, elite athletes), the type of exercise used for testing (rowing, cycling, running, swimming), the daily dose of beta-alanine consumed (2 to 6.4 g/day) and the duration of the intervention period (4 weeks to 10 weeks). In the majority of the studies the drop-out rate was zero or very low, power calculations were not performed and statistical adjustments for multiple outcome measures were not taken into consideration.

3.1. Human intervention studies measuring time

Six studies assessed the effect of beta-alanine on the time spent to run, row, swim or cycle a pre-defined distance (including eight different outcomes). No effect of beta-alanine on the time spent to row 2 000 metres (Baguet et al., 2010), run 400 metres (Derave et al., 2007), complete three repeated sprints (Hoffman et al., 2008) or run a 300-yard shuttle (Kern and Robinson, 2011), or for elite and non-elite athletes to complete repeated sprints (Saunders et al., 2012), or on the log-transformed performance times during training and competition swimming (Chung et al., 2012), were found.

The Panel notes that beta-alanine did not have a significant effect on the time spent to perform different pre-defined physical tasks in these studies (eight outcomes).

3.2. Human intervention studies measuring power output

Five studies assessed the effect of beta-alanine on power output (including six different outcomes). One study found no effect of beta-alanine on average power output during a single maximal bout of four minutes' cycling (Bellinger et al., 2012). In a similar study, no effect of beta-alanine on mean power during cycling on a cycle ergometer at maximal speed for 60 seconds was reported (Hoffman et al., 2008). Sweeney et al. (2010) found no effect of beta-alanine on mean power output measured during two sets of five-second sprints (running) on a treadmill. In another study, Van Thienen et al. (2009) did not find an effect of beta-alanine on mean power output during a 10-minute cycling trial but showed an effect on mean power output ($p = 0.005$) during a 30-second all-out sprint performed after a 110-minute simulated cycling race. Derave et al. (2007) assessed knee extension torque in an isokinetic test on repeated bouts of maximal exhaustive knee extensions but the differences between intervention and placebo groups were not reported. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that beta-alanine did not have a significant effect on mean power output in five out of the six tests evaluated in these studies.

3.3. Pooled analysis

The applicant also provided pooled analysis which included the four studies which assessed different outcomes related to physical exercise together with muscle carnosine content and which were submitted in the original application for the scientific substantiation of the claim (Derave et al., 2007; Hill et al., 2007; Baguet et al., 2010; Del Favero et al., 2012). The Panel notes that the analysis considered only a selection of the studies which are pertinent for the scientific substantiation of the claim. The Panel also notes that outcome measures (e.g. increase of time to exhaustion during ramped treadmill test, increase in duration when cycling at 110 % of maximum power output) which are not appropriate for the assessment of a claim on physical performance were included in the analysis. The Panel therefore considers that no conclusions can be drawn from this pooled analysis for the scientific substantiation of the claim.

In weighing the evidence, the Panel took into account that beta-alanine did not have an effect on 13 out of the 14 outcomes (assessed in 11 human intervention studies) from which conclusions could be drawn for the scientific substantiation of a claim on physical performance during short-duration, high-intensity exercise.

The Panel concludes that a cause and effect relationship has not been established between the consumption of beta-alanine and increase in physical performance during short-duration, high-intensity exercise.

CONCLUSIONS

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

- The food product, beta-alanine, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is “increases performance during short-duration high-intensity exercise”. The target population as proposed by the applicant is healthy adults between 19 and 71 years of age involved in intense muscular activity. An increase in physical performance during short-duration, high-intensity exercise is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of beta-alanine and increase in physical performance during short-duration, high-intensity exercise.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on beta-alanine and increase in physical performance during short-duration high-intensity exercise pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0404_UK). December 2013. Submitted by Natural Alternatives International.

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