



EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to carbohydrate solutions and maintenance of physical performance during endurance 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 carbohydrate solutions and maintenance of physical performance during endurance 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 the British Specialist Nutrition Association Ltd, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of the United Kingdom, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to carbohydrate solutions and maintenance of physical performance during endurance exercise. The food, which is proposed by the applicant to be the subject of the health claim, is “carbohydrate solutions including sports ‘gels’ (to be consumed with water) which will either be able to maintain endurance performance for longer or improve performance relative to plain water or water/electrolyte placebo”. The Panel notes that, whereas carbohydrate solutions, the food which is the subject of the health claim, and one of the proposed comparators, water, are sufficiently characterised, no specifications have been provided for the other comparator, “water/electrolyte placebo”. Therefore, the Panel considers that a cause and effect relationship between the consumption of carbohydrate solutions and maintenance of physical performance during endurance exercise as compared to “water–electrolyte solutions” cannot be established on the basis of the information provided. Maintenance of physical performance during endurance exercise is a beneficial physiological effect. Three meta-analyses of human intervention studies were provided by the applicant for the scientific substantiation of this health claim. The Panel considers that these meta-analyses cannot be used to substantiate a claim on the effect of carbohydrate solutions on the maintenance of physical performance during endurance exercise as compared to water. The Panel concludes that a cause and effect relationship has not been established between the consumption of carbohydrate solutions and maintenance of physical performance during endurance exercise as compared to water.

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KEY WORDS

carbohydrate solutions, performance, endurance exercise, health claims

¹ On request from the Competent Authority of the United Kingdom following an application by the British Specialist Nutrition Association Ltd, Question No EFSA-Q-2014-00058, adopted on 18 September 2014.

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SUMMARY

Following an application from the British Specialist Nutrition Association Ltd, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of the United Kingdom, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to carbohydrate solutions and maintenance of physical performance during endurance exercise.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.

The food, which is proposed by the applicant to be the subject of the health claim, is “carbohydrate solutions including sports ‘gels’ (to be consumed with water) which will either be able to maintain endurance performance for longer or improve performance relative to plain water or water/electrolyte placebo”. The Panel notes that, whereas carbohydrate solutions, the food which is the subject of the health claim, and one the proposed comparators, water, are sufficiently characterised, no specifications have been provided for the other comparator, “water/electrolyte placebo”. Therefore, the Panel considers that a cause and effect relationship between the consumption of carbohydrate solutions and maintenance of physical performance during endurance exercise as compared to “water–electrolyte solutions” cannot be established on the basis of the information provided.

The claimed effect proposed by the applicant is “contribute to the maintenance of endurance performance during prolonged endurance exercise”. The target population proposed by the applicant is “active, trained or highly trained adult sports participants engaged in endurance exercise of one hour duration or longer”. The Panel considers that maintenance of physical performance during endurance exercise is a beneficial physiological effect.

For the scientific substantiation of an effect of carbohydrate solutions on the maintenance of physical performance during endurance exercise as compared to water or to “water/electrolyte solutions”, the applicant provided three meta-analyses of human intervention studies.

The Panel notes that no information was provided by the applicant on how the products investigated in the human intervention studies, which were included in the meta-analyses, related to the food that is the subject of the claim and to the food that is proposed as comparator. The Panel considers that the three meta-analyses provided by the applicant cannot be used to substantiate a claim on the effect of carbohydrate solutions on the maintenance of physical performance during endurance exercise as compared to water.

The Panel concludes that a cause and effect relationship has not been established between the consumption of carbohydrate solutions and maintenance of physical performance during endurance exercise as compared to water.

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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 24/01/2014.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- On 14/02/2014, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 12/03/2014, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 18/03/2014.
- On 06/05/2014, 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. The clock was stopped on 19/05/2014, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 03/06/2014, EFSA received the requested information and the clock was restarted.
- During its meeting on 18/09/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to carbohydrate solutions and maintenance of physical performance during endurance 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: carbohydrate solutions and maintenance of physical performance during endurance exercise.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of carbohydrate solutions, a positive assessment of its safety, nor a decision on whether carbohydrate solutions 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: British Specialist Nutrition Association Ltd, 6 Catherine Street, London WC2B 5JJ, UK.

Food/constituent as stated by the applicant

According to the applicant, the food for which the health claim is made is solutions containing 50 to 80 g/L of carbohydrates including sports "gels" (to be consumed with water) containing 20–70 g/100 g of carbohydrates that induce a high glycaemic response, for example glucose, glucose polymers and sucrose. Sports "gels" are viscous, concentrated carbohydrate solutions that have been thickened with ingredients such as xanthan gum, carboxymethylcellulose or similar.

Health relationship as claimed by the applicant

According to the applicant, when the specified carbohydrate solution including sports gels (to be consumed with water) is consumed at a rate to provide from 30 to 80 g carbohydrate per hour, active individuals engaged in endurance exercise of at least one hour's duration will either be able to maintain their endurance performance for longer or improve their performance in a time trial (with or without a preload), relative to plain water or water/electrolyte placebo.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "carbohydrate solutions contribute to the maintenance of endurance performance during prolonged endurance exercise".

Specific conditions of use as proposed by the applicant

The target population proposed by the applicant is active, trained or highly trained adult sports participants engaged in endurance exercise of one hour's duration or longer.

The applicant has proposed that sufficient solution to provide at least 30 g of carbohydrate per hour should be consumed to achieve the claimed effect. This may be achieved by consuming a suitable quantity of a 5–8 % carbohydrate solution or by consuming a suitable quantity of a sports carbohydrate gel with sufficient water so as to deliver a comparable concentration of carbohydrate, when consumed as per the manufacturer's instructions. Consumption should be by means of frequent ingestion of portions (boluses) on a timely basis, for example every 20 to 30 minutes. A recommended consumption pattern is to ingest a portion up to 20 minutes prior to exercise (optional) and to repeat at the commencement of exercise and every 20 to 30 minutes during exercise. Consumption of 250 mL of a 5–8 % carbohydrate solution every 20 minutes is readily achievable by the target population. By means of example, 750 mL of a 6 % solution ingested in 250 mL boluses every 20 minutes will provide 45 g carbohydrate per hour on average. The same dose of carbohydrate at an effective concentration may be achieved by ingesting one portion of gel (approximately 60 g) containing 22.5 g carbohydrate with 250 mL water every 30 minutes.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is "solutions containing 50 to 80 g/L of carbohydrates including sports 'gels' (to be consumed with water) containing 20–70 g/100 g of carbohydrates that induce a high glycaemic response, for example glucose, glucose polymers and sucrose".

The Panel noted that a health claim on carbohydrate–electrolyte solutions and maintenance of endurance performance during prolonged endurance exercise had already been assessed by the NDA Panel with a favourable outcome (EFSA NDA Panel, 2011) and was authorised (Commission Regulation (EU) No 432/2012). The target population is active individuals performing endurance exercise. The conclusion of the Panel was based on general consensus about the role of beverages containing carbohydrates and electrolytes (in particular sodium) in maintaining performance during prolonged endurance exercise through the maintenance of fluid and electrolyte balance and the provision of carbohydrates to skeletal muscle as a source of energy, relative to plain water (EFSA NDA Panel, 2011, 2013). The conditions of use of that claim specify the type and content of carbohydrates, the content of sodium and the osmolality of beverages (i.e. carbohydrate–electrolyte solutions) in order to bear the claim.

Upon a request by EFSA for clarification on whether the claim submitted could be covered by the health claim already authorised on carbohydrate–electrolyte solutions, the applicant indicated that the food constituent that is the subject of this claim is carbohydrate solutions that do not include electrolytes. The applicant specified that carbohydrate solutions contain 50–80 g/L (or 200–320 kcal/L) of carbohydrates that induce high glycaemic responses (e.g. glucose, glucose polymers, sucrose) and include sports “gels” (to be consumed with water) containing 20–70 g of carbohydrates/100 g. The applicant indicated that a portion (approximately 60 g) of sports “gels” containing about 22.5 g of carbohydrate should be consumed with 250 mL of water.

In the submitted application, the applicant indicated that “carbohydrate solutions including sports ‘gels’ (to be consumed with water) will either be able to maintain endurance performance for longer or improve performance relative to plain water or water/electrolyte placebo”. Considering the important role of water and electrolytes in addition to carbohydrates in maintaining endurance performance (SCF, 2001; Rodriguez et al., 2009; EFSA NDA Panel, 2011), the applicant was requested by EFSA to also characterise the comparator. The Panel notes that the applicant did not provide any information on the comparator “water/electrolyte placebo”.

The Panel notes that, whereas “carbohydrate solutions”, the food which is the subject of the health claim, and the comparator “plain water” are sufficiently characterised, no specifications have been provided for the comparator “water/electrolyte placebo”. Therefore, the Panel considers that a cause and effect relationship between the consumption of carbohydrate solutions and maintenance of physical performance during endurance exercise as compared to “water/electrolyte solutions” cannot be established on the basis of the information provided.

The Panel considers that carbohydrate solutions, the food which is the subject of the health claim, and one of the proposed comparators, water, are sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is “contribute to the maintenance of endurance performance during prolonged endurance exercise”. The target population proposed by the applicant is “active, trained or highly trained adult sports participants engaged in endurance exercise of one hour duration or longer”.

The Panel notes that the claimed effect refers to the maintenance of physical performance during endurance exercise (one hour’s duration or longer).

Physical performance relates to the ability to complete certain physical tasks with higher intensity, faster, or with a 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, maximal distance cycled during a specified time resulting in a higher average power output).

Endurance capacity refers to the exercise time to fatigue when exercising at a given workload or speed. Measures of endurance 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 Panel considers that maintenance of physical performance during endurance exercise is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a preliminary literature search in PubMed using the search terms “(carbohydrate OR sugar OR sucrose OR glucose OR glucose polymer OR maltodextrin OR maltose) AND (performance OR endurance OR exercise OR running OR cycling OR sport OR athletic)”. Given the large number of publications retrieved with this preliminary search, a restricted literature search was performed to focus on articles published in the last five years, and related to carbohydrate and endurance performance exercise, using the following search terms: “((((carbohydrate[Title]) AND (endurance OR exercise OR performance[Title])) NOT (intermittent OR intermittent-exercise[Title])) NOT (training OR skill OR recovery[Title])) NOT (mouth rinse OR mouth rinsing[Title])”.

For the scientific substantiation of an effect of carbohydrate solutions on the maintenance of physical performance during endurance exercise as compared to water or to “water/electrolyte solutions”, the applicant provided three meta-analyses of human intervention studies (Karelis et al., 2010; Temesi et al., 2011; Vandenberghe and Hopkins, 2011).

The Panel noted that the 195 human intervention studies that were included in these three meta-analyses, and which were not provided by the applicant, used “carbohydrate solutions” or “carbohydrate–electrolyte solutions” with or without added protein as the intervention and either unspecified placebos or “water–electrolyte solutions” as the comparator. However, the characterisation of the intervention(s) and the comparator(s) used in each study in relation to the claimed effect was unclear in the meta-analyses. Therefore, during the scientific evaluation, the applicant was requested by EFSA to clarify how the products investigated in these studies related to the food that is the subject of the claim and to the food that is proposed as comparator. The Panel notes that no information was provided by the applicant on this point. The Panel considers that the three meta-analyses provided by the applicant cannot be used to substantiate a claim on the effect of carbohydrate solutions on the maintenance of physical performance during endurance exercise as compared to water.

The Panel concludes that a cause and effect relationship has not been established between the consumption of carbohydrate solutions and maintenance of physical performance during endurance exercise as compared to water.

CONCLUSIONS

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

- Carbohydrate solutions, the food which is the subject of the health claim, and one of the proposed comparators, water, are sufficiently characterised, whereas the other comparator, “water–electrolyte solutions”, is not sufficiently characterised. A cause and effect relationship between the consumption of carbohydrate solutions and maintenance of physical performance during endurance exercise as compared to “water–electrolyte solutions” cannot be established.
- The claimed effect proposed by the applicant is “contribute to the maintenance of endurance performance during prolonged endurance exercise”. The target population proposed by the applicant is “active, trained or highly trained adult sports participants engaged in endurance exercise of one hour duration or longer”. Maintenance of physical performance during endurance exercise is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of carbohydrate solutions and maintenance of physical performance during endurance exercise as compared to water.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on carbohydrate solutions and maintenance of physical performance during endurance exercise pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0408_UK). January 2014. Submitted by the British Specialist Nutrition Association Ltd.

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