

# Carbohydrate solutions and contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise: evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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# **SCIENTIFIC OPINION**



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# Carbohydrate solutions and contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise: evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), Dominique Turck, Jean-Louis Bresson, Barbara Burlingame, Tara Dean, Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Kristina Pentieva, Yolanda Sanz, Anders Sjödin, Martin Stern, Daniel Tomé, Henk Van Loveren, Marco Vinceti, Peter Willatts, Ambroise Martin, Sean (JJ) Strain and Alfonso Siani

# Abstract

Following an application from Specialised Nutrition Europe (SNE), submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, 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 contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise. The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The food proposed by the applicant as the subject of the health claim is carbohydrate solutions containing glucose, mixtures of glucose and fructose, sucrose and/or maltodextrins. The Panel considers that carbohydrate solutions are sufficiently characterised in relation to the claimed effect. The claimed effect proposed by the applicant is 'contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise', which is considered by the Panel as a beneficial physiological effect. The Panel concludes that a cause and effect relationship has been established between the consumption of carbohydrate solutions and the improvement of physical performance during high-intensity and long-lasting physical exercise. The target population is healthy trained adults performing high-intensity (at least at 65% of the  $VO_{2max}$ ) and long-lasting (at least 60 min) physical exercise.

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**Keywords:** carbohydrate solutions, physical performance, trained adults, endurance exercise, health claim

**Requestor:** Competent Authority of France following an application by Specialised Nutrition Europe (SNE)

Question number: EFSA-Q-2017-00621

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# Summary

Following an application from Specialised Nutrition Europe (SNE), submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, 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 (CHO) solutions and contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise.

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

The general approach of the NDA Panel for the evaluation of health claims applications is outlined in the EFSA general guidance for stakeholders on health claim applications and the guidance on the scientific requirements for health claims related physical performance.

The food proposed by the applicant as the subject of the health claim is CHO solutions. The Panel considers that CHO solutions (containing glucose, mixtures of glucose and fructose, sucrose and/or maltodextrins), which are the subject of the health claim, are sufficiently characterised in relation to the claimed effect.

The claimed effect proposed by the applicant is 'contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise'. The proposed target population is 'healthy physically active, trained or well-trained adults (male and female) engaged in a high-intensity exercise lasting more than one hour'. The applicant defines high-intensity and long-lasting physical exercises being performed at least at 65% of the VO<sub>2max</sub>, at maximal effort, or during a time trial test for at least 60 min. The Panel considers that contribution to the improvement of physical performance during a high-intensity and long-lasting physical exercise is a beneficial physiological effect.

A total of 14 human intervention studies investigating the effect of CHO solutions on physical performance were provided by the applicant. Among these, five were conducted in non-fasting conditions after a standardised meal and seven were conducted after an overnight fast. In the remaining two studies, the nutritional conditions before the test were not sufficiently specified.

The Panel considers that human intervention studies investigating the effects of CHO solutions compared to water, or the effects of CHO–electrolyte solutions compared to water/electrolyte-matched solutions, on physical performance could provide evidence for the substantiation of the claim proposed by the applicant on CHO solutions. The Panel also considers that no conclusions can be drawn from three of the studies provided for the scientific substantiation of the claim owing to the lack of control for the electrolytes present in the test beverages.

In weighing the evidence, the Panel took into account that the consumption of CHO solutions providing about 30–60 g CHO/h, and up to about 90 g CHO/h when about one-third of the CHO were in the form of fructose, during high-intensity exercise and long duration physical exercise consistently improved physical performance in four studies conducted in non-fasting conditions with standardised feeding protocols before the trial sessions. The Panel also took into account that the effect is supported by four studies conducted in fasting conditions and by two studies in which the nutritional status of participants before the test was not sufficiently specified. In addition, the Panel considered that the mechanisms by which the consumption of CHO solutions during high-intensity and long-lasting physical exercise could exert the claimed effect are well established.

The Panel concludes that a cause and effect relationship has been established between the consumption of CHO solutions and the improvement of physical performance during high-intensity and long-lasting physical exercise.

The following wording reflects the scientific evidence: 'Carbohydrate solutions can contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise in healthy trained adults'.

In order to obtain the claimed effect, CHO solutions (containing glucose, mixtures of glucose and fructose, sucrose and/or maltodextrins) should be consumed to provide between 30 and 60 g of CHO/h, and up to 90 g CHO/h if fructose constitutes about one-third of the CHO mixture. The target population is healthy trained adults performing high-intensity (at least at 65% of the  $VO_{2max}$ ) and long-lasting (at least 60 min) physical exercise.



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# 1. Introduction

# **1.1.** Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1924/2006<sup>1</sup> 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).

### **1.2.** Interpretation of the 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 contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise.

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of carbohydrate solutions, a positive assessment of their safety, nor a decision on whether carbohydrate solutions are, or are 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.

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.

# 2. Data and methodologies

#### 2.1. Data

#### Information provided by the applicant

#### Food/constituent as stated by the applicant

According to the applicant, the food for which the health claim is made is 'glycaemic carbohydrates. Glycaemic carbohydrates can be classified, according to their degree of polymerisation, as simple (monosaccharides and disaccharides) or complex (oligosaccharides and polysaccharides). Glycaemic carbohydrates are digested and absorbed in the human small intestine, and provide glucose to body cells as a source of energy'.

#### Health relationship as claimed by the applicant

According to the applicant, the claimed effect relates to: 'Physical performance relates to the ability to complete certain physical tasks with higher intensity, faster, or with a higher power output. According to the EFSA, improvement of physical performance may be a beneficial physiological effect for individuals performing physical exercise, either athletes preparing for a competition or during a competition, or individuals engaged in physical work or recreational activities, especially during a high-intensity (performed at a minimal of 65% of the VO<sub>2 max</sub> of the subjects, or at maximal effort, or during time trial test) and long-lasting (longer than one hour) physical exercise. The outcome variables of physical performance used to assess the claimed effect are time spent to run or cycle a certain distance or distance cycled or run during a certain time, which are considered as appropriate outcome measures by the EFSA. The methods of measurement are adequate methods to easily measure time or a distance: chronometer or distance-measuring equipment'.

<sup>&</sup>lt;sup>1</sup> 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.

11/10/12/24]. See the Terms and Conditions (https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5191 by Cochrane France, Wiley Online Library on [11/01/12/24]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5191 by Cochrane France, Wiley Online Library on [11/01/12/24]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons Licensee

# Mechanism by which the food/constituent could exert the claimed effect as proposed by the applicant

The applicant claims that 'There are several mechanisms by which CHO feeding during physical exercise may improve physical performance. These include 1/maintaining blood glucose and high levels of CHO oxidation, 2/sparing endogenous glycogen, 3/synthesizing glycogen during low-intensity exercise, or 4/a central effect of CHO. The mechanisms may be different for relatively short-duration ( $\approx 1$  h) high-intensity exercise (80–85% of VO<sub>2max</sub>) than for long-duration (> 2 h) low- to moderate-intensity exercise (60–75% of VO<sub>2max</sub>)'.

#### Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: 'Glycaemic carbohydrate intake during a high-intensity and long-lasting physical exercise contributes to the improvement of physical performance'.

#### Specific conditions of use as proposed by the applicant

According to the applicant, the target population for the intended health claim are healthy physically active, trained or well-trained adults (male and female) engaged in a high-intensity exercise lasting more than one hour. The doses of glycaemic carbohydrates consumed during a high-intensity and long-lasting physical exercise to achieve a significant effect are 24–72 g/h of single glycaemic carbohydrate and up to 100 g/h for a mixture of fructose (30 g/h) with another glycaemic carbohydrates containing glucose (e.g. maltodextrin, starch or glucose) (24–72 g/h). The glycaemic carbohydrates are intended to be consumed at regular intervals during a high-intensity and long-lasting physical exercise. A recommended consumption pattern is to ingest a portion just before exercise (optional) and to ingest the glycaemic carbohydrates every 15–20 min during exercise.

#### Data provided by the applicant

Health claim application on glycaemic carbohydrates and contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise pursuant to Article 13.5 of Regulation 1924/2006, presented in a common and structured format as outlined in the Scientific and technical guidance for the preparation and presentation of applications for authorisation of health claims.<sup>2</sup>

As outlined in the General guidance for stakeholders on health claim applications,<sup>3</sup> it is the responsibility of the applicant to provide the totality of the available evidence.

# 2.2. Methodologies

The general approach of the NDA Panel for the evaluation of health claims applications is outlined in the EFSA general guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016).

The scientific requirements for health claims related to endurance performance are outlined in a specific EFSA guidance on health claims on physical performance (EFSA NDA Panel, 2012).

The application does not contain data claimed as proprietary and confidential.

# 3. Assessment

# 3.1. Characterisation of the food/constituent

The food/constituent proposed by the applicant as the subject of the health claim is 'glycaemic carbohydrates'.

Glycaemic carbohydrates provide carbohydrate, mainly in the form of glucose, to body cells. The main glycaemic carbohydrates are glucose and fructose (monosaccharides), sucrose and lactose (disaccharides), as well as malto-oligosaccharides and starch (polysaccharides) (FAO/WHO, 1998; EFSA NDA Panel, 2010).

Upon a request from EFSA, the applicant clarified that the human intervention studies provided for the substantiation of the claim had tested the effects of sugars (glucose, mixtures of glucose and fructose, sucrose) and maltodextrins in liquid form, and therefore the food/constituent for which the

<sup>&</sup>lt;sup>2</sup> EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (revision 1). EFSA Journal 2011;9(5):2170, 36 pp. https://doi.org/10.2903/j.efsa.2011.2170

<sup>&</sup>lt;sup>3</sup> EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016. General scientific guidance for stakeholders on health claim applications. EFSA Journal 2016;14(1):4367, 38 pp. https://doi.org/10.2903/j.efsa.2016.4367

claim is requested are the glycaemic carbohydrates glucose, mixtures of glucose and fructose, sucrose and maltodextrins in liquid form.

The Panel considers that carbohydrate (CHO) solutions (containing glucose, mixtures of glucose and fructose, sucrose and/or maltodextrins), which are the subject of the health claim, are sufficiently characterised in relation to the claimed effect.

#### **3.2.** Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is 'improvement of physical performance during a high-intensity and long-lasting physical exercise'. The proposed target population are 'healthy physically active, trained or well-trained adults (male and female) engaged in a high-intensity exercise lasting more than one hour'.

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).

The applicant defines high-intensity and long-lasting physical exercises being performed at least at 65% of the  $VO_{2max}$ , at maximal effort, or during a time trial test for at least 60 min.

The Panel considers that contribution to the improvement of physical performance during a highintensity and long-lasting physical exercise is a beneficial physiological effect.

#### 3.3. Scientific substantiation of the claimed effect

A health claim on carbohydrate–electrolyte solutions and maintenance of endurance performance pursuant to Article 13(1) of Regulation (EC) No 1924/2006 was assessed by the Panel with a positive outcome (EFSA NDA Panel, 2011a,b). In order to bear the claim, carbohydrate–electrolyte solutions should contain 80–350 kcal/L from carbohydrates, and at least 75% of the energy should be derived from carbohydrates which induce a high glycaemic response, such as glucose, glucose polymers and sucrose. In addition, these beverages should contain between 20 mmol/L (460 mg/L) and 50 mmol/L (1,150 mg/L) of sodium, and have an osmolality between 200 and 330 mOsm/kg water. The target population was active individuals performing endurance exercise.

The Panel also evaluated a health claim related to CHO solutions and maintenance of physical performance during endurance exercise pursuant to Article 13(5) of Regulation (EC) No 1924/2006 with a negative outcome because the characterisation of the intervention(s) and the comparator(s) used in each study submitted for the substantiation of the claim was unclear (EFSA NDA Panel, 2014).

The applicant performed a literature search in Medline and CAB Abstracts databases with the following key words: physical activity/or exercise/or sport/or sports/or athletics/or ball games/or bicycling/or combative sports/or competitive sports/or gymnastics/or winter sports/or physical fitness/or (sport\* or "physical activity" or "physical activities" or exercise\* or running\* or walking\* or cycling\* or bicycling\*) AND sport performance/or athletic performance/or performance AND carbohydrate loading/or carbohydrates/ad or sugars/ad or dietary carbohydrates/or dietary carbohydrate/or maltodextrins/or sucrose/ad or Dietary Sucrose/ad or oligosaccharides/ad or glucose/ad or monosaccharides/ad or polysaccharides/ad or fructose/ ad or (CHO or carbohydrate\* or glucose or fructose or sucrose or monosaccharide\* or oligosaccharide\* or maltodextrin\* or sugar\*) AND (supplementation or consumption or administration or ingestion or ingesting or intake or receiving or dose\* or dosage) NOT mouth rins\*. The literature search was limited to articles published from the year 2000.

The applicant identified 10 published human intervention studies as being pertinent to the claim. The majority of the human intervention studies provided, however, was conducted after an overnight fast, a condition under which high-intensity and long-lasting physical exercise is generally not undertaken. Upon a request from EFSA, the applicant performed an additional literature search and provided four additional human intervention studies published before 2000.

A total of 14 human intervention studies investigating the effect of CHO solutions on physical performance were provided by the applicant. Among these, five were conducted in non-fasting conditions after a standardised meal (Mitchell et al., 1988, 1989; Langenfeld et al., 1994; Desbrow et al., 2004; Baur et al., 2014) and seven were conducted after an overnight fast (Campbell et al., 2001; Currell and Jeukendruop, 2008; Siahkohian et al., 2008; Currell and Robson-Ansley et al., 2009; Smith et al., 2010; Roberts et al., 2014; Newell et al., 2015). In the remaining two studies, the nutritional conditions before the test were not sufficiently specified (El-Sayed et al., 1995; MacLaren and Close, 2000).

The Panel considers that human intervention studies investigating the effects of CHO solutions compared to water, or the effects of CHO–electrolyte solutions compared to water/electrolyte-matched solutions, on physical performance could provide evidence for the substantiation of the claim proposed by the applicant on CHO solutions as characterised in Section 3.1.

Two of the seven studies provided conducted after an overnight fast (Roberts et al., 2014; Newell et al., 2015) investigated the effects of CHO–electrolyte solutions (containing about 370–800 mg/L of sodium) on physical performance against a water placebo with no sodium. The Panel notes that CHO– electrolyte solutions containing between 20 mmol/L (460 mg/L) and 50 mmol/L (1,150 mg/L) of sodium have shown to be effective in maintaining endurance performance compared to plain water, and that sodium plays a major role in maintaining fluid and electrolyte balance during prolonged exercise (EFSA NDA Panel, 2011a). In this context, the Panel notes that plain water is not an appropriate control to investigate the effect of CHO in CHO–electrolyte solutions on performance, and therefore considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

One of the five studies conducted in non-fasting conditions after a standardised meal (Desbrow et al., 2004) evaluated the effect of a CHO–electrolyte solution (Gatorade<sup>®</sup>, Quaker Oats, 6% CHO) vs an artificially sweetened placebo on a time-trial cycling performance. The Panel notes that the precise CHO mixture in the 6% CHO solution was not reported. The Panel also notes that the electrolytes present in the 6% CHO solution were not controlled for in the placebo beverage. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

It is well established that the limiting step in the oxidation of exogenous carbohydrates ingested during exercise is their absorption in the small intestine. Glucose (consumed as such or as glucose polymers, such as maltodextrins) is absorbed via a sodium-dependent transporter (SGLT1), which becomes saturated at a carbohydrate intake of around 60 g/h, whereas fructose is absorbed by facilitated diffusion (GLUT5). Unabsorbed glucose in the small intestine may lead to gastrointestinal symptoms and impair water absorption during exercise. The Panel notes that, in some of the remaining studies submitted for the substantiation of the claim (n = 11), glucose was provided in CHO solutions at a rate (about 90 g/h or more) which exceeded the absorption capacity of the small intestine, and that this is outside the conditions of use proposed by the applicant.

#### Human intervention studies conducted in non-fasting conditions after a standardised meal

Four human intervention studies investigated the effect of CHO solutions on endurance performance in non-fasting conditions after a standardised meal (Mitchell et al., 1988, 1989; Langenfeld et al., 1994; Baur et al., 2014).

Mitchell et al. (1988) tested the effect of three CHO solutions (containing 5%, 6% and 7.5% of carbohydrates) against a water placebo on gastric emptying and physical performance in a randomised, four-period, single-blind, cross-over study.

The 5% CHO solution contained 2.7 g of maltrin and 2.3 g of glucose per 100 mL, whereas the 6% CHO solution contained 2.14 g of maltrin, 1.88 g of fructose and 1.95 g of sucrose per 100 mL and the 7.5% CHO solution had 5.5 g of maltrin and 2 g of glucose per 100 mL. The doses of CHO tested were 33.5, 39.4 and 50.1 g/h, respectively.

Eight trained male cyclists (mean age  $21.5 \pm 0.67$  years, VO<sub>2max</sub>  $4.7 \pm 0.13$  L) performed four trials of 8 intermittent bouts at 70% VO<sub>2max</sub> lasting 12 min each with a 3-min rest between each bout. During the final 12-min self-paced maximal ride, total work output was assessed. The total duration of performance was 108 min. The day before each trial, subjects consumed a standard mixed meal containing 3,000 kcal and 400 g of CHO. The day of the test, subjects consumed a standard breakfast providing 740 kcal and 116 g of CHO 4–6 h before the trial. The test solutions were consumed at a rate of 8.5 mL/kg per h prior to each 12-min bout (mean total 1,336 mL/2 h).

All data were analysed using a two-way analysis of variance (ANOVA) for repeated measures. The totalwork output in the final 12-min self-paced maximal ride was significantly higher in all three CHO trials compared to the water placebo trial (5% CHO =  $1.98 \pm 0.09 \times 10^5$  Nm; 6% CHO =  $1.96 \pm 0.09\% \times 10^5$  Nm; 7.5% CHO =  $2.05 \pm 0.13 \times 10^5$  Nm; water =  $1.83 \pm 0.11 \times 10^5$  Nm, p < 0.05 for all three CHO trials against the water placebo trial).

The Panel considers that this study shows an effect of CHO solutions (containing mixtures of maltodextrins with either glucose or fructose at 5%, 6% and 7% and providing from 33.5, 39.4 and 50 g of CHO/h) on physical performance during a high-intensity physical exercise lasting about 108 min.

In another study with a similar design, the same authors (Mitchell et al., 1989) tested the effect of three CHO solutions (containing 6%, 12% and 18% of CHO) against a water placebo on physical performance and muscle glycogen utilisation.

The 6% CHO solution contained 4 g of a glucose polymer (dextrose equivalent = 20) and 2 g of sucrose per 100 mL, whereas the 12% CHO solution contained 8.5 g of the same glucose polymer and 3.5 g of fructose per 100 mL and the 18% CHO solution had 14.5 g of the glucose polymer and 3.5 g of fructose per 100 mL. The doses of CHO tested were 37.1, 74.1 and 111.2 g/h, respectively. A total of 10 trained male cyclists (mean age  $24.2 \pm 1.9$  years, mean VO<sub>2max</sub> =  $4.45 \pm 0.16$  L) were enrolled in this randomised, five-period, single-blind, cross-over study. The CHO solutions and the water placebo were tested in 4 continuous trials where the first 105 min were at 70% of VO<sub>2max</sub> and the final 15 min were an all-out performance ride on an isokinetic cycle ergometer to measure total work output. The 12% CHO solution was also tested in an intermittent trial, in which seven 15-min rides at 70% VO<sub>2max</sub> with 3-min rest periods between each ride were used, followed by a 15-min all-out performance ride. During the first 105 min, the participants consumed 8.5 mL/kg per h (~ 150 mL) every 15 min of one of the tested beverages. As in the previous study, subjects consumed a standard mixed meal containing about 3,000 kcal (55% CHO, 30% fat, 15% protein) the day before each trial. A liquid pretest meal (225 mL, 360 kcal, 48 g CHO) was ingested 3 h before each exercise trial. Trials were separated by 1 week.

All data were analysed using a two-way ANOVA for repeated measures. The subjects performed significantly more work in both trials (continuous and intermittent) with the 12% CHO solution than in the trial with water placebo ( $2.28 \pm 0.12$  and  $2.22 \pm 0.15$  vs  $2.01 \pm 0.15$  Nm x  $10^5$ ; p < 0.05 for both comparisons). Total work output was not significantly different between the trials with the 6% or the 18% CHO solutions and the water placebo trial.

The Panel notes that the improvement in performance was shown with the 12% CHO solution providing about 74 g of CHO per hour, either under intermittent or continuous exercise, but not with the 6% or 18% CHO solutions under continuous exercise. The authors argue that the nature of the exercise (continuous vs intermittent) does not explain the different results obtained in the previous study (Mitchell et al., 1988) with 5% and 6% CHO solutions, but rather the fact that these lower doses of CHO may be borderline to obtain significant benefits on performance. The authors also explain that the lack of effect on performance of the 18% CHO solution may be due to impaired fluid delivery associated with gastric emptying. The Panel agrees with the explanations given by the authors and notes that, during the administration of the 18% CHO solution, the dose of glucose (about 90 g/h) exceeded the absorption capacity of the intestine.

The Panel considers that this study shows an effect of a CHO solution (containing a mixture of glucose polymers and fructose at 12% and providing about 74 g of CHO/h) on physical performance during high-intensity and long-lasting physical exercise, either intermittent or continuous. The Panel also considers that CHO solutions at higher (18%, providing about 111 g of CHO/h) or lower (6%, providing about 37 g of CHO/h) concentrations did not show an effect on performance during a high-intensity physical exercise lasting about 120 min.

Langenfeld et al. (1994) studied the effect of a 7% CHO–electrolyte solution (5% maltodextrin and 2% fructose) vs an identical electrolyte solution without CHO (placebo) on physical performance and blood biochemistry in a two-period, randomised, double-blind, cross-over trial.

Fourteen trained cyclists (mean age 20.6  $\pm$  2.5 years, mean VO<sub>2max</sub> 55.9  $\pm$  4.7 mL/kg per minute) were included. For two days before each trial, subjects consumed a standardised diet containing 50% CHO, 35% fat and 15% protein. A standardised pretest meal was given 3–4 h prior to exercise (energy and nutritional composition not reported). Trials were performed the same day of the week, one week separating each trial.

At each trial, participants were requested to cycle 80 miles as fast as possible. Following each 10-mile segment, participants ingested either a non-caloric placebo or the 7% CHO solution within 10 min. The mean intake at each feeding time was 0.25 g CHO/kg body weight (bw), corresponding to about 260 mL and 37 g CHO/h). Statistical analysis was performed by ANOVA with Bonferroni corrections for multiple comparisons. Total mean finishing times were significantly lower with the 7% CHO solution than with placebo (241.0  $\pm$  2.1 min vs 253.2  $\pm$  2.1 min, p < 0.05). Significant differences were also observed for split times at 60 and 70 miles.

The Panel notes that duration of the exercise in this study was very long (about 4 h) and that the intensity (never exceeding 65% of the  $VO_{2max}$ ) was more moderate as compared to other studies.

The Panel considers that this study shows an effect of a CHO solution (a mixture of maltodextrins and fructose at 7% and providing about 37 g of CHO/h) on physical performance during a moderate to high intensity physical exercise lasting about 4 h.

Baur et al. (2014) investigated the effect of three different CHO–electrolyte solutions vs a water– electrolyte solution on performance during a cycling time trial in a randomised, four-period, doubleblind, placebo-controlled cross-over study.

Ten male endurance trained cyclists and triathletes (mean age  $25 \pm 6$  years, VO<sub>2max</sub> > 55 mL/kg per minute) were included. Subjects were asked to record food consumption for 24-h prior each trial, to replicate their food intake for the 24 h preceding the subsequent trial, to consume a meal replacement the night before the trial (providing 20–25% of their estimated energy expenditure) and to consume a standard breakfast 2 h before each trial, providing about 500 kcal.

The experimental trials on cycle ergometer consisted of 120 min of constant-load cycling at 55%  $W_{max}$  (195  $\pm$  6 W), followed by a simulated 30-km time trial with a maximal effort. The whole exercise lasted about 3 h. Trials were separated by 6–14 days. During each trial, subjects consumed a total of 2,250 mL of one of four beverages (600 mL before exercise and 150 mL every 15 min during the constant-load part of the trial and at 7.5, 15 and 22.5 km during the 30-km time trial). The beverages were a 12% glucose-fructose solution (2:1 ratio) and a 12% glucose solution, both providing 95.3 g CHO/h, an 8% glucose solution providing 63.5 g CHO/h, and artificially sweetened water. Each beverage (including the control) also contained 470 mg/L of sodium chloride and 200 mg/L of potassium chloride.

Performance was assessed by the time spent to finish the 30-km time trial and by the mean power output during this trial. Data were analysed by univariate ANOVA. Eight participants completed the study (drop-outs unrelated to the study).

Compared to placebo, the time spent to complete the time trial was significantly shorter (all p < 0.05) and the power output significantly higher for the 8% glucose solution and the 12% glucose-fructose solution (52.9  $\pm$  3.7 min (217  $\pm$  40 W) vs 51.1  $\pm$  2.4 min (237  $\pm$  30 W) and 50.4  $\pm$  2.2 min (244  $\pm$  27 W), respectively, p < 0.05 for all comparisons), but not for the 12% glucose solution, for which time and power output did not differ significantly from placebo. The Panel notes that the ingestion of glucose during the 12% glucose solution trial (95.3 g glucose/h) was likely to exceed the absorption capacity of the intestine.

The Panel considers that this study shows an effect of CHO solutions (containing either glucose at 8% providing 63.5 g CHO/h or mixture of glucose and fructose at 12% providing 95.3 g of CHO/h) on physical performance during a high-intensity physical exercise lasting about 180 min.

The Panel notes that the consumption of CHO solutions during high-intensity exercise (lasting about 1.5 h or more) consistently improved physical performance in the four studies from which conclusions could be drawn that were conducted in non-fasting conditions and used standardised feeding protocols before the trial sessions (Mitchell et al., 1988, 1989; Langenfeld et al., 1994; Baur et al., 2014). The effect was consistently shown in two studies (Mitchell et al., 1989; Baur et al., 2014) for CHO solutions providing about 60 g CHO/h and up to about 90 g CHO/h when about one-third of the CHO were in the form of fructose, whereas solutions providing only glucose at rates of about 90 g/h consistently showed no effect on performance as compared to placebo in these two studies. The effect of CHO solutions providing lower CHO doses (between 33 and 50 g CHO/h) was investigated in three studies (Mitchell et al., 1988, 1989; Langenfeld et al., 1994), two of which showed a significant effect on physical performance (Mitchell et al., 1988; Langenfeld et al., 1994). The Panel also notes that the rate of CHO consumption needed to achieve the claimed effect may depend on the intensity and duration of the exercise performed, as well as on the training status of the subjects and their dependence of CHO as source of energy.

#### Human intervention studies conducted after an overnight fast

Five human intervention studies investigated the effect of CHO solutions on endurance performance after an overnight fast (Campbell et al., 2001; Currell and Jeukendrup, 2008; Siahkohian et al., 2008; Robson-Ansley et al., 2009; Smith et al., 2010).

In two studies (Currell and Jeukendrup, 2008; Siahkohian et al., 2008), the nutritional status of the study subjects prior to the performance test was not specified in the publications. However, the Panel notes that the tests were performed early in the morning, and that blood glucose concentrations at baseline were compatible with the fasted state.

Siahkohian et al. (2008) evaluated the effect of a 5% CHO solution vs a placebo solution (composition not specified) on 200-m sprint performance in a randomised, double-blind, two-arm, parallel study.

A total of 30 young active men participated in the study (n = 15 per group). The trials consisted of a 200-m sprint (pre-test), a 90-min running at 70–80% of maximal heart rate reserve and a 200-m sprint immediately after. Performance was measured as the time spent to complete the 200-m sprint.

During the trials, participants consumed either a 5% CHO solution (sucrose) or the placebo solution. The solutions were given at 10-min intervals throughout the 90-min exercise in a volume of 3 mL/kg bw, corresponding to 1,900–2,100 mL during the whole trial (about 67 g of CHO/h).

Independent t-tests were used to compare 200-m sprint times between groups at baseline and at the end of the trial. The mean time to complete the second 200-m sprint was significantly lower in the group consuming the 5% CHO solution than in the placebo group ( $28.94 \pm 2.64$  s vs  $30.67 \pm 1.95$  s, p = 0.025), with no differences between groups at baseline ( $27.85 \pm 1.57$  s vs  $28.21 \pm 1.94$  s). The Panel notes, however, that baseline values account for about half of the difference observed between groups at the end of the trial and considers that the statistical analysis, which does not take into account baseline values, does not allow drawing conclusions from this study.

The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

In a randomised, placebo-controlled, three-period, cross-over study, Currell and Jeukendrup (2008) compared the effect of two CHO solutions at 14.4% (glucose alone or glucose and fructose at a ratio of 2:1) vs a water placebo on endurance cycling performance. No references to blinding procedures are reported in the publication. The Panel assumes that this was an open-label study.

Eight trained male cyclists (mean age  $32 \pm 7$  years, mean VO<sub>2max</sub>  $64.7 \pm 3.9$  mL/kg per minute, mean W<sub>max</sub>  $364 \pm 31$  W) were recruited for the study. Subjects completed the three experimental trials in a randomised order. Each trial was separated by 7–14 days. Subjects cycled first for 2 h at an intensity of 55% W<sub>max</sub>, with a cycle ergometer set in cadence-independent mode. Then, the cycle ergometer was set to linear mode (workload increases as the pedalling rate increases) and participants were asked to perform a certain amount of work (about 60 min of cycling at 75% W<sub>max</sub>) as fast as possible. During the exercise, the subjects received continuous information about the recorded power output, cadence, and total work completed. The mean power output during the trial, the time to complete the trial work, VO<sub>2</sub>, expiratory exchange ratio (RER), plasma lactate and glucose, heart rate, cadence and rating of perceived exertion (RPE) were measured.

A 600-mL bolus of the beverages was administered before the beginning of exercise, then 150 mL of the beverages were consumed every 15 min throughout the steady-state period and at 25, 50, and 75% of the time trial. The 14.4% CHO solutions were given at a rate of 1.8 g/min. The glucose solution provided 108 g of glucose/h, whereas the glucose/fructose solution provided 72 g of glucose and 36 g of fructose per h.

A two-way repeated measures-ANOVA (RM-ANOVA) was used for the statistical analysis. In case of significant differences being identified, post hoc analysis were undertaken with Tukey's honest significant difference (HSD) test.

The mean power output during the trial was significantly higher for the glucose ( $254 \pm 8$  W) and the glucose/fructose ( $275 \pm 10$  W) solutions than for placebo ( $231 \pm 9$  W; p < 0.05 for both comparisons), whereas the time to complete the target work was significantly lower for the glucose and the glucose/fructose solutions than for placebo. The mean power output during the trial was also significantly higher and the time to complete the target work significantly lower for the glucose/fructose solution as compared to the glucose solution.

The Panel considers that this study shows an effect of CHO solutions (at 14.4%, containing glucose or glucose and fructose at a ratio of 2:1, and providing about 108 g CHO/h) on physical performance during a high-intensity physical exercise lasting about 180 min. The Panel also notes that the 14.4% glucose solution was likely to exceed the absorption capacity of the intestine.

Campbell et al. (2001) studied the effect of a 6% CHO solution vs water on glucose kinetics and physical exercise performance during the follicular and luteal phases of the menstrual cycle in a randomised, double-blind, four-period, cross-over study.

The study was performed in a group of eight healthy, non-smoking, eumenorrheic, endurance-trained women (aged 24  $\pm$  2 years) with VO<sub>2peak</sub>  $\geq$  50 mL/kg per min. Four experiments were conducted over the course of at least two menstrual cycles, during the follicular and luteal phases of the menstrual cycle, with glucose or placebo in a random order. The experiments were performed in the morning in fasting conditions.

Participants cycled for two hours at 70%  $VO_{2peak}$  and then completed a 4 kJ/kg bw time trial as quickly as possible. The subjects were asked to drink 400 mL of a beverage at the start of the exercise and additionally 230 mL every 15 min for the entire steady-state exercise period. Beverages contained a 6% glucose solution providing 55.4 g glucose/hour or flavour-matched water. The measure of performance was the time to complete the time trial.

All statistical comparisons were made using two- or three-way ANOVA. Specific differences were tested with a Newman–Keuls *F*-test.

Consumption of the 6% glucose solution decreased the time taken to perform the time trial by 19% in the follicular phase (19:53  $\pm$  0:52 vs. 24:30  $\pm$  2:07 min: sec) and by 26% in the luteal phase (20:55  $\pm$  0:56 vs. 28:17  $\pm$  3:13 min: sec) compared to the water control (p < 0.05 for both comparisons).

The Panel considers that this study shows an effect of a CHO solution (containing glucose at 6% and providing about 55 g CHO/h) on physical performance in women during a high-intensity physical exercise lasting about 140 min, regardless the menstrual phase.

Robson-Ansley et al. (2009), using a randomised, two-period, placebo-controlled, double-blind, cross-over design, investigated the effect of an 8% CHO solution (maltodextrin) vs a flavoured water placebo on the interleukin-6 (IL-6) response to a 90-min running time trial (primary outcome). Performance was assessed as the distance run in the time trial (secondary outcome).

Seven recreationally trained male runners (mean age  $24 \pm 4$  years) performed two times, each separated by one week, a 90-min self-paced time trials on a treadmill after an overnight fast. The participants consumed a fluid bolus of 8 mL/kg bw followed by 2 mL/kg bw every 20 min throughout the exercise of the 8% CHO solution (providing about 63 g of CHO/h) or the placebo solution in a randomised order. The participants were not aware of the distance completed during the exercise.

RM ANOVA or paired Student's t-test were used in statistical analysis. When significance was identified with the RM-ANOVA, a Tukey–Kramer post hoc test for multiple comparisons was performed to determine the minimum significant difference (MSD). The q-value from each pairwise comparison was compared against the MSD to determine significance.

The distance covered in the 90-min run was significantly greater during the 8% CHO solution trial than during the placebo trial (19.13  $\pm$  1.7 km vs 18.29  $\pm$  1.9 km, p = 0.0022).

The Panel considers that this study shows an effect of a CHO solution (containing maltodextrin at 8% and providing about 63 g CHO/h) on physical performance during a high-intensity physical exercise lasting about 90 min.

Smith et al. (2010) investigated the effect of CHO–electrolyte solutions containing different amounts of glucose (1.5%, 3% and 6%) vs a water-electrolyte solution on endurance performance in a four-period, single-blind (subjects blinded), placebo-controlled, cross-over study.

Twelve trained recreational male cyclists or triathletes (mean age  $31.7 \pm 3.8$  years and VO<sub>2peak</sub>  $55.3 \pm 3.6$  mL/kg per minute) were recruited for the study. Participants completed four exercise trials after an over-night fast, with at least 7 days between trials. Each exercise trial began with a 2-h constant load bicycle ride (average workload  $228 \pm 26$  W or  $77 \pm 5\%$  VO<sub>2peak</sub>). It was followed by a 20-km time trial in which participants were asked to cover the distance as quickly as possible. During the first part of the exercise (2-h ride), participants ingested 2,000 mL (250 mL every 15 min) of one of the four beverages: a water–electrolyte solution (18 mmol/L Na<sup>+</sup>, 3 mmol/L K<sup>+</sup> and 11 mmol/L Cl<sup>-</sup>), or the same water–electrolyte solution with 1.5%, 3% or 6% glucose (providing 0, 15, 30 or 60 g of CHO/h, respectively). The four beverages were similar in flavour and appearance. No fluid was ingested during the 20-km time trial. The total time of the exercise was about 150 min. Mean power output was recorded to assess the effect on performance.

Between-treatment differences were assessed by one-way (dose or time) and two-way (dose  $\times$  time) RM-ANOVA and Duncan's post hoc comparisons, when appropriate.

The consumption of the glucose solutions significantly decreased the time to complete the 20-km time trial (1.5% glucose:  $35.2 \pm 2.8$  min; 3% glucose:  $35.0 \pm 2.6$  min; 6% glucose:  $34.7 \pm 2.1$  min) as compared to placebo ( $36.4 \pm 2.8$  min) and significantly increased the average power output accordingly (placebo =  $210 \pm 36$  W;  $1.5\% = 225 \pm 40$  W, p = 0.014;  $3\% = 227 \pm 40$  W, p = 0.009;  $6\% = 232 \pm 34$  W, p = 0.001), with no significant differences among the different glucose solutions.

The Panel considers that this study shows an effect of CHO solutions (containing glucose at 1.5, 3 and 6% and providing 15, 30 and 60 g CHO/h) on physical performance during a high-intensity physical exercise lasting about 150 min.

The Panel considers that the four studies conducted after an overnight fast from which conclusions can be drawn for the scientific substantiation of the claim (Campbell et al., 2001; Currell and

Jeukendrup, 2008; Robson-Ansley et al., 2009; Smith et al., 2010) support an effect of CHO solutions on physical performance during high-intensity, long-lasting physical exercise. The Panel considers, however, that these studies cannot be used to establish conditions of use for the claim because highintensity and long-lasting physical exercises are generally not undertaken after an overnight fast.

#### Human intervention studies conducted under poorly specified nutritional conditions

Two human intervention studies investigated the effect of CHO solutions on endurance performance under poorly specified nutritional conditions (El-Sayed et al., 1995; MacLaren and Close, 2000).

El-Sayed et al. (1995) investigated the effect of an 8% CHO solution (glucose) vs an artificially sweetened, orange-flavoured, glucose-free placebo on cycling performance in a randomised, placebo-controlled, single-blind (for participants), cross-over study.

Nine male cyclists (mean age 23.8  $\pm$  4.4 years, mean VO<sub>2max</sub> 60.7  $\pm$  2.2 mL/kg per minute) were enrolled. The participants performed two identical 70-min exercise tests separated by 7 days which consisted of cycling at 70% of VO<sub>2max</sub> for 60 min followed by a self-paced maximal ride for 10 min. Subjects were fasted for 4 h before the exercise test. The study beverages were administered at 20, 40 and 60 min of the exercise (3 mL/kg bw), and provided 33.5 g of CHO/h (CHO solution) and 0 g of CHO/h (placebo), respectively.

The statistical analysis was performed using two-way RM-ANOVA. When ANOVA showed a significant difference, the Tukey post hoc test was used to investigate which mean values were significantly different.

The distance covered during the 10-min self-paced maximal ride was significantly higher during the 8% CHO solution test than during the placebo test (results presented in a graph only, the exact numbers not given, p < 0.05).

The Panel considers that this study shows an effect of a CHO solution (containing glucose at 8% and providing about 34 g of CHO/h) on physical performance during a high-intensity physical exercise lasting about 70 min.

MacLaren and Close (2000) investigated the effect of a 6% CHO solution (maltodextrin) on physical performance in rugby referees (n = 8, mean age 28.4  $\pm$  1.5 years and an estimated VO<sub>2max</sub> of 52.2  $\pm$  3.1 mL/kg per min) while undertaking a simulated rugby league game in a placebo controlled, two-period, single-blind (presumably for participants) study. The order in which the study beverages were administered was 'counterbalanced', as reported in the publication, but it is unclear whether subjects were randomised to the two possible sequences.

Subjects were asked to keep their dietary intake constant 24-h prior the test and were tested at the same time of the day (unspecified) after not consuming any foods or drinks (other than water) for at least four hours.

During one trial, 200 mL of orange-flavoured 6% CHO solution (maltodextrin) providing 72 g of CHO/h was ingested at eight time points, while in the other trial a placebo of similar taste was administered. The trials were separated by 1 week. The simulation of a rugby match involved performing four 10-min blocks of shuttle activity. Then, after a 10-min break, three further 10-min blocks of shuttle activity were performed. Timed 15-m sprints took place during each of the 10-min blocks. Finally, a performance test to exhaustion involving 20-m shuttles at paces varying between 55% and 95% of a predetermined VO<sub>2max</sub> was undertaken. Fatigue was deemed to have occurred when subjects were unable to maintain the selected pace for two successive shuttles. The Panel notes that the number of shuttles to fatigue and the RPE assessed during this last part of the trial are not measures of physical performance.

Multifactorial RM-ANOVA was used for the statistical analysis of the 15-m sprint times during the 10-min blocks. The mean sprint times for the seven 10-min blocks of 15-m sprints were shorter in the 6% CHO solution trial compared to the placebo trial ( $2.40 \pm 0.09$  s vs  $2.51 \pm 0.14$  s; p < 0.05).

The Panel considers that this study shows an effect of a CHO solution (containing maltodextrin at 6% and providing about 72 g of CHO/h) on physical performance during a high-intensity physical exercise lasting about 70 min.

The Panel considers that the two studies in which the nutritional status of participants before the test was not sufficiently specified (El-Sayed et al., 1995; MacLaren and Close, 2000) support an effect of CHO solutions on physical performance during high-intensity physical exercise lasting 70 min or more.

#### Conclusion on the human intervention studies

The consumption of CHO solutions during high-intensity, long-lasting physical exercise consistently improved physical performance in the four studies from which conclusions could be drawn that were

conducted in non-fasting conditions and used standardised feeding protocols before the trial sessions (Mitchell et al., 1988, 1989; Langenfeld et al., 1994; Baur et al., 2014). In two studies, the effect was shown for CHO solutions providing about 60 g CHO/h and up to about 90 g CHO/h when about one-third of the CHO were in the form of fructose, whereas solutions providing only glucose at rates of about 90 g/h consistently showed no effect on performance as compared to placebo. An effect of CHO solutions providing lower CHO doses (between 33 and 50 g CHO/h) on performance was shown in two out of three studies.

The effect of CHO solutions on physical performance during high-intensity, long-lasting physical exercise is supported by the results of four interventions studies conducted after an overnight fast (Campbell et al., 2001; Currell and Jeukendrup, 2008; Robson-Ansley et al., 2009; Smith et al., 2010) and by the results of two intervention studies (El-Sayed et al., 1995; MacLaren and Close, 2000) conducted after at least a 4-h fast in which the nutritional status of participants before the test was not otherwise specified.

The Panel notes that the rate of CHO consumption needed to achieve the claimed effect may depend on the intensity and duration of the exercise performed, as well as on dietary factors that affect pre-exercise glycogen stores and on the training status of the individuals undertaking the exercise.

#### Mechanism(s) by which the food/constituent could exert the claimed effect

It is well established that carbohydrates are a key energy substrate for skeletal muscle, that the size of body carbohydrate stores is relatively limited and can be acutely manipulated by dietary intake, and that the performance of prolonged (continuous or intermittent) high-intensity exercise can be maintained by maintaining carbohydrate availability, while the inability to maintain carbohydrate availability is associated with fatigue in the form of reduced work rates, and increased perception of effort. The mechanisms by which CHO solutions can improve physical performance during high-intensity, long-lasting exercise include glycogen sparing, provision of an exogenous muscle substrate, prevention of hypoglycaemia, activation of reward centres in the central nervous system, and the provision of fluids to main hydration (Thomas et al., 2016).

The Panel considers that the mechanisms by which the consumption of CHO solutions during highintensity and long-lasting physical exercise could exert the claimed effect are well established.

#### Weighing the evidence

In weighing the evidence, the Panel took into account that the consumption of CHO solutions providing about 30–60 g CHO/h, and up to about 90 g CHO/h when about one-third of the CHO were in the form of fructose, during high-intensity exercise and long duration physical exercise consistently improved physical performance in four studies conducted in non-fasting conditions with standardised feeding protocols before the trial sessions (Mitchell et al., 1988, 1989; Langenfeld et al., 1994; Baur et al., 2014). The Panel also took into account that the effect is supported by four studies conducted in fasting conditions (Campbell et al., 2001; Currell and Jeukendrup, 2008; Robson-Ansley et al., 2009; Smith et al., 2010) and by two studies in which the nutritional status of participants before the test was not sufficiently specified (El-Sayed et al., 1995; MacLaren and Close, 2000). In addition, the Panel considered that the mechanisms by which the consumption of CHO solutions during high-intensity and long-lasting physical exercise could exert the claimed effect are well established (Thomas et al., 2016).

The Panel concludes that a cause and effect relationship has been established between the consumption of CHO solutions and the improvement of physical performance during high-intensity and long-lasting physical exercise.

#### **3.4.** Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: 'Carbohydrate solutions can contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise in healthy trained adults'.

**3.5.** Conditions and restrictions of use

In order to obtain the claimed effect, CHO solutions (containing glucose, mixtures of glucose and fructose, sucrose and/or maltodextrins) should be consumed to provide between 30 and 60 g of CHO/h, and up to 90 g CHO/h if fructose constitutes about 1/3 of the CHO mixture.

The target population is healthy trained adults performing high-intensity (at least at 65% of the  $VO_{2max}$ ) and long-lasting (at least 60 min) physical exercise.

# 4. Conclusions

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

- the food/constituent, CHO solutions (containing glucose, mixtures of glucose and fructose, sucrose and/or maltodextrins), which are the subject of the health claim, are sufficiently characterised in relation to the claimed effect.
- the claimed effect proposed by the applicant is 'improvement of physical performance during a high-intensity and long-lasting physical exercise'. The target population proposed by the applicant is 'healthy physically active, trained or well-trained adults (male and female) engaged in a high-intensity exercise lasting more than one hour'. Improvement of physical performance during a high-intensity and long-lasting physical exercise is a beneficial physiological effect.
- a cause and effect relationship has been established between the consumption of CHO solutions and the improvement of physical performance during high-intensity and long-lasting physical exercise.
- the following wording reflects the scientific evidence: `Carbohydrate solutions can contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise in healthy trained adults'.
- in order to obtain the claimed effect, CHO solutions (containing glucose, mixtures of glucose and fructose, sucrose and/or maltodextrins) should be consumed to provide between 30 and 60 g of CHO/h, and up to 90 g CHO/h if fructose constitutes about one-third of the CHO mixture. The target population is healthy trained adults performing high-intensity (at least at 65% of the VO<sub>2max</sub>) and long-lasting (at least 60 min) physical exercise.

# Steps taken by EFSA

Health claim application on 'carbohydrate solutions' and 'improvement of physical performance during endurance exercise' pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0462\_FR). Submitted by Specialised Nutrition Europe (SNE), Avenue des Nerviens, 9-31, 1040 Brussels, Belgium.

- 1) This application was received by EFSA on 10/8/2017.
- 2) The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- 3) The scientific evaluation procedure started 22/9/2017.
- 4) On 16/11/2017, 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 scientific evaluation was suspended on 29/11/2017 and was restarted on 13/12/2017, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- 5) During its meeting on 7/2/2017, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to glycaemic carbohydrates and improvement of physical performance during endurance exercise.

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# Abbreviations

- ANOVA analysis of variance
- bw body weight
- CAB Centre for Agriculture and Biosciences
- CHO carbohydrate
- HSD honest significant difference
- IL-6 interleukin-6
- MSD minimum significant difference
- NDA EFSA Panel on Dietetic Products, Nutrition and Allergies



RERrespiratory exchange ratioRM-ANOVArepeated measures analysis of varianceRPErating of perceived exertionVO2maxmaximum oxygen consumption