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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to glycaemic carbohydrates and recovery of normal muscle function (contraction) after strenuous exercise pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

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

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Aptonia, 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 glycaemic carbohydrates and recovery of normal muscle function (contraction) after strenuous exercise. The food constituent, glycaemic carbohydrates, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect. Recovery of normal muscle function (contraction) after strenuous exercise is a beneficial physiological effect. Based on the well-established role of glycaemic carbohydrates (consumed especially in the first hours following strenuous exercise) on the replenishment of skeletal muscle glycogen stores, which leads to the recovery of normal skeletal muscle function (contraction), the Panel concludes that a cause and effect relationship has been established between the consumption of glycaemic carbohydrates and recovery of normal muscle function (contraction) after strenuous exercise.

KEY WORDS

glycaemic carbohydrates, recovery, muscle function, muscle contraction, health claims

[1] On request from the Competent Authority of France following an application by Aptonia, Question No EFSA-Q-2013-00234, adopted on 09 October 2013.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Sean (J.J.) Strain, Inge Tetens, Hendrik Van Loveren, Hans Verhagen and Peter Willatts for the preparatory work on this scientific opinion.

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SUMMARY

Following an application from Aptonia, 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 glycaemic carbohydrates and recovery of normal muscle function (contraction) after strenuous exercise.

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

The food constituent that is the subject of the health claim is glycaemic carbohydrates. The Panel considers that glycaemic carbohydrates are sufficiently characterised in relation to the claimed effect.

The claimed effect proposed by the applicant is "after a strenuous exercise, stimulate the replenishment of muscle glycogen stores. Low muscle glycogen content impairs muscle functioning". The target population proposed by the applicant is "active individuals performing strenuous exercise". Upon a request by EFSA for clarification, the applicant indicated that the claimed effect relates to the faster recovery of normal muscle function/contraction after strenuous exercise by increasing muscle glycogen re-synthesis rates and muscle glycogen concentrations, and that the target population is "all populations having performed a strenuous exercise whatever their physical fitness". The Panel considers that recovery of normal muscle function (contraction) after strenuous exercise is a beneficial physiological effect.

Muscle glycogen, which is used primarily as a source of energy within the muscles, can only be stored in a limited amount in the skeletal muscles. It is well-established that strenuous exercise depletes skeletal muscle glycogen stores, that low glycogen stores limit energy production in muscles and limit skeletal muscle contraction, and that glycaemic carbohydrates, consumed especially in the first hours following strenuous exercise, stimulate glycogen re-synthesis in muscle and contribute to the replenishment of skeletal muscle glycogen stores to a greater extent than other energy-containing macronutrients, and which leads to the recovery of normal skeletal muscle function (contraction).

The Panel considers that the human intervention studies, which were provided by the applicant as being pertinent to the health claim, do not provide additional evidence to the well-established role of glycaemic carbohydrates in the recovery of normal muscle function (contraction) after strenuous exercise.

The Panel concludes that a cause and effect relationship has been established between the consumption of glycaemic carbohydrates and recovery of normal muscle function (contraction) after strenuous exercise.

The following wording reflects the scientific evidence: "Glycaemic carbohydrates contribute to recovery of normal muscle function (contraction) after strenuous exercise".

In order to achieve the claimed effect, glycaemic carbohydrates should be consumed at doses of 4 g per kg of body weight in the first 4 to 6 hours following strenuous exercise. The target population is subjects who have performed strenuous exercise.

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BACKGROUND

Regulation (EC) No 1924/2006[4] harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. 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 14/02/2013.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- On 11/03/2013, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 29/04/2013, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 07/05/2013.
- On 26/06/2013, 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 08/07/2013, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 19/07/2013, EFSA received the requested information and the clock was restarted on 19/07/2013, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- During its meeting on 09/10/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to glycaemic carbohydrates and recovery of normal muscle function (contraction) after strenuous 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: glycaemic carbohydrates and recovery of normal muscle function (contraction) after strenuous exercise.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of glycaemic carbohydrates, a positive assessment of their safety, nor a decision on whether

[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.

glycaemic carbohydrates 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.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Aptonia, 4, Boulevard de Mons, 59665 Villeneuve d'Ascq, France.

Food/constituent as stated by the applicant

According to the applicant, the constituent for which the claim is made is glycaemic carbohydrates, which provide carbohydrates to the body cells mainly in the form of glucose, and include glucose and fructose (monosaccharides), sucrose and lactose (disaccharides), malto-oligosaccharides (such as maltodextrin) and starch (polysaccharides).

Health relationship as claimed by the applicant

According to the applicant, glycaemic carbohydrates, when taken immediately after a strenuous exercise either in liquid or solid form, stimulate the replenishment of muscle glycogen stores.

The applicant states that, considering that low muscle glycogen content impairs muscle functioning, muscle glycogen content is one of the major determinants of proper muscle contraction.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "Glycaemic carbohydrates increase muscle glycogen repletion following strenuous exercise".

Specific conditions of use as proposed by the applicant

The applicant has proposed as the target population active individuals performing strenuous exercise.

The applicant has proposed a dose of 1 g/kg body weight to be consumed immediately after exercise and then every hour at a dose of 0.5 g/kg body weight, for a recovery period up to 6 hours, reaching an overall dose of about 100-300 g.

As for the food products eligible to bear the claim, the applicant proposes that products can be consumed either in a liquid or solid form, and should supply at least 75 % carbohydrate as a main source of energy (Energy %), and that 75 % of the energy should be derived from glycaemic carbohydrates. If it is a drink, the carbohydrate concentration should exceed 10 % of weight by volume.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is 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).

The Panel considers that the food constituent, glycaemic carbohydrates, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is "after a strenuous exercise, stimulate the replenishment of muscle glycogen stores. Low muscle glycogen content impairs muscle functioning". The target population proposed by the applicant is "active individuals performing strenuous exercise".

During the evaluation process, EFSA requested the applicant to clarify the claimed effect and the target population proposed for scientific evaluation by the Panel. The applicant indicated that the claimed effect relates to the faster recovery of normal muscle function/contraction after strenuous exercise by increasing muscle glycogen re-synthesis rates and muscle glycogen concentrations. The target population proposed by the applicant is "all populations having performed a strenuous exercise whatever their physical fitness".

The Panel notes that in this context, strenuous exercise refers to a physical activity which leads to muscle fatigue and the depletion of glycogen stores in skeletal muscle through high intensity or extended duration, or through the combination of both high intensity and extended duration of the physical activity.

The Panel considers that recovery of normal muscle function (contraction) after strenuous exercise is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed, ScienceDirect, Springerlink, and GoogleScholar, using the search terms "carbohydrate* AND glycogen AND (depletion OR repletion OR exercise OR post-exercise OR recovery OR skeletal muscle)". The applicant selected English and French publications of human intervention studies in physically active (trained or untrained) healthy adults, which investigated muscle glycogen re-synthesis rate or muscle glycogen concentration, with a maximum of 12 hours as post-exercise period. The applicant also performed a manual search in a number of specified journals which targeted sport and exercise activities. No time limit restrictions were applied to the literature search.

The applicant identified through the literature search 16 human intervention (six randomised controlled, three non-randomised controlled and seven uncontrolled) studies on the effects of different glycaemic carbohydrate solutions (e.g. maltodextrin, glucose, and mixtures of glucose, fructose, sucrose and maltose in different combinations) on muscle glycogen concentrations and on the rate of glycogen synthesis in physically active individuals after performing different types of physical exercises, generally compared to low energy or energy-free placebo solutions (Blom et al., 1987; Ivy et al., 1988; Pascoe et al., 1993; Tarnopolsky et al., 1997; Roy and Tarnopolsky, 1998; Haub et al., 1999; Bowtell et al., 2000; Casey et al., 2000; Rotman et al., 2000; van Hall et al., 2000; van Loon et al., 2000; Bilzon et al., 2002; Tsintzas et al., 2003; Gusba et al., 2008; Wallis et al., 2008; Howarth et al., 2009). The applicant also provided 65 publications as supporting evidence, including reviews and consensus opinions from authoritative bodies, human studies on methods used for measuring muscle glycogen stores, and mechanistic *in vitro* and animal studies.

The Panel notes that it is well established that glucose, which is mainly provided to body cells from glycaemic carbohydrates, can be stored as glycogen in the liver and in the muscles. The storage capacity is limited, in total to around 500 g for a typical adult person, of which 300 to 400 g can be stored in the muscles. While liver glycogen is essential for liver functions, and is used to maintain normal blood glucose concentrations between meals, muscle glycogen is used primarily as a source of energy within the muscles (EFSA NDA Panel, 2010). It is also well established that strenuous exercise depletes skeletal muscle glycogen stores, that low glycogen stores limit energy production in muscles and limit skeletal muscle contraction, and that glycaemic carbohydrates, consumed especially in the first hours following strenuous exercise, stimulate glycogen re-synthesis in muscle and

contribute to the replenishment of skeletal muscle glycogen stores to a greater extent than other energy-containing macronutrients, and which leads to the recovery of normal skeletal muscle function (contraction) (Bergström et al., 1967; Costill et al., 1981; Burke et al., 1996; SCF, 2001; Jentjens and Jeukendrup, 2003; Rodriguez et al., 2009; Ortenbland et al., 2013). It has also been established that about 4 g of glycaemic carbohydrates per kg of body weight need to be consumed in the first 4 to 6 hours after the performance of strenuous exercise in order to increase glycogen re-synthesis in muscle and restore skeletal muscle glycogen stores (SCF, 2001; Rodriguez et al., 2009).

The Panel considers that the 16 human intervention studies submitted by the applicant do not provide additional evidence to the well-established role of glycaemic carbohydrates in the recovery of normal muscle function (contraction) after strenuous exercise.

The Panel concludes that a cause and effect relationship has been established between the consumption of glycaemic carbohydrates and recovery of normal muscle function (contraction) after strenuous exercise.

4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: "Glycaemic carbohydrates contribute to recovery of normal muscle function (contraction) after strenuous exercise".

5. Conditions and restrictions of use

In order to achieve the claimed effect, glycaemic carbohydrates should be consumed at doses of 4 g per kg of body weight within 4 to 6 hours following strenuous exercise. The target population is subjects who have performed strenuous exercise.

CONCLUSIONS

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

- The food constituent, glycaemic carbohydrates, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.
- The claimed effect proposed by the applicant is "after a strenuous exercise, stimulate the replenishment of muscle glycogen stores. Low muscle glycogen content impairs muscle functioning". The target population proposed by the applicant is "active individuals performing strenuous exercise". Recovery of normal muscle function (contraction) after strenuous exercise is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of glycaemic carbohydrates and recovery of normal muscle function (contraction) after strenuous exercise.
- The following wording reflects the scientific evidence: "Glycaemic carbohydrates contribute to recovery of normal muscle function (contraction) after strenuous exercise".
- In order to achieve the claimed effect, glycaemic carbohydrates should be consumed at doses of 4 g per kg of body weight in the first 4 to 6 hours following strenuous exercise. The target population is subjects who have performed strenuous exercise.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on glycaemic carbohydrates and recovery of normal muscle function (contraction) after strenuous exercise pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0377_FR). February 2013. Submitted by Aptonia.

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