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EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to glucose and contribution to energy-yielding metabolism 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 glucose and contribution to energy-yielding metabolism 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 Dextro Energy GmbH & Co. KG, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to glucose and “supports normal physical activity”. 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 glucose, which is sufficiently characterised. The claimed effect is “supports normal physical activity”. The proposed target population is healthy, active, as well as endurance trained, men and women. The Panel notes that the claimed effect refers to the contribution of the food constituent to energy-yielding metabolism in active individuals. Energy-yielding metabolism is needed for all functions and activities of the body, including physical activity and exercise. The Panel considers that contribution to energy-yielding metabolism is a beneficial physiological effect. A claim on glucose and contribution to energy-yielding metabolism has already been assessed with a favourable outcome. © European Food Safety Authority, 2012

KEY WORDS

Glucose, energy-yielding metabolism, health claims

¹ On request from the Competent Authority of Germany following an application by Dextro Energy GmbH & Co. KG, Question No EFSA-Q-2012-00267, adopted on 25 April 2012.

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SUMMARY

Following an application from Dextro Energy GmbH & Co. KG, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to glucose and “supports normal physical activity”.

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 glucose. Glucose can be consumed in the diet as a monosaccharide or be obtained from disaccharides, oligosaccharides and polysaccharides, which are digested and absorbed in the human small intestine and provide glucose to body cells as a source of energy. Besides glucose itself, the main glycaemic carbohydrates providing glucose in the diet are sucrose and lactose (disaccharides), as well as malto-oligosaccharides and starch (polysaccharides). This evaluation refers to glucose from all dietary sources. The Panel considers that the food constituent, glucose, which is the subject of the health claim, is sufficiently characterised.

The claimed effect is “supports normal physical activity”. The target population proposed by the applicant is healthy, active, as well as endurance trained, men and women. In the context of the information provided, and in the context of the clarifications provided by the applicant during the validation of this application, the Panel notes that the claimed effect refers to the contribution of the food constituent to energy-yielding metabolism in active individuals. Normal energy-yielding metabolism is needed for all functions and activities of the body, including physical activity and exercise. The Panel considers that contribution to energy-yielding metabolism is a beneficial physiological effect.

A claim on glucose and contribution to energy-yielding metabolism has already been assessed with a favourable outcome.

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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 Art 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 27/01/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- On 12/03/2012, during the validation process of the application, EFSA sent a request to the applicant to provide clarifications/missing information.
- The applicant provided the clarifications/missing information on 29/03/2012.
- The scientific evaluation procedure started on 30/03/2012.
- During its meeting on 25/04/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to glucose and contribution to energy-yielding metabolism.

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: glucose and "supports normal physical activity".

EFSA DISCLAIMER

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

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.

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.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Dextro Energy GmbH & Co. KG, Hafenstrasse 77, 47809, Krefeld, Germany.

Food/constituent as stated by the applicant

According to the applicant, glucose (synonymous dextrose), $C_6H_{12}O_6$, $M=180.16$ g/mol

Health relationship as claimed by the applicant

According to the applicant, “during physical activity muscle glycogen and blood glucose are major substrates for oxidative metabolism, generation of adenosine triphosphate (ATP) and thus muscle contraction. Muscle glycogen has to be broken down into its monosaccharides (glucose monomers). Carbohydrates present in limited amounts in muscle (300 g glycogen), liver (90 g glycogen) and body fluids (30 g glycogen) are a major fuel for physical performance. The ATP stored in muscle cells can only give high-power output for a few seconds. If the maximum effort lasts for 30 seconds or longer, then breakdown of muscle glycogen and subsequent degradation within glycolysis, citrate cycle and respiratory chain can supply the energy by producing ATP. Most physical activity requires an energy source that can power muscles for longer periods. In conclusion ingestion of glucose during physical activity can increase the amount of metabolic energy for skeletal muscle and associated extend time to exhaustion. Thus it is a beneficial physiological effect because glucose is needed for normal muscle metabolism, whereby it supports adequate energy supply during exercise. Therefore, total as well as endogenous and exogenous glucose, respectively carbohydrate oxidation is used to assess the claimed effect. Numerous studies have shown significant relationships between glucose ingestion and the oxidation of glucose (total, endogenous and exogenous oxidation) during physical activity. For example one study showed significantly higher rates of total carbohydrate oxidation rates during physical training after glucose and maltodextrin ingestion (0.7 g/kg body mass) compared to placebo (2.35±0.37 vs. 1.97±0.33 g/min; $p<0.001$). During exercise the carbohydrate oxidation rates were significantly higher ($p<0.05$) by ingestion of similar quantities of glucose (1 g/kg body mass) compared to placebo (2.34±0.09 vs. 2.11±0.09 g/min). Furthermore, earlier studies have shown that glucose ingestion (200 g) during physical activity results in augmented uptake and oxidation of glucose by the exercising muscle compared to placebo. Finally, glucose feedings (120 g) upon exercise leads to 0.53 g/min greater rate of carbohydrate utilization than during placebo trial. It should be noted that factors such as the carbohydrate content of the habitual diet or intake during training sessions may play a role in determine capacity of oxidizing carbohydrates ingested during physical activity”.

Description of the mechanism(s) by which the food/constituent exerts the claimed effect as proposed by the applicant

According to the applicant, “the claimed effect was thoroughly examined in scientific analysis and studies and is well established in scientific literature. Furthermore, the mechanism by which glucose exerts the claimed effect is described below.

Glucose is a major source of metabolic energy for most body cells including the brain which requires glucose for its energy needs. Glucose is ingested in form of monosaccharides or in form of polysaccharides, mainly starch, which has to be broken down into its constituent monosaccharide glucose before absorption. The membranes of human cells which contain a high level of lipids are relatively impermeable to hydrophylic polar molecules such as glucose. The entry and exit of glucose are mediated by specific transport processes. Carrier proteins located in the plasma membranes of cells can bind glucose and facilitate their traverse through the lipid membrane barrier, thus releasing the hexose into the cellular cytoplasm (e.g. skeletal muscle) or body fluids (e.g. blood). The Insulin-

Responsive Glucose Transporter is the major glucose transporter of the insulin-sensitive tissues, brown and white fat, and skeletal and cardiac muscle. Insulin stimulation causes a rapid increase in the number of glucose transporters on the membrane and then fuse with it, releasing the molecule. This process ensures a high density of glucose transporters and enhances the ability to move glucose from the surrounding cellular fluid into the interior of the cell especially during physical activity.

Glucose is stored in liver and muscle as the branched polymer glycogen. Although it occurs in concentrations of up to 6 % of liver mass but only 1 % of muscle, muscle mass is so much greater that it represents three to four times as much glycogen as stored in the liver. Muscle glycogen is mainly used by the muscle, but liver glycogen is for storage, hydrolysis and export as glucose, and the maintenance of blood glucose concentrations. Carbohydrates present in limited amounts in muscle (300 g glycogen), liver (90 g glycogen) and body fluids (30 g glycogen) are a major fuel for physical performance. The ATP stored in muscle cells can only give high-power output for a few seconds. If the maximum effort lasts for 30 seconds or longer, then breakdown of muscle glycogen and subsequent degradation within glycolysis, citrate cycle and respiratory chain can supply the energy by producing ATP. Most physical activity requires an energy source that can power muscles for longer periods than the body's own stores can deliver.

Both duration and intensity of exercise determine the mix of fuel used. At light to moderate activity levels (45 % $\text{VO}_2 \text{ max}$), as duration of exercise lengthens, the contribution of fat to energy production increases. In contrast, as the intensity of activity increases from rest to light to moderate to intense (45 % $\text{VO}_2 \text{ max}$, 65 % $\text{VO}_2 \text{ max}$, 845 % $\text{VO}_2 \text{ max}$), the contribution of carbohydrates to energy production increases. Ultimately, the amount of carbohydrates stored in the body (muscle, liver, body fluids) sets the limits for continued performance, and fatigue arises when the glycogen stores become depleted. The stores of carbohydrates usually suffice for just 1 to 3 hours of physical exertion, depending on the intensity of effort. Muscle glycogen use increases after 90 min exercise after consumption of glucose solution (6.4 % glucose in 8 ml solution/kg body mass) compared to placebo (4.2 \pm 2.8 mmol/kg dry mass*min vs. 2.5 \pm 0.7 mmol/kg dry mass*min; p=0.1). Ingestion of glucose increases glucose uptake when it is taken during prolonged, strenuous exercise and does not appear to limit physical performance. In conclusion ingestion of glucose during physical activity can increase the amount of metabolic energy for skeletal muscle and associated extend time to exhaustion. Thus it is a beneficial physiological effect because glucose is needed for normal muscle metabolism, whereby it supports adequate energy supply during exercise”.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “glucose supports normal physical activity”.

Specific conditions of use as proposed by the applicant

As proposed by the applicant, “the target population for consumption of glucose which supports physical activity are healthy active as well as well and endurance trained men and women”.

According to the applicant, “the quantity of glucose required to obtain the claimed effect is less than 30 g/h (0.5 g/min) for sports lasting 1 h, 30-60 g/h (0.5-1.0 g/min) for sports of longer duration and 90 g/h (1.5 g/min) for events >2.5 h. 50-75 g ingestion as a single bolus is effective as well. Prolonging the rate of glucose absorption enhances insulin economy and glucose disposal. A study showed that a mild rebound hypoglycaemia following pre-exercise glucose ingestion does not affect performance. Altering the timing of the ingestion (15, 45 or 75 min before exercise) resulted in differences in plasma glucose/insulin responses which disappeared within 10 min of exercise and which had no effect on performance. Ingestion of carbohydrates in the form of a solid bar resulted in similar mean and peak exogenous carbohydrate oxidation rates and showed similar oxidation efficiency as an

isocarbohydrated drink. It should be noted that factors such as the carbohydrate content of the habitual diet or intake during training sessions may play a role in determine capacity of oxidizing carbohydrates ingested during physical activity”.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is glucose.

Glucose can be consumed in the diet as a monosaccharide or be obtained from disaccharides, oligosaccharides and polysaccharides, which are digested and absorbed in the human small intestine and provide glucose to body cells as a source of energy. Besides glucose itself, the main glycaemic carbohydrates providing glucose in the diet are sucrose and lactose (disaccharides), as well as malto-oligosaccharides and starch (polysaccharides) (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010; FAO/WHO, 1998).

This evaluation refers to glucose from all dietary sources.

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

2. Relevance of the claimed effect to human health

The claimed effect is “supports normal physical activity”. The target population proposed by the applicant is healthy, active, as well as endurance trained, men and women.

In the context of the information provided, and in the context of the clarifications provided by the applicant during the validation of this application, the Panel notes that the claimed effect refers to the contribution of the food constituent to energy-yielding metabolism in active individuals. Energy-yielding metabolism is needed for all functions and activities of the body, including physical activity and exercise.

The Panel considers that contribution to energy-yielding metabolism is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

A claim on glucose and contribution to energy-yielding metabolism has already been assessed by the Panel with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2012).

The references provided by the applicant as being pertinent to the scientific substantiation of this claim were the same as in the previous submission which led to the favourable outcome indicated above.

CONCLUSIONS

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

- The food constituent, glucose, which is the subject of the health claim, is sufficiently characterised.

- The claimed effect is “supports normal physical activity”. The proposed target population is healthy, active, as well as endurance trained men and women. Contribution to energy-yielding metabolism is a beneficial physiological effect.
- A claim on glucose and contribution to energy-yielding metabolism has already been assessed with a favourable outcome.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on glucose and contribution to energy-yielding metabolism pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0323_DE). March 2012. Submitted by Dextro Energy GmbH & Co. KG.

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- EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA), 2012. Scientific Opinion on the substantiation of a health claim related to glucose and contribution to energy-yielding metabolism pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 10(5):2694, 10 pp.
- EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA), 2010. Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre. EFSA Journal 8(3):1462, 77 pp.
- FAO/WHO (Food and Agriculture Organization/World Health Organization), 1998. Carbohydrates in human nutrition. Report of a Joint FAO/WHO expert consultation. FAO Food and Nutrition Paper - 66, Rome.

GLOSSARY/ABBREVIATIONS

ATP Adenosine Triphosphate