



## Scientific Opinion on the substantiation of health claims related to glycaemic carbohydrates and maintenance of normal brain function pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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## SCIENTIFIC OPINION

### Scientific Opinion on the substantiation of health claims related to glycaemic carbohydrates and maintenance of normal brain function pursuant to Article 13(5) of Regulation (EC) No 1924/2006<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

Following applications from Dextro Energy GmbH & Co. KG, submitted for the authorisation of health claims pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of health claims related to glycaemic carbohydrates and maintenance of normal brain function. The scope of the applications was proposed to fall under health claims based on newly developed scientific evidence. The Panel considers that the food constituent, glycaemic carbohydrates, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effect. Maintenance of normal brain function is a beneficial physiological effect. A claim on glycaemic carbohydrates and maintenance of normal brain function has already been assessed by the Panel with a favourable outcome.

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#### KEY WORDS

glycaemic carbohydrates, brain function, health claims

<sup>1</sup> On request from the Competent Authority of Germany following the applications by Dextro Energy GmbH & Co. KG, Question Nos EFSA-Q-2014-00554, EFSA-Q-2014-00556 and EFSA-Q-2014-00557, adopted on 6 February 2015.

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<sup>3</sup> 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 applications from Dextro Energy GmbH & Co. KG, submitted for the authorisation of health claims pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of health claims related to glycaemic carbohydrates and maintenance of normal brain function.

The scope of the applications was proposed to fall under health claims based on newly developed scientific evidence.

The applicant proposed “glucose”, “glycaemic carbohydrates” and “dextrose tablets” as the food constituents that are the subject of the health claims. The main constituent of “dextrose tablets” is dextrose, i.e. glucose monohydrate.

Glucose (i.e. dextrose) is one of the main glycaemic carbohydrates in the diet. The Panel considers that the food constituent, glycaemic carbohydrates, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effect.

The claimed effect proposed by the applicant is “contributes to the maintenance of normal brain function”. The target population proposed by the applicant is the general population. The Panel considers that maintenance of normal brain function is a beneficial physiological effect.

A claim on glycaemic carbohydrates and maintenance of normal brain function has already been assessed by the Panel with a favourable outcome.

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## BACKGROUND

Regulation (EC) No 1924/2006<sup>4</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).

## STEPS TAKEN BY EFSA

- The applications were received on 01/08/2014.
- The scope of the applications was proposed to fall under health claims based on newly developed scientific evidence.
- On 10/09/2014, during the validation process of the applications, EFSA sent a request to the applicant to provide missing information.
- On 10/11/2014, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 27/11/2014.
- During its meeting on 06/02/2015, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of health claims related to glycaemic carbohydrates and maintenance of normal brain function.

## 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 health claims related to: glycaemic carbohydrates and maintenance of normal brain function.

## 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 its safety, nor a decision on whether glycaemic carbohydrates are, or are not, classified as foodstuffs. 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.

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<sup>4</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.

## INFORMATION PROVIDED BY THE APPLICANT

See Appendices A, B, and C.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The applicant proposed “glucose”, “glycaemic carbohydrates” and “dextrose tablets” as the food constituents that are the subject of the health claims. The applicant indicated that the main constituent of “dextrose tablets” is dextrose, i.e. glucose monohydrate (about 89 %).

Glucose (i.e. dextrose) is one of the main glycaemic carbohydrates in the diet. 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 (EFSA NDA Panel, 2010).

The Panel considers that the food constituent, glycaemic carbohydrates, which is the subject of the health claims, 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 “contributes to the maintenance of normal brain function”. The target population proposed by the applicant is the general population.

The Panel considers that maintenance of normal brain function is a beneficial physiological effect.

### 3. Scientific substantiation of the claimed effect

A claim on glycaemic carbohydrates and maintenance of normal brain function has already been assessed by the Panel with a favourable outcome (EFSA NDA Panel, 2011).

## CONCLUSIONS

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

- The food constituent, glycaemic carbohydrates, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effect.
- The claimed effect proposed by the applicant is “contributes to the maintenance of normal brain function”. The target population proposed by the applicant is the general population. Maintenance of normal brain function is a beneficial physiological effect.
- A claim on glycaemic carbohydrates and maintenance of normal brain function has already been assessed by the Panel with a favourable outcome.

## DOCUMENTATION PROVIDED TO EFSA

1. Health claim applications on glycaemic carbohydrates and maintenance of normal brain function pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial Nos 0420\_DE, 0422\_DE and 0423\_DE). August 2014. Submitted by Dextro Energy GmbH & Co. KG.

## REFERENCES

- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2010. Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre. EFSA Journal 2010;8(3):1462, 77 pp. doi:10.2903/j.efsa.2010.1462
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2011. Scientific Opinion on the substantiation of health claims related to glycaemic carbohydrates and maintenance of normal brain function (ID 603, 653) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2226, 13 pp. doi:10.2903/j.efsa.2011.2226

## APPENDICES

### Appendix A. Information provided by the applicant for application Question No EFSA-Q-2014-00554 – Claim serial No 0420\_DE

**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, the food constituent that is the subject of the health claim is glucose (synonymous dextrose),  $C_6H_{12}O_6$ ,  $M=180.16$  g/mol.

#### Health relationship as claimed by the applicant

According to the applicant, the claimed effect is normal brain function. For the human body, energy is available in the form of the cellular energy-carrying molecule such as adenosine triphosphate, most of which is generated through aerobic cellular respiration of carbohydrate such as glucose. Thus, glucose is the preferred energy source for most body cells including the brain which requires glucose for its energy needs, it consumes 20 % of the energy provided by the diet. Glucose is ingested in form of monosaccharides or in form of di- oligo- and polysaccharides, mainly starch, which has to be broken down into its constituent monosaccharide glucose before absorption. The claimed effect refers to a general function of glucose within the human body, agreeing that the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) already considered that the contribution of glycaemic carbohydrates to the maintenance of normal brain function is a beneficial physiological effect in general (EFSA NDA Panel, 2011).

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

The applicant has proposed the following wording for the health claim: “glucose contributes to the maintenance of normal brain function”.

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

According to the applicant, the target population is the general population.

According to the applicant, a total intake of 130 g of dietary glycaemic carbohydrates (e.g. glucose) per day, for both children (>1 year) and adults, is estimated to cover the whole glucose requirement of the brain and its general function. According to the applicant, lower amounts of glucose which do not cover the total glucose requirements of the brain nevertheless contribute to its normal function and to unique function. Ingestion of a significant amount of carbohydrates might be defined as 15 % (about 20 g) of the daily dose of 130 g carbohydrates needed for normal brain function. Analogous to the condition of use for vitamins and minerals 15 % should also be seen as significant and defined as the condition of use of the claim for glucose and the maintenance of normal brain function. This amount was also chosen by the European Commission for the claim on glycaemic carbohydrates and the maintenance of normal brain function already authorised (Reg. (EC) No 1018/2013; EFSA NDA Panel, 2011).



## **Appendix B. Information provided by the applicant for application Question No EFSA-Q-2014-00556 – Claim serial No 0422\_DE**

**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, the food constituent that is the subject of the claimed effect 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 ingested and absorbed in the human small intestine, and provide glucose to body cells as a source of energy. The main glycaemic carbohydrates in the diet are glucose and fructose (monosaccharides), sucrose and lactose (disaccharides), malto-oligosaccharides and starch (polysaccharide) (EFSA NDA Panel, 2010).

### **Health relationship as claimed by the applicant**

According to the applicant, the claimed effect is normal brain function. For the human body, energy is available in the form of the cellular energy-carrying molecule such as adenosine triphosphate, most of which is generated through aerobic cellular respiration of carbohydrate. Thus, glycaemic carbohydrates are the main source of energy in most human diet. In particular glucose is the preferred energy source for most body cells including the brain which requires glucose for its energy needs, it consumes 20 % of the energy provided by the diet. Glucose is ingested in form of monosaccharides or in form of di- oligo and polysaccharides, mainly starch, which has to be broken down into its constituent monosaccharide glucose before absorption. Thus, the claimed effect has already been approved by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) who considered that the contribution of glycaemic carbohydrates to the maintenance of normal brain function is a beneficial physiological effect in general (EFSA NDA Panel, 2011).

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

The applicant has proposed the following wording for the health claim: “glycaemic carbohydrates contribute to the maintenance of normal brain function”.

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

According to the applicant, the target population is the general population.

According to the applicant, a total intake of 130 g of dietary glycaemic carbohydrates (e.g. glucose) per day, for both children (>1 year) and adults, is estimated to cover the whole glucose requirement of the brain and its general function. The sources of glycaemic carbohydrates should be food which contains at least 20 g carbohydrates which are metabolised by humans, excluding polyols, per quantified portion. According to the applicant, lower amounts of glucose which do not cover the total glucose requirements of the brain nevertheless contribute to its normal function and to unique function. Ingestion of a significant amount of carbohydrates might be defined as 15 % (about 20 g) of the daily dose of 130 g carbohydrates needed for normal brain function. Analogous to the condition of use for vitamins and minerals 15 % should also be seen as significant and defined as the condition of use of the claim for glycaemic carbohydrates and the maintenance of normal brain function. This amount was also chosen by the European Commission for the claim on glycaemic carbohydrates and the maintenance of normal brain function already authorised (Reg. (EC) No 1018/2013; EFSA NDA Panel, 2011).

## **Appendix C. Information provided by the applicant for application Question No EFSA-Q-2014-00557 – Claim serial No 0423\_DE**

**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, the food that is the subject of the claimed effect is Dextrose Tablets.

### **Health relationship as claimed by the applicant**

According to the applicant, the significance of dextrose/glucose as the main food constituent of dextrose tablets in normal brain function is well established. For the human body, energy is available in the form of the cellular energy-carrying molecule such as adenosine triphosphate, most of which is generated through aerobic cellular respiration of carbohydrate such as glucose. Thus, glucose is the preferred energy source for most body cells including the brain which requires glucose for its energy needs, it consumes 20 % of the energy provided by the diet. Glucose is ingested in form of monosaccharides or in form of di- oligo- and polysaccharides, mainly starch, which has to be broken down into its constituent monosaccharide glucose before absorption. The claimed effect refers to a general function of glucose within the human body, agreeing that the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) already considered that the contribution of glycaemic carbohydrates to the maintenance of normal brain function is a beneficial physiological effect in general (EFSA NDA Panel, 2011).

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

The applicant has proposed the following wording for the health claim: "Dextrose Tablets contribute to the maintenance of normal brain function".

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

According to the applicant, the target population is the general population.

According to the applicant, a total intake of 130 g of dietary glycaemic carbohydrates (e.g. glucose) per day, for both children (>1 year) and adults, is estimated to cover the whole glucose requirement of the brain and its general function. According to the applicant, lower amounts of glucose which do not cover the total glucose requirements of the brain nevertheless contribute to its normal function and to unique function. Ingestion of a significant amount of carbohydrates might be defined as 15 % (about 20 g) of the daily dose of 130 g carbohydrates needed for normal brain function. Analogous to the condition of use for vitamins and minerals 15% should also be seen as significant and defined as the condition of use of the claim for dextrose tablets and the maintenance of normal brain function. This amount was also chosen by the European Commission for the claim on glycaemic carbohydrates and the maintenance of normal brain function already authorised (Reg. (EC) No 1018/2013; EFSA NDA Panel, 2011). Daily consumption of dextrose tablets should not exceed 5 tablets (ca. 23.3 g dextrose/glucose) per day.