

SCIENTIFIC OPINION

Melgaço mineral water and reduction of glycaemia

Scientific substantiation of a health claim related to Melgaço® mineral water and reduction of glycaemia pursuant to Article 14 of Regulation (EC) No 1924/2006¹

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

(Question No EFSA-Q-2008-219)

Adopted on 22 January 2009

PANEL MEMBERS

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SUMMARY

Following an application from Unicer Bebidas de Portugal SGPS, SA submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Portugal, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to Melgaço mineral water and reduction of glycaemia.

The scope of the application was proposed to fall under a health claim referring to disease risk reduction.

The food for which the claim is made is Melgaço® naturally sparkling mineral water, containing 52.2 mg/L of silica, 793mg/L of bicarbonate, 12.4mg/L of chloride, <0.1 mg/L of nitrate, 135 mg/L of calcium, 95.3 mg/L of sodium, 29.3mg/L of magnesium, with a pH of 5.8. The Panel considers that Melgaço® naturally sparkling mineral water is sufficiently characterised.

The claimed effect is to “reduce body hyperglycaemic levels”. The disease for which hyperglycaemia is a risk factor is not clearly specified in the application. The Panel assumes it to be type 2 diabetes mellitus, as it is the only disease referred to in the application.

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The target population is hyperglycaemic individuals. The Panel interprets the target population for this application (i.e, hyperglycaemic individuals) as subjects with fasting plasma glucose (FPG) $\geq 110\text{mg/dL}$ and $<126\text{mg/dL}$, which excludes individuals with a diagnosis of diabetes mellitus (DM). The Panel considers that long-term reduction in fasting and post-prandial blood glucose concentrations is beneficial to the health of subjects with impaired glucose tolerance by delaying the onset of type 2 diabetes mellitus.

The applicant identified one human intervention study and two animal studies as being pertinent to the claimed effect.

In the human intervention study, 100 subjects attending the Melgaço Spa were enrolled as presenting pathologies of the upper respiratory tract, of the osteo-articular system, or type 2 diabetes mellitus. It is not specified how many subjects of the total sample were hyperglycaemic but not diabetic. When all subjects were considered together, FPG significantly decreased after the 14-day intervention and significantly increased during the 9-month follow-up. Out of the 34 patients with type 2 diabetes mellitus, those with FPG $>110\text{mg/dL}$ at baseline ($n = 28$) were selected for post-hoc analyses. FPG in these subjects significantly decreased after the 14-day intervention. No significant changes were observed in fasting plasma insulin or glycated haemoglobin during this period, or in FPG, fasting plasma insulin or glycated haemoglobin at the end of the 9-month follow-up as compared to the end of the intervention. The nature of the treatment (including the frequency and amount of Melgaço mineral water consumption), background diet and medication use are not reported. The Panel considers that the significant weaknesses of this study greatly limit its value as a source of data to support the claimed effect.

The scarcity of data provided regarding one of the animal studies (number of animals per group, statistical analyses used and quantitative results not provided) does not allow the Panel to consider such study as a source of data to support the claimed effect.

The second animal study investigated the effects of Melgaço mineral water on glucose homeostasis, insulin secretion, and insulin resistance in diabetic Goto-Kakizaki rats (a model of type 2 diabetes) and in normal (non-diabetic) Wistar rats. The Panel considers that the significant weaknesses of this animal study (lack of adequate controls, no data available regarding the baseline characteristics of the animals nor on the changes observed in the intervention and control groups during the study) and the fact that results obtained in this experimental animal model cannot be extrapolated with any confidence to human subjects with hyperglycaemia greatly limit its value as a source of data to support the claimed effect.

On the basis of the data presented, the Panel concludes that a cause-effect relationship has not been established between the consumption of Melgaço® naturally sparkling mineral water and the reduction of hyperglycaemia in hyperglycaemic individuals.

Key words: Melgaço® naturally sparkling mineral water, hyperglycemia, type 2 diabetes mellitus.

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BACKGROUND

Regulation (EC) No 1924/2006² 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 that Regulation and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14 to 17 of that Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to Article 15 of that Regulation, an application for authorisation or 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, who will make the application and any supplementary information supplied by the applicant available to European Food Safety Authority (EFSA).

Steps taken by EFSA:

- The application was received on 17/03/2008.
- The scope of the application was proposed to fall under a health claim referring to disease risk reduction.
- During the check for completeness³ of the application, the applicant was requested to provide missing information on 02/04/2008 and 13/05/2008.
- The applicant provided the missing information on 10/07/2008.
- The scientific evaluation procedure started on 15/11/2008.
- During the meeting on 22/01/2009, the NDA Panel, after having evaluated the overall data submitted, adopted an opinion on the scientific substantiation of a health claim related to Melgaço mineral water and reduction of glycaemia.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 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: Melgaço® mineral water and reduction of glycaemia.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of Melgaço® mineral water, a positive assessment of its safety, nor a decision on whether Melgaço® mineral water 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.

² European Parliament and Council (2006). 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. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

³ In accordance with EFSA “Scientific and Technical guidance for the Preparation and Presentation of the Application for Authorisation of a Health Claim”

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 17 of Regulation (EC) No 1924/2006.

ACKNOWLEDGEMENTS

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1. Information provided by the applicant

Applicant's name and address: Unicer Bebidas de Portugal SGPS, SA. Apartado 1044, 4466-955 São Mamede Infesta, Portugal.

The application includes proprietary data.

1.1. Food/constituent as stated by the applicant

Melgaço® naturally sparkling mineral water.

1.2. Health relationship as claimed by the applicant

The applicant claims that high levels of calcium and magnesium can improve glycaemic profile in hyperglycaemic individuals.

1.3. Wording of the health claim as proposed by the applicant

“The regular consumption of Melgaço mineral water reduces body hyperglycaemic levels”

1.4. Specific conditions of use as proposed by the applicant

The specific target population for the intended health claim are hyperglycaemic individuals and the quantity of “Melgaço” water required to obtain the claimed effect is 1 litre per day.

2. Assessment

2.1. Characterisation of the food/constituent

The food for which the claim is made is Melgaço® naturally sparkling mineral water, containing 52.2 mg/L of silica, 793mg/L of bicarbonate, 12.4mg/L of chloride, <0.1 mg/L of nitrate, 135 mg/L of calcium, 95.3 mg/L of sodium, 29.3mg/L of magnesium, with a pH of 5.8.

The Panel considers that Melgaço® naturally sparkling mineral water is sufficiently characterised.

2.2. Relevance of the claimed effect to human health

The claimed effect is to “reduce body hyperglycaemic levels”. The disease for which hyperglycaemia is a risk factor is not clearly specified in the application. The Panel assumes it to be type 2 diabetes mellitus, as it is the only disease referred to in the application.

The target population is hyperglycaemic individuals. Hyperglycaemia is defined as fasting plasma glucose (FPG) ≥ 110 mg/dL. On the basis of FPG alone, this definition includes impaired fasting glucose (FPG ≥ 110 mg/dL and < 126 mg/dL) and diabetes mellitus (FPG ≥ 126 mg/dL) (ESC and EASD, 2007). The Panel interprets the target population for this application (i.e., hyperglycaemic individuals) as subjects with FPG ≥ 110 mg/dL and < 126 mg/dL, which excludes individuals with a diagnosis of diabetes mellitus.

Changes in lifestyle (including diet) may reduce fasting and post-prandial blood glucose concentrations by e.g., improving insulin sensitivity, which may delay the onset of type 2 diabetes in subjects with impaired glucose tolerance (ESC and EASD, 2007).

The Panel considers that long-term reduction in fasting and post-prandial blood glucose concentrations is beneficial to the health of subjects with impaired glucose tolerance by delaying the onset of type 2 diabetes mellitus.

2.3. Scientific substantiation of the claimed effect

The applicant performed a literature search in Infos@centreevian.com and PubMed Medline using the key words diabetes type 2, magnesium, calcium, and mineral waters to identify scientific articles published in the last 30 years in English, French, Spanish, German and Portuguese on the effects of the ingestion of mineral waters with high levels of magnesium and calcium on the glycaemic and lipidemic profile of type 2 diabetic subjects. However, the rationale and the decision tree used to select publications as being pertinent to the health claim under evaluation are unclear.

The applicant identified one human intervention study (Costa et al., 2003, unpublished, proprietary data) and two animal studies (Seiça R. and Nunes 2001 and 2007, unpublished, proprietary data) as pertinent to the claimed effect.

In the human intervention study (Costa et al., 2003, unpublished), 100 subjects attending the Melgaço Spa between June and October 2001 were enrolled with disorders/diseases of the upper respiratory tract (n = 33), of the osteo-articular system (n = 33), and with type 2 diabetes mellitus (n = 34). It is not specified how many subjects of the total sample were hyperglycaemic but not diabetic. It is stated that all subjects enrolled received “standardised treatment, according to the protocol for their pathology” for 14 days, with follow-up visits at 3, 6 and 9 months, but the nature of the treatment (including the frequency and amount of Melgaço mineral water consumption) is not reported. Background diet and medication use are not reported. All statistical analyses were performed as per protocol.

When all subjects were considered together, FPG significantly decreased after the 14-day intervention and significantly increased during the 9-month follow-up. Out of the 34 patients with type 2 diabetes mellitus, those with FPG >110mg/dL at baseline (n = 28) were selected for post-hoc analyses. FPG in these subjects significantly decreased after the 14-day intervention. No significant changes were observed in fasting plasma insulin or glycated haemoglobin during this period, or in FPG, fasting plasma insulin or glycated haemoglobin at the end of the 9-month follow-up as compared to the end of the intervention.

The Panel notes a number of weaknesses in this study: the study population was not well characterised with respect to FPG concentrations at baseline (i.e., total number of subjects who were hyperglycaemic but not diabetic), background diet, medication use and nature of the intervention were not reported, the study lacked adequate controls, and no intention-to-treat analysis was performed.

The Panel considers that the significant weaknesses of this study greatly limit its value as a source of data to support the claimed effect.

One of the animal studies presented is available in summary form only (Seiça R and Nunes E, 2001, unpublished). The scarcity of data provided (number of animals per group, statistical analyses used and quantitative results not available) does not allow the Panel to consider this study as a source of data to support the claimed effect.

The second animal study (Seiça R and Nunes E, 2007, unpublished) investigated the effects of Melgaço mineral water on glucose homeostasis, insulin secretion, and insulin resistance in diabetic Goto-Kakizaki rats (GK, a model of type 2 diabetes mellitus) and in normal (non-diabetic) Wistar (W) rats. The first intervention consisted of feeding adult (8-12 months old) GK (n=8) and W (n=8) rats Melgaço mineral water *ad libitum* for 6 weeks. The Panel considers

that the lack of adequate controls limits the conclusions that can be drawn from this experiment. The second intervention consisted of feeding young (8 weeks old) male and female GK rats with either Melgaço mineral water or tap water for 6 weeks *ad libitum*. Comparisons between intervention and control groups for the outcome variables are only presented for values obtained at the end of the intervention (no data are available regarding the baseline characteristics of the animals, nor on the changes observed in the intervention and control groups during the study).

The Panel considers that the significant weaknesses of this animal study and the fact that results obtained in this experimental animal model cannot be extrapolated with any confidence to human subjects with hyperglycaemia greatly limit its value as a source of data to support the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Melgaço® naturally sparkling mineral water and the reduction of hyperglycaemia in hyperglycemic individuals.

CONCLUSIONS

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

- The food for which the claim is made (i.e., Melgaço® naturally sparkling mineral water) is sufficiently characterised
- The claimed effect is to “reduce body hyperglycaemic levels”. The target population is hyperglycaemic individuals. Long-term reduction in fasting and post-prandial blood glucose concentrations is beneficial to the health of subjects with impaired glucose tolerance by delaying the onset of type 2 diabetes mellitus
- A cause and effect relationship has not been established between the consumption of Melgaço® naturally sparkling mineral water and the reduction of hyperglycemia in hyperglycaemic individuals

DOCUMENTATION PROVIDED TO EFSA

Health claim application on Melgaço mineral water and reduction of glycaemia pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0137-PT). July 2008. Submitted by Unicer Bebidas de Portugal SGPS, SA.

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- Seiça R and Nunes E, 2001 (unpublished). Effect of Melgaço Thermal Waters on Diabetes Mellitus.
- Seiça R and Nunes E, 2007 (unpublished). Effects of consumption of Melgaço Mineral Water in Type 2 Diabetes.

GLOSSARY / ABBREVIATIONS

EASD	European Association for the Study of Diabetes
ESC	European Society of Cardiology
FPG	Fasting plasma glucose