



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to Vichy Catalan carbonated natural mineral water and reduction of post - prandial lip a emic response 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 Vichy Catalan carbonated natural mineral water and reduction of post-prandial lipaemic response 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 S.A. Vichy Catalan, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Spain, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to Vichy Catalan carbonated natural mineral water and reduction of post-prandial lipaemic response. The food, Vichy Catalan carbonated natural mineral water, that is the subject of the health claim is sufficiently characterised. The claimed effect, reduction of post-prandial lipaemic response, is a beneficial physiological effect. In weighing the evidence, the Panel took into account that the results of the only study from which conclusions could be drawn for the scientific substantiation of the claim do not support an effect of Vichy Catalan carbonated natural mineral water on the reduction of post-prandial lipaemic response. A cause and effect relationship has not been established between the consumption of Vichy Catalan carbonated natural mineral water and reduction of post-prandial lipaemic response.

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KEY WORDS

Vichy Catalan, mineral water, triglycerides, lipaemic response, health claims.

¹ On request from the Competent Authority of Spain following an application by S.A. Vichy Catalan, Question No EFSA-Q-2012-00872, adopted on 24 January 2013.

² Panel members: Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean (J.J.) Strain, Inge Tetens, Daniel Tomé, Dominique Turck and Hans Verhagen. Correspondence: nda@efsa.europa.eu

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SUMMARY

Following an application from S.A. Vichy Catalan submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Spain, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to Vichy Catalan carbonated natural mineral water and reduction of post-prandial lipaemic response.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included a request for the protection of proprietary data.

The food that is the subject of the health claim is Vichy Catalan carbonated natural mineral water. The Panel considers that Vichy Catalan carbonated natural mineral water is sufficiently characterised.

The claimed effect is “reduction of post-prandial triglyceride concentrations”. The target population proposed by the applicant is “the healthy adult population”. The Panel considers that reduction of post-prandial lipaemic response is a beneficial physiological effect.

The applicant identified through a literature search five human intervention studies reported in six publications and one letter to the editor as being pertinent to the claim.

Two of these human intervention studies assessed the effect of Vichy Catalan carbonated natural mineral water on post-prandial lipaemic response.

An open-label, randomised, three-way cross-over study in 18 post-menopausal women investigated the effect of consuming Vichy Catalan carbonated natural mineral water, Vichy Catalan carbonated natural mineral water high in fluoride (7.9 mg/L), and a non-carbonated mineral water low in minerals (control) on post-prandial triglyceride concentrations. Mineral water (0.5 L) was consumed with a standard meal after an overnight fast and a standardised dinner. Endpoints investigated in the study were post-prandial serum and chylomicron triglyceride and cholesterol concentrations. The primary endpoint of the study was not specified. *Post-hoc* power calculations performed by the applicant showed that the study had 70 % power to detect differences in post-prandial triglyceride concentrations calculated as total area under the curve (tAUC) between groups. Statistically significant main effects of treatment were observed for both serum and chylomicron triglyceride concentrations ($p=0.028$ and $p=0.049$, respectively) using two factor repeated-measures analysis of variance with treatment and time as factors. No statistically significant treatment x time interactions were reported for any of these variables. Pair-wise comparisons showed significant differences in post-prandial serum triglyceride concentrations between the Vichy Catalan carbonated natural mineral water and control ($p=0.05$). Pair-wise comparisons performed with respect to chylomicron triglycerides did not reach statistical significance. Similar results were obtained from the analysis using the tAUC, which showed a significant decrease in the tAUC of serum triglycerides after consumption of Vichy Catalan carbonated natural mineral water vs. control ($p<0.05$). No statistically significant differences in the tAUC for chylomicron triglycerides, or in peak concentrations of serum and chylomicron triglycerides, were observed between individual mineral waters.

The Panel notes the small sample size of the study, that the primary outcome of the study was not specified, and that the level of significance used in the statistical analysis was not adjusted to take into account the multiple endpoints assessed in the study. The Panel considers that this study does not support an effect of Vichy Catalan carbonated natural mineral water on post-prandial lipaemic response.

In the open-label, randomised, four-way cross-over study, which was provided by the applicant as supportive evidence, the effect of consumption of Vichy Catalan carbonated natural mineral water vs. a non-carbonated mineral water low in minerals, with and without a standard meal, on post-prandial

blood concentrations of triglycerides was investigated in 21 subjects. The Panel notes that blood triglyceride concentrations were still rising at the time blood sampling was terminated at 120 min and that the duration of blood sampling was insufficient to allow an assessment of the post-prandial blood triglyceride curve. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that in the absence of evidence for an effect of Vichy Catalan carbonated natural mineral water on post-prandial lipaemia in humans, studies on potential mechanisms do not provide evidence for the scientific substantiation of the claim.

In weighing the evidence, the Panel took into account that the results of the only study from which conclusions could be drawn for the scientific substantiation of the claim do not support an effect of Vichy Catalan carbonated natural mineral water on the reduction of post-prandial lipaemic response.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Vichy Catalan carbonated natural mineral water and reduction of post-prandial lipaemic response.

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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 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 02/10/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included a request for the protection of proprietary data.
- On 23/10/2012, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 20/11/2012, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 27/11/2012.
- On 14/12/2012, 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 19/12/2012 and restarted on 03/01/2013, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 14/01/2013 EFSA received the requested information (which was made available to EFSA in electronic format on 09/01/2013).
- During its meeting on 24/01/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to Vichy Catalan carbonated natural mineral water and reduction of post-prandial lipaemic response.

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: Vichy Catalan carbonated natural mineral water and reduction of post-prandial lipaemic response.

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.

EFSA DISCLAIMER

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

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: S.A. Vichy Catalan, Roger de Llúria, 126, 08037-Barcelona, Spain.

The application includes a request for the protection of proprietary data in accordance with Article 21 of Regulation (EC) No 1924/2006.

Food/constituent as stated by the applicant

According to the applicant, the food which is the subject of the claim is Vichy Catalan, which is a carbonated mineral water with a known electrolyte composition.

Health relationship as claimed by the applicant

According to the applicant, randomised controlled trials consistently show a reduction of post-prandial triglycerides levels (post-prandial lipaemia) by consumption of Vichy Catalan water with a standard meal compared with a low mineral content water (0.5 L of water per meal). These effects indicate that this mineral water reduces lipid absorption.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "Vichy Catalan, a bicarbonated natural mineral water rich in mineral salts, contributes to reduce blood triglycerides rise during digestion."

Specific conditions of use as proposed by the applicant

According to the applicant, the quantity of the water required to obtain the claimed effect is 0.5 L consumed with a meal. The target population is the healthy adult population.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is Vichy Catalan carbonated natural mineral water.

Vichy Catalan is a slightly acidic carbonated mineral water fulfilling the minimum criteria for the indications "rich in mineral salts" (>1,500 mg/L calculated as fixed residue), "contains bicarbonate" (>600 mg/L), "contains chloride" (>200 mg/L), "contains sodium" (> 200 mg/L) and is "acidic" (free CO₂ content >250 mg/L) laid down in Annex III of Directive 2009/54/EC⁵. Based on quarterly analysis performed over a time span of 10 years, provided by the applicant upon a request from EFSA, Vichy Catalan contains on average 2882±50 mg/L mineral salts calculated as fixed residue, 2049±40 mg/L bicarbonate, 618±18 mg/L chloride, 1104±27 mg/L sodium and 4400±400 mg/L free CO₂. The fluoride content of the water amounts to around 0.8 mg/L.

According to the applicant, the water is stable under room temperature for more than 10 years. Information about the bottling process has been provided. Minerals and bicarbonate can be measured in foods by established methods.

⁵ Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters (Recast). OJ L 164, 26.6.2009, p. 45–58.

The Panel considers that Vichy Catalan carbonated natural mineral water, which is the subject of the claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect is “reduction of post-prandial triglyceride concentrations”. The target population proposed by the applicant is “the healthy adult population”.

Postprandial lipaemia is generally characterised by an increase in blood triglyceride concentrations after consumption of a fat containing meal and/or food. This is a normal physiological response that varies in magnitude and duration, and which may be influenced by the chemical and physical nature of the food or meal consumed, as well as by individual factors (Jackson et al., 2012). In general, decreasing post-prandial lipaemic response is beneficial to the adult population.

The Panel considers that reduction of post-prandial lipaemic response is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed with the search terms “bicarbonated mineral water” OR “carbonated water” to identify interventions in humans using natural mineral water from the Vichy Catalan manufacturer or the Vichy Catalan source. No limits were applied to the search. Publications using other mineral waters were excluded. Literature was also hand searched.

Through this literature search the applicant identified five human intervention studies reported in six publications (Perez-Granados et al., 2010; Schoppen et al., 2004; Schoppen et al., 2005a; Schoppen et al., 2005b; Schoppen et al., 2008; Toxqui et al., 2012) and one letter to the editor (Vaquero et al., 2011) as being pertinent to the claim.

Two human intervention studies (Perez-Granados et al., 2010; Schoppen et al., 2004) assessed the effect of Vichy Catalan carbonated natural mineral water on fasting rather than post-prandial blood concentrations of triglycerides and two publications (Schoppen et al., 2005b; Schoppen et al., 2008) did not report on post-prandial lipaemia. The letter to the editor (Vaquero et al., 2011) did not contain any original data which could be used for the scientific substantiation of the claim. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Two human intervention studies (Schoppen et al., 2005a; Toxqui et al., 2012) assessed the effect of Vichy Catalan carbonated natural mineral water on post-prandial lipaemic response.

An open-label, randomised, three-way cross-over study (Schoppen et al., 2005a) investigated the effect of consuming Vichy Catalan carbonated natural mineral water, Vichy Catalan carbonated natural mineral water high in fluoride (7.9 mg/L), and a non-carbonated mineral water low in minerals (control) on post-prandial triglyceride concentrations in 18 post-menopausal women (mean age 55.7 ± 2.4 years, BMI 26.9 ± 3.0 kg/m²) not receiving oestrogen replacement therapy or lipid lowering medication, and with fasting triglyceride concentrations of 0.99 ± 0.31 mmol/L. Mineral water (0.5 L) was consumed with a standard meal which provided 4,552 kJ [8 E% protein (21.5 g), 30 E% carbohydrates (86.5 g) and 62 E% fat (75.3 g)] after an overnight fast and a standardised dinner. The sequence in which the natural mineral waters were administered was randomised, and a two-week wash-out period was applied. Blood samples were taken at baseline and 30, 60, 120, 240, 360 and 420 minutes after the end of the study meal. Endpoints investigated in the study were post-prandial serum and chylomicron triglyceride and cholesterol concentrations. The primary endpoint of the study was not specified. *Post-hoc* power calculations performed by the applicant showed that the study had 70 % power to detect differences in post-prandial triglyceride concentrations calculated as total area

under the curve (tAUC) between groups. Serum and chylomicron triglyceride concentrations were analysed after logarithmic transformation using two factor repeated-measures analysis of variance (RM-ANOVA) with treatment and time as factors. The tAUC and peak concentrations were analysed with one-factor RM-ANOVA. Time to peak was calculated and analysed by the Friedman test. *Post-hoc* comparisons were performed using the Bonferroni test. Upon a request from EFSA to also present results of an analysis using the incremental AUC (iAUC) for both serum and chylomicron triglyceride concentrations, the applicant provided a p-value only without giving further details of the statistical analysis performed. The Panel notes that information on a p-value alone is insufficient to draw conclusion from the results of this analysis. Statistically significant main effects of treatment were observed for both serum and chylomicron triglyceride concentrations ($p=0.028$ and $p=0.049$, respectively). No statistically significant treatment x time interactions were observed for any of these variables. Pair-wise comparisons showed significant differences in post-prandial serum triglyceride concentrations between the Vichy Catalan carbonated natural mineral water and the control ($p=0.05$). Pair-wise comparisons performed with respect to chylomicron triglycerides did not reach statistical significance. Similar results were obtained from the analysis using the tAUC which showed a significant decrease in the tAUC of serum triglycerides after consumption of Vichy Catalan carbonated natural mineral water vs. control (949.55 ± 249.99 vs. 1123.56 ± 392.34 mmol/L*min; $p<0.05$). No statistically significant differences in the tAUC for chylomicron triglycerides or in peak concentrations of serum and chylomicron triglycerides were observed between individual mineral waters.

The Panel notes the small sample size of the study, that the primary outcome of the study was not specified, and that the level of significance used in the statistical analysis was not adjusted to take into account the multiple endpoints assessed in the study. The Panel considers that this study does not support an effect of Vichy Catalan carbonated natural mineral water on post post-prandial lipaemic response.

In the open-label, randomised, four-way cross-over study by Toxqui et al. (2012) which was provided by the applicant as supportive evidence, the effect of consumption of Vichy Catalan carbonated natural mineral water vs. a non-carbonated mineral water low in minerals, with and without a standard meal, on post-prandial blood concentrations of triglycerides was investigated in 21 subjects with fasting triglyceride concentrations of <2.82 mmol/L and not on medications which could affect lipid metabolism. On each occasion, 0.5 L of mineral water was consumed either with or without the meal after an overnight fast and a standardised dinner. Blood samples were taken at baseline, 30, 60 and 120 minutes after water consumption. The Panel notes that blood triglyceride concentrations were still rising at the time blood sampling was terminated, and that the duration of blood sampling was insufficient to allow an assessment of the post-prandial blood triglyceride curve (Jackson et al., 2012). The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

With respect to the mechanism by which Vichy Catalan carbonated natural mineral water could exert the claimed effect, the applicant indicated that Vichy Catalan carbonated natural mineral water reduces lipid absorption by reducing gastric lipase activity through an increase in gastric pH, which may reduce the release of cholecystokinin and the secretion of pancreatic lipase/co-lipase and consequently gall bladder emptying.

The Panel notes that in the absence of evidence for an effect of Vichy Catalan carbonated natural mineral water on post-prandial lipaemia in humans, studies on potential mechanisms do not provide evidence for the scientific substantiation of the claim.

In weighing the evidence, the Panel took into account that the results of the only study from which conclusions could be drawn for the scientific substantiation of the claim do not support an effect of Vichy Catalan carbonated natural mineral water on the reduction of post-prandial lipaemic response.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Vichy Catalan carbonated natural mineral water and reduction of post-prandial lipaemic response.

CONCLUSIONS

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

- The food, Vichy Catalan carbonated natural mineral water, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is “reduction of post-prandial triglyceride concentrations”. The target population proposed by the applicant is the “healthy adult population”. The Panel considers that reduction of post-prandial lipaemic response is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of Vichy Catalan carbonated natural mineral water and reduction of post-prandial lipaemic response.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on Vichy Catalan carbonated natural mineral water and reduction of post-prandial lipaemic response pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0367_ES). November 2012. Submitted by S.A. Vichy Catalan.

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GLOSSARY AND ABBREVIATIONS

CO ₂	Carbon dioxide
BMI	Body mass index
tAUC	Total area under the curve
RM-ANOVA	Repeated-measures analysis of variance
iAUC	Incremental area under the curve