

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to Rosbacher drive[®] and increased attention pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

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ABSTRACT

Following an application from Hassia Mineralquellen GmbH & Co KG, submitted for authorisation of a health claim 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 a health claim related to Rosbacher drive[®] and increased attention. The Panel considers that Rosbacher drive[®], which contains natural mineral water plus grape juice, lemon juice, pomegranate juice, elderberry juice, isomaltulose, sucrose, fructose syrup, caffeine, ascorbic acid and natural flavourings, is sufficiently characterised. The claimed effect, increased attention, is a beneficial physiological effect. The single study which was carried out with Rosbacher drive[®] was an open-label, non-randomised sequential study and the study did not report on any outcomes of attention. No conclusions can be drawn from this study for the scientific substantiation of the claim. The Panel concludes that a cause and effect relationship has not been established between the consumption of Rosbacher drive[®] and increased attention.

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KEY WORDS

Rosbacher drive[®], attention, concentration, health claims

¹ On request from the Competent Authority of Germany following an application by Hassia Mineralquellen GmbH & Co KG, Question No EFSA-Q-2013-00444, adopted on 5 February 2014.

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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.

Suggested citation: EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to Rosbacher drive[®] and increased attention pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2014;12(2):3576, 8 pp. doi:10.2903/j.efsa.2014.3576

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Following an application from Hassia Mineralquellen GmbH & Co KG, submitted for authorisation of a health claim 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 a health claim related to Rosbacher drive® and increased attention.

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 Rosbacher drive®, which contains natural mineral water plus grape juice (17.5 %), lemon juice (5 %), pomegranate juice (2 %), elderberry juice (0.5 %), isomaltulose (30 g/L), sucrose (15 g/L), fructose syrup (10 g/L), caffeine (100 mg/L), ascorbic acid (200 mg/L) and natural flavourings. The Panel considers that the food, Rosbacher drive®, which is the subject of the health claim, is sufficiently characterised.

The claimed effect proposed by the applicant is “maintenance and increase in concentration”. The target population proposed by the applicant is “people wishing to support their mental performance”. Concentration, i.e. attention, refers to the ability to attend to, select and use incoming sensory information. Attention is a well-defined construct which can be measured by validated psychometric tests. The Panel considers that increased attention is a beneficial physiological effect.

The applicant identified a total of 31 published studies and one unpublished study as being pertinent to the health claim.

The 31 published studies were not carried out with a food complying with the characterisation of the food which is the subject of the claim. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

Only one study carried out with Rosbacher drive® was provided. This study was an open-label, non-randomised sequential study which did not report on any outcomes of attention. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Rosbacher drive® and increased attention.

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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 15/05/2013.
- 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 05/07/2013, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 24/09/2013, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 10/10/2013.
- On 22/11/2013, 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 03/12/2013 and restarted on 18/12/2013, in compliance with Article 18(3) of Regulation (EC) No 1924/2006. EFSA received the requested information on 24/01/2014, beyond the legal deadline (the information was made available to EFSA in electronic format on 22/01/2014).
- During its meeting on 05/02/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to Rosbacher drive® and increased attention.

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: Rosbacher drive® and increased attention.

EFSA DISCLAIMER

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

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.

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: Hassia Mineralquellen GmbH & Co KG, Gießener Straße 30, D-61118 Bad Vilbel, Germany.

The application includes a request for the protection of proprietary data for one unpublished study (Wagner et al., 2007), in accordance with Article 21 of Regulation (EC) No 1924/2006.

Food/constituent as stated by the applicant

According to the applicant, the food that is the subject of the health claim is an energy drink marketed as Rosbacher drive® which contains as a basis natural mineral water plus grape juice (17.5 %), lemon juice (5 %), pomegranate juice (2 %), elderberry juice (0.5 %), isomaltulose (Palatinose™, 30 g/L), sucrose (15 g/L), fructose syrup (10 g/L), caffeine (100 mg/L), ascorbic acid (200 mg/L) as antioxidant agent and natural flavourings. The carbohydrate content in Rosbacher drive®, comprising sugars from fruit juices and added sugars, was indicated by the applicant as 30 g/L isomaltulose, 25 g/L glucose and 35 g/L fructose.

Health relationship as claimed by the applicant

According to the applicant, the caffeine, glucose, fructose, sucrose and isomaltulose contained in Rosbacher drive® support the intellectual ability/readiness to perform in situations of mental challenge [original in German: “fördert die geistige Leistungsbereitschaft bei mentalen Anforderungen”].

Wording of the health claim as proposed by the applicant

The applicant proposed the following wording for the health claim: “helps/supports/maintains concentration” [original in German: “unterstützt die Konzentration”].

The following alternative wordings were proposed: “helps/supports/maintains the human ability to concentrate”, “stabilises concentration” [originals in German: “unterstützt die menschliche Konzentrationsfähigkeit”, “stabilisiert die Konzentration”].

Specific conditions of use as proposed by the applicant

The applicant proposed the consumption of 500 mL of Rosbacher drive® in order to obtain the claimed effect.

The target population is people wishing to support their mental performance in certain situations, e.g. during studies, professional activities, while driving car or doing household chores [original in German: “wird für Personen/für Lebenssituationen empfohlen, in denen mentale Leistungsfähigkeit von Bedeutung ist, wie im Studium, im Beruf, beim Autofahren, im Haushaltsmanagement”].

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is Rosbacher drive®, which is marketed as an “energy drink”.

Rosbacher drive® contains natural mineral water plus grape juice (17.5 %), lemon juice (5 %), pomegranate juice (2 %), elderberry juice (0.5 %), isomaltulose (Palatinose™, 30 g/L), sucrose (15 g/L), fructose syrup (10 g/L), caffeine (100 mg/L), ascorbic acid (as antioxidant agent, 200 mg/L) and natural flavourings. Rosbacher drive® contains 25 g/L glucose and 35 g/L fructose comprising sugars from fruit juices and added sugars.

Detailed product sheets for the various fruit juices in Rosbacher drive® were provided.

The applicant stated that appropriate stability tests were carried out on the product and these tests showed compliance with the stability requirements of the product until the “best before” date.

The Panel considers that the food, Rosbacher drive®, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The applicant indicated that the proposed claimed effect is “maintenance and increase in concentration”. The target population proposed by the applicant is “people wishing to support their mental performance”.

Concentration, i.e. attention, refers to the ability to attend to, select and use incoming sensory information (i.e. to concentrate while processing information). There are two broad categories of attention. Selective attention is the ability to concentrate on one task or source of information to the exclusion of others. Sustained attention (vigilance) is the ability to concentrate over a period of time. Attention is a well-defined construct which can be measured by validated psychometric tests.

The Panel considers that increased attention is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed and Google using the search terms “glucose”, “carbohydrate”, “Palatinose”, “isomaltulose”, “caffeine”, “liquid”, “dehydration” and “fluidity” in combination with “cognition”, “intelligence”, “memory”, “reaction time”, “concentration”, “alertness” and “vigilance”. In addition, the applicant searched for pertinent studies in literature lists of CIAA (Confederation of food and drink industries of Europe), ERNA (European Responsible Nutrition Alliance), EHPM (European Federation of Associations of Health Product Manufacturers) and EBF (European Botanical Forum). Studies were included if they were carried out in humans and assessed the effects of hydration, caffeine, carbohydrates/glucose, or a combination of these, on the ability to concentrate.

The Panel notes that a health claim on caffeine and increased attention has already been assessed with a favourable outcome (EFSA NDA Panel, 2011), and that the conditions of use for that claim were set at 75 mg caffeine per serving. The Panel also notes that with respect to the health claim under evaluation the consumption of 500 mL of Rosbacher drive® (as proposed by the applicant as conditions of use for the claim) would lead to an intake of 50 mg caffeine.

The applicant identified a total of 31 published studies and one unpublished study as being pertinent to the health claim.

The 31 published studies were carried out with caffeine (17 studies), carbohydrates or isomaltulose (nine studies), and various combinations of caffeine plus carbohydrates (four studies). One study assessed the effect of dehydration on mental function. The Panel notes that these studies were not carried out with a food which complies with the specifications indicated in section 1 and considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

Only one study (Wagner et al., 2007, unpublished, claimed as proprietary by the applicant) was carried out with Rosbacher drive®. This study was an open-label, non-randomised sequential study in 10 male students. The primary outcome was alertness as measured by a self-rated questionnaire (“Alertometer”). The Panel notes that the primary outcome of the study was a subjective measure of alertness, which cannot be used as a measure of attention (EFSA NDA Panel, 2012). A number of other outcomes were provided which did not assess attention. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Rosbacher drive® and increased attention.

CONCLUSIONS

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

- The food, Rosbacher drive®, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is “maintenance and increase in concentration”. The target population proposed by the applicant is “people wishing to support their mental performance”. Increased attention is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of Rosbacher drive® and increased attention.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on Rosbacher drive® and increased attention pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0382_DE). May 2013. Submitted by Hassia Mineralquellen GmbH & Co KG.

REFERENCES

- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2011. Scientific Opinion on the substantiation of health claims related to caffeine and increased fat oxidation leading to a reduction in body fat mass (ID 735, 1484), increased energy expenditure leading to a reduction in body weight (ID 1487), increased alertness (ID 736, 1101, 1187, 1485, 1491, 2063, 2103) and increased attention (ID 736, 1485, 1491, 2375) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2054, 29 pp. doi:10.2903/j.efsa.2011.2054
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2012. Guidance on the scientific requirements for health claims related to functions of the nervous system, including psychological functions. EFSA Journal 2012;10(7):2816, 13 pp. doi:10.2903/j.efsa.2012.2816
- Wagner G, et al., 2007 (unpublished, claimed as proprietary by the applicant). Wirkung von Rosbacher drive® auf die mentale Leistungsfähigkeit.