EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to high-fibre sourdough rye bread and reduction of post-prandial glycaemic responses 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 high-fibre sourdough rye bread and reduction of post-prandial glycaemic responses pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Oy Karl Fazer AB, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Finland, 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 high-fibre sourdough rye bread and a reduction of post-prandial glycaemic responses. The Panel considers that the food, high-fibre sourdough rye bread, and its "comparator", glucose, are sufficiently characterised in relation to the claimed effect. A reduction of post-prandial glycaemic responses might be a beneficial physiological effect. The Panel notes that in the four human intervention studies submitted as pertinent to the health claim the consumption of high-fibre sourdough rye bread induced a significant reduction of post-prandial blood glucose responses when compared with glucose. The Panel also notes that, when comparable amounts of available carbohydrates from different carbohydrate-containing foods are tested, almost any carbohydrate-containing food would induce a reduction of post-prandial blood glucose responses compared with glucose. In addition, foods containing low amounts of, or no available carbohydrates, will also induce lower post-prandial blood glucose responses when compared with glucose. The Panel concludes that a cause and effect relationship has been established between the consumption of almost any food and a reduction of post-prandial blood glucose responses as compared with glucose. However, the Panel considers that solid foods, including high-fibre sourdough rye bread, are generally not considered as an alternative to glucose solutions. In this context, conditions of use cannot be established for this health claim.

KEY WORDS

high-fibre sourdough rye bread, post-prandial glycaemic responses, blood glucose, health claims

[1] On request from the Competent Authority of Finland following an application by Oy Karl Fazer AB, Question No EFSA-Q-2014-00012, adopted on 19 September 2014.

[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. One member of the Panel did not participate in the discussion on the subject referred to above because of potential conflicts of interest identified in accordance with the EFSA policy on declarations of interests. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, 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 an application from Oy Karl Fazer AB, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Finland, 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 high-fibre sourdough rye bread and a reduction of post-prandial glycaemic responses.

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 high-fibre sourdough rye bread, which should be consumed instead of glucose in order to obtain the claimed effect (i.e. reduction of post-prandial glycaemic responses). The Panel considers that the food, high-fibre sourdough rye bread, and its "comparator", glucose, are sufficiently characterised in relation to the claimed effect. The Panel notes that high-fibre sourdough rye bread and glucose are not generally considered as alternatives to be consumed on similar occasions and/or for the same purpose.

The claimed effect proposed by the applicant is "a reduced glycaemic response accompanied by a decreased insulin response after a meal". The target population proposed by the applicant is the healthy adult population, including people with impaired glucose tolerance without diabetes. The Panel considers that a reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionately increased) might be a beneficial physiological effect.

The applicant submitted four human intervention studies as being pertinent to the health claim.

The Panel notes that in the four studies the consumption of high-fibre sourdough rye bread induced a significant reduction of post-prandial blood glucose responses when compared with glucose. In addition, two studies showed a reduction of insulinaemic responses after consumption of high-fibre sourdough rye bread when compared with glucose.

The Panel also notes that, when comparable amounts of available carbohydrates from different carbohydrate-containing foods are tested, almost any carbohydrate-containing food would induce a reduction of post-prandial blood glucose responses compared with the blood glucose responses elicited by the consumption of glucose. In addition, the Panel notes that foods containing low amounts of, or no available carbohydrates, will also induce lower post-prandial blood glucose responses when compared with glucose.

The Panel concludes that a cause and effect relationship has been established between the consumption of almost any food and a reduction of post-prandial blood glucose responses as compared with glucose.

However, the Panel considers that solid foods, including high-fibre sourdough rye bread, are generally not considered as an alternative (i.e. to be consumed on similar occasions and/or for the same purpose) to glucose solutions. In this context, conditions of use cannot be established for this health claim.

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BACKGROUND

Regulation (EC) No 1924/2006[4] 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 09/01/2014.
- 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 14/03/2014, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 19/03/2014, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 21/03/2014.
- On 07/05/2014, 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 19/05/2014 and was restarted on 03/06/2014, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 10/06/2014, EFSA received the requested information (which was made available to EFSA in electronic format on 30/05/2014).
- During its meeting on 19/09/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to sourdough rye bread and a reduction of post-prandial glycaemic responses.

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: high-fibre sourdough rye bread and a reduction of post-prandial glycaemic responses.

[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 high-fibre sourdough rye bread, a positive assessment of its safety, nor a decision on whether high-fibre sourdough rye bread 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: Oy Karl Fazer AB, PL 4, FI-00941 Helsinki, Finland.

The application includes a request for the protection of proprietary data for six unpublished studies (Blanco and Granfeldt, 2006; Henry and Lightowler, 2006, 2007a, b; Suutari et al., 2012; Niskanen et al., 2013), 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 high-fibre sourdough rye bread with a minimum content of 70 % rye (whole-grain) and a maximum content of 30 % wheat, oat or barley of the total cereal content. The bread is manufactured by natural sourdough fermentation and contains at least 10 g fibre per 100 g (10-16 g/100 g). The typical acidity values of the bread are pH $\leq$ 4.7 and total titratable acidity (TTA) of $\geq$ 8.5 mL (0.1 M NaOH/10 g bread).

Health relationship as claimed by the applicant

According to the applicant, the consumption of high-fibre sourdough rye bread contributes to a reduced glycaemic response accompanied by a decreased insulin response after a meal.

The applicant claims that the main mechanism by which the food exerts the claimed effect is a hindrance of carbohydrate digestion and absorption in the small intestine, which leads to a lower and delayed rise of post-prandial blood glucose levels, and decreased insulin levels. The applicant also claims delayed gastric emptying owing to the presence of intact/dense structures not accessible to human amylases, a high fibre content and a high amount of organic acids (low pH) in the bread; and inhibition of digestive enzymes because of low pH and soluble fibre content. Furthermore, the applicant hypothesised that the high polyphenol content, in addition to zinc, in rye bread may contribute to the effect by inhibiting carbohydrate-metabolising enzymes or glucose transport.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "Consumption of high-fibre sourdough rye bread contributes to a reduction of glycaemic response accompanied with a decreased insulin response after a meal".

Specific conditions of use as proposed by the applicant

The applicant proposed a daily intake of 100 g high-fibre sourdough rye bread. The proposed target population is the healthy adult population, including also people with impaired glucose tolerance without diabetes.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is high-fibre sourdough rye bread, which should be consumed instead of glucose in order to obtain the claimed effect (i.e. reduction of post-prandial glycaemic responses).

The content of rye (*Secale cereale*) ingredients (flour, flake, cut and crushed grain, whole kernels and/or rye bran) in the bread amounts to at least 70 % of all the cereals used, with the remaining 30 %

being wheat, oat or barley (flour or grain). Part of the rye is included in the sourdough and, thus, is fermented during the incubation process. Other ingredients are water, yeast and salt. Furthermore, small amounts of spices, malt extract or syrup may be added. No butter, oil or extra acids are added.

The bread is manufactured in a one-stage sourdough process with at least eight hours of fermentation, which leads to the dense structure and acidity of the bread. The typical acidity values of the bread are pH $\leq$ 4.7 and total titratable acidity (TTA) of $\geq$ 8.5 mL (0.1 M NaOH/10 g bread). The fibre content in the bread varies from 10-16 g/100 g and comprises 4-9 g/100 g soluble fibre and 8-11 g/100 g insoluble fibre. The typical nutrient composition of high-fibre sourdough rye bread was provided.

An overview of the manufacturing process, stability data and batch-to-batch variability were provided.

The applicant claimed that consumption of high-fibre sourdough rye bread would reduce post-prandial blood glucose and insulinaemic responses and presented four human intervention studies as being pertinent to the claim. In all four studies (Blanco and Granfeldt, 2006; Henry and Lightowler, 2006; Suutari et al., 2012; Niskanen et al., 2013; all four unpublished and claimed as proprietary by the applicant), various types of high-fibre sourdough rye bread were tested for their ability to reduce post-prandial blood glucose responses in comparison with a glucose reference drink.

EFSA informed the applicant that claims on the reduction of post-prandial blood glucose responses refer to the ability of a food/constituent to reduce the blood glucose rise after consumption of a food or meal rich in available carbohydrates in comparison with a reference food or meal, and that, therefore, such claims are considered comparative claims (EFSA NDA Panel, 2011). The applicant was also informed that, in presenting such claims, applicants should take into account the Guidance on the implementation of Regulation (EC) No 1924/2006 of the Standing Committee on the Food Chain and Animal Health for the use of comparative claims[5], which specifies that a comparison may only be made between foods of the same category, that the notion of food category should also take account of the occasion of consumption and/or the purpose of the consumption, and that the reference product should be explicitly mentioned.

In this context, the applicant was requested to specify and characterise the food/constituent that is the subject of the health claim and the food/constituent that is being used as the comparator (reference). In reply, the applicant indicated that glucose was the reference food with which the high-fibre sourdough rye bread should be compared in relation to the claimed effect.

EFSA issued positive opinions in relation to the proposed claimed effect (i.e. reduction of post-prandial blood glucose responses) in the following cases:

- sugars (e.g. fructose) were intended to replace other sugars (e.g. glucose, sucrose) within the same food/beverage (EFSA NDA Panel, 2011b);
- food/constituents with no effect or a reduced effect on post-prandial blood glucose responses (e.g. non/low-digestible carbohydrates, intense sweeteners and sugar alcohols) were intended to replace food/constituents (e.g. sugars, other digestible carbohydrates) with an independent role in increasing post-prandial glycaemic responses within the same food/beverage (EFSA NDA Panel, 2011c, d, g, h, 2014);
- food/constituents (e.g. different types of dietary fibre) which, when present in carbohydrate-containing foods, could reduce post-prandial blood glucose responses to such foods by, for example, decreasing the rate of absorption of available carbohydrates. In these cases, the reference food/beverage was the test food/beverage without the food/constituent for which the claim was made (EFSA NDA Panel, 2010a, b, 2011e, f, 2012).

[5] Guidance on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods – Conclusions of the Standing Committee on the Food Chain and Animal Health, 14 December 2007.

In all these aforementioned cases, the test food/beverage and the reference food/beverage were considered as alternative products to be consumed on similar occasions and/or for the same purpose. The Panel notes that high-fibre sourdough rye bread and glucose are not generally considered as alternatives to be consumed on similar occasions and/or for the same purpose.

The Panel considers that the food, high-fibre sourdough rye bread, which is the subject of the health claim, and its "comparator", glucose, are 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 "a reduced glycaemic response accompanied by a decreased insulin response after a meal". The target population proposed by the applicant is the healthy adult population, including people with impaired glucose tolerance without diabetes.

The elevation of blood glucose concentrations after consumption of a food and/or meal, i.e. post-prandial glycaemia, is a normal physiological response which 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 (Venn and Green, 2007). Decreasing post-prandial glycaemic responses may, for example, be beneficial to individuals with impaired glucose tolerance, as long as post-prandial insulinaemic responses are not disproportionately increased. Impaired glucose tolerance is common in the general population of adults.

The Panel considers that a reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionately increased) might be a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed and the Cochrane Database of systematic reviews using the search terms "rye", "bread", "glucose", "insulin", "postprandial", "glycemic", "glycaemic" and "response" in various combinations. In addition to this search, the reference lists of articles were screened manually. Studies were included if they were intervention or observational trials, used rye bread (containing more than 50 % rye of all cereal ingredients) as a study product, assessed post-prandial effects on glucose and, if possible, insulin response, used glucose as a reference product and were carried out in study subjects with normal or impaired glucose metabolism. Studies performed in subjects with non-insulin-dependent or insulin-dependent diabetes mellitus were excluded.

The applicant submitted four human intervention studies as being pertinent to the health claim (Blanco and Granfeldt, 2006; Henry and Lightowler, 2006; Suutari et al., 2012; Niskanen et al., 2013; all four unpublished and claimed as proprietary by the applicant).

In these four cross-over studies, various high-fibre sourdough rye breads were tested for their ability to reduce post-prandial blood glucose responses in comparison with a glucose reference drink. Standard methodology (Wolever et al., 2003; Wolever, 2004; Brouns et al., 2005) was used to determine the blood glucose incremental areas under the curve (iAUC) of the breads. The sourdough rye breads used in the four studies complied with the specifications indicated in section 1. The Panel notes that in the four studies (Blanco and Granfeldt, 2006; Henry and Lightowler, 2006; Suutari et al., 2012; Niskanen et al., 2013), submitted as pertinent for the scientific substantiation of the claim, the consumption of high-fibre sourdough rye bread induced a significant reduction of post-prandial blood glucose responses when compared with glucose. In addition, two studies (Suutari et al., 2012; Niskanen et al., 2013) showed a reduction of insulinaemic responses after consumption of high-fibre sourdough rye bread when compared with glucose.

The Panel also notes that, when comparable amounts of available carbohydrates from different carbohydrate-containing foods are tested, almost any carbohydrate-containing food would induce a reduction of post-prandial blood glucose responses compared with the blood glucose responses elicited by the consumption of glucose (Foster-Powell et al., 2002; Atkinson et al., 2008). In addition, the Panel notes that foods containing low amounts of carbohydrates or no available carbohydrates will also induce lower post-prandial blood glucose responses when compared with glucose.

The Panel concludes that a cause and effect relationship has been established between the consumption of almost any food and a reduction of post-prandial blood glucose responses as compared with glucose.

The Panel could have reached this conclusion without the human studies (Blanco and Granfeldt, 2006; Henry and Lightowler, 2006; Suutari et al., 2012; Niskanen et al., 2013) claimed as proprietary by the applicant.

However, the Panel considers that solid foods, including high-fibre sourdough rye bread, are generally not considered as an alternative (i.e. to be consumed on similar occasions and/or for the same purpose) to glucose solutions. In this context, the Panel cannot establish conditions of use for this claim.

4. Wording

The Panel considers that the following wording reflects the scientific evidence: "Consumption of almost any food instead of glucose induces a lower blood glucose rise".

5. Conditions of use

The Panel considers that solid foods, including high-fibre sourdough rye bread, are generally not considered as an alternative (i.e. to be consumed on similar occasions and/or for the same purpose) to glucose solutions. In this context, conditions of use cannot be established for this claim.

CONCLUSIONS

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

- The food, high-fibre sourdough rye bread, which is the subject of the health claim, and its "comparator", glucose, are sufficiently characterised in relation to the claimed effect.
- The claimed effect is "a reduced glycaemic response accompanied by a decreased insulin response after a meal". The target population proposed by the applicant is the healthy adult population, including people with impaired glucose tolerance without diabetes. A reduction of post-prandial glycaemic responses might be a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of almost any food and a reduction of post-prandial blood glucose responses as compared with glucose.
- The following wording reflects the scientific evidence: "Consumption of almost any food instead of glucose induces a lower blood glucose rise".
- Solid foods, including high-fibre sourdough rye bread, are generally not considered as an alternative to glucose solutions. In this context, conditions of use cannot be established for this claim.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on high-fibre sourdough rye bread and a reduction of post-prandial glycaemic responses pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0405_FI). January 2014. Submitted by Oy Karl Fazer AB.

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