



EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to Nutriose®06 and a 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 Nutriose[®]06 and a reduction of post-prandial glycaemic responses 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 Roquette Italia S.P.A., submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Italy, 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 Nutriose[®]06 and a reduction of post-prandial glycaemic responses. Non-digestible carbohydrates, including resistant dextrin in Nutriose[®]06, are resistant to hydrolysis and absorption in the small intestine and therefore do not contribute to post-prandial glycaemia. This opinion applies to non-digestible carbohydrates (e.g. non-starch polysaccharides, resistant oligosaccharides and resistant starch), which should replace glycaemic carbohydrates in foods or beverages in order to obtain the claimed effect. The Panel considers that the food constituent, non-digestible carbohydrates, which is the subject of the health claim, and the food constituent (i.e. glycaemic carbohydrates) that non-digestible carbohydrates should replace in foods or beverages are both sufficiently characterised in relation to the claimed effect. The Panel considers that a reduction of post-prandial glycaemic responses might be a beneficial physiological effect. A claim on non-digestible carbohydrates and reduction of post-prandial glycaemic responses has already been assessed by the Panel with a favourable outcome. The previous evaluation, including the proposed wording and the conditions of use, also applies to this application. The Panel concludes that a cause and effect relationship has been established between the consumption of foods/beverages containing non-digestible carbohydrates and a reduction of post-prandial glycaemic responses as compared with foods/beverages containing glycaemic carbohydrates.

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KEY WORDS

resistant dextrin, Nutriose[®]06, non-digestible carbohydrates, post-prandial glycaemic responses, health claims

¹ On request from the Competent Authority of Italy following an application by Roquette Italia S.P.A., Question No EFSA-Q-2014-00073, adopted on 18 September 2014.

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SUMMARY

Following an application from Roquette Italia S.P.A., submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Italy, 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 Nutriose[®]06 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 resistant dextrin in Nutriose[®]06, which should replace glycaemic carbohydrates in foods or beverages in order to obtain the claimed effect (i.e. reduction of post-prandial glycaemic responses). The Panel notes that the characteristic which is most relevant to the claimed effect is not unique to resistant dextrin but is common to other non-digestible carbohydrates (e.g. non-starch polysaccharides and resistant oligosaccharides) because, similar to resistant dextrin, non-digestible carbohydrates are resistant to hydrolysis and absorption in the small intestine and therefore do not contribute to post-prandial glycaemia. This opinion applies to non-digestible carbohydrates (e.g. non-starch polysaccharides, resistant oligosaccharides and resistant starch), which should replace glycaemic carbohydrates in foods or beverages in order to obtain the claimed effect. The Panel considers that the food constituent, non-digestible carbohydrates, which is the subject of the health claim, and the food constituent (i.e. glycaemic carbohydrates) that non-digestible carbohydrates should replace in foods or beverages are both sufficiently characterised in relation to the claimed effect.

The claimed effect proposed by the applicant relates to the reduction of post-prandial blood glucose responses. The target population proposed by the applicant is individuals wishing to reduce their post-prandial glycaemic responses. 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 six unpublished human studies as being pertinent to the health claim.

A claim on non-digestible carbohydrates and reduction of post-prandial glycaemic responses has already been assessed by the Panel with a favourable outcome.

The Panel considers that the previous evaluation on the replacement of sugars with non-digestible carbohydrates applies to the replacement of all glycaemic carbohydrates with non-digestible carbohydrates, including the proposed wording and the conditions of use.

The Panel concludes that a cause and effect relationship has been established between the consumption of foods/beverages containing non-digestible carbohydrates and a reduction of post-prandial glycaemic responses as compared with foods/beverages containing glycaemic carbohydrates.

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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 03/02/2014.
- 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.
- The scientific evaluation procedure started on 24/03/2014.
- 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, and the clock was stopped on 19/05/2014, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 27/05/2014, EFSA received the requested information and the clock was restarted, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- During its meeting on 18/09/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to non-digestible carbohydrates 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: non-digestible carbohydrates (including resistant dextrin in Nutriose®06) and a reduction of post-prandial glycaemic responses.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of non-digestible carbohydrates, a positive assessment of their safety, nor a decision on whether non-digestible carbohydrates are, or are 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: Roquette Italia S.P.A., Via Serravalle 26, 15063 Cassano Spinola, Alessandria, Italy.

The application includes a request for the protection of proprietary data for six unpublished studies (Donazzolo and Latreille-Barbier, 2000; GI labs, 2007; Thondre and Lightowler, 2012; Yuexin et al., 2012; Gendre, 2013; Salvi, 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 Nutriose[®]06, described as a resistant dextrin produced from wheat or maize starch.

Health relationship as claimed by the applicant

According to the applicant, the consumption of foods/drinks containing Nutriose[®]06 instead of high glycaemic carbohydrates leads to a reduced blood glucose rise. The applicant argues that this is owing to the fact that only 15 % of Nutriose[®]06 is hydrolysed in the upper digestive tract while 75 % are fermented in the large intestine and 10 % are excreted into the faeces. This low digestibility of Nutriose[®]06 is claimed to lead to a lower post-prandial glycaemia when replacing available carbohydrates in a meal, without any disproportionate increase in post-prandial insulinaemic response.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "Consumption of foods/drinks containing Nutriose[®]06 instead of high glycaemic carbohydrates induces a lower blood glucose rise after their consumption compared to high glycaemic carbohydrates-containing foods/drinks".

Specific conditions of use as proposed by the applicant

According to the applicant, high-glycaemic carbohydrates in foods or drinks should be replaced by Nutriose[®]06 so that foods or drinks contain reduced amounts of high-glycaemic carbohydrates, in accordance with the Annex of Regulation (EC) No 1924/2006. The proposed target population is individuals from the general population wishing to reduce their post-prandial glycaemic responses.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is Nutriose[®]06, which should replace "high glycaemic carbohydrates" in foods or beverages in order to obtain the claimed effect (i.e. reduction of post-prandial glycaemic responses).

Nutriose[®]06 is produced from wheat or maize starch by dry roasting under acidic conditions (i.e. dextrinisation). The ensuing dextrin is treated enzymatically and then purified by chromatographic partitioning in order to minimise the content of mono- and disaccharides. During the manufacturing process, linear and/or branched glycosidic bonds (i.e. α -1,2; α -1,3; β -1,2; β -1,3; β -1,4; β -1,6) are formed, which render dextrins resistant to digestion by salivary and pancreatic amylases. The final product contains about 85 % resistant dextrin with an average degree of polymerisation of 12-25, and

less than 0.5 % mono- and disaccharides. An overview of the manufacturing process, stability data and batch-to-batch variability were provided.

Following a request for clarification, the applicant indicated that the term “high-glycaemic carbohydrates” refers to “any carbohydrate rapidly digested and absorbed in the small intestine which induces a high increase in plasma glucose level, e.g. glucose, sucrose, maltose, glucose syrup, maltodextrin and high digestible starches”. The Panel notes that glycaemic carbohydrates include sugars, oligosaccharides and polysaccharides which can be digested and absorbed in the small intestine and contribute to post-prandial glycaemic responses (EFSA NDA Panel, 2010).

The Panel notes that the main characteristic of Nutriose[®]06 which contributes to the claimed effect is the non-digestibility of the resistant dextrin contained in Nutriose[®]06 in the small intestine, and that replacing digestible (glycaemic) carbohydrates by any non-digestible carbohydrate would contribute to the claimed effect. The applicant was requested to indicate which characteristics or properties of resistant dextrin in Nutriose[®]06 make it unique compared with other non-digestible carbohydrates (e.g. non-starch polysaccharides and resistant oligosaccharides) in relation to the claimed effect. In reply, the applicant stated that Nutriose[®]06 is manufactured through a “unique and patented manufacturing process during which transglycosylation reactions occur”. The applicant claims that the “unique arrangement” of the glycosidic bonds in Nutriose[®]06 is responsible for the low glycaemic and low insulinaemic response of Nutriose[®]06. The Panel notes that no evidence was provided to indicate that the resistant dextrin in the product was different from other non-digestible carbohydrates in relation to the claimed effect.

The Panel considers that in the context of this application the main characteristic of Nutriose[®]06 which contributes to the claimed effect (i.e. reduction of post-prandial glycaemic responses by replacing glycaemic carbohydrates in foods and beverages) is the non-digestibility of the resistant dextrin contained in Nutriose[®]06. The Panel also considers that this characteristic, which is relevant to the claimed effect, is not unique to resistant dextrin but is common to other non-digestible carbohydrates (e.g. non-starch polysaccharides and resistant oligosaccharides) because, similar to resistant dextrin, non-digestible carbohydrates are resistant to hydrolysis and absorption in the small intestine and therefore do not contribute to post-prandial glycaemia.

This opinion applies to non-digestible carbohydrates (e.g. non-starch polysaccharides, resistant oligosaccharides and resistant starch; EFSA NDA Panel, 2010), which should replace glycaemic carbohydrates in foods or beverages in order to obtain the claimed effect.

The Panel considers that the food constituent, non-digestible carbohydrates (including resistant dextrin in Nutriose[®]06), which is the subject of the health claim, and the food constituent (i.e. glycaemic carbohydrates) that non-digestible carbohydrates should replace in foods or beverages are both sufficiently characterised in relation to the claimed effect.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant relates to the reduction of post-prandial blood glucose responses. The target population proposed by the applicant is individuals wishing to reduce their post-prandial glycaemic responses.

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 Medline, using the search term “Nutriose”. Randomised controlled trials performed with Nutriose[®]06 in healthy subjects on post-prandial glycaemia were considered eligible. No such published studies were identified.

The applicant submitted six unpublished human studies (Donazzolo and Latreille-Barbier, 2000; GI labs, 2007; Thondre and Lightowler, 2012; Yuexin et al., 2012; Gendre, 2013; Salvi, 2013; all claimed as proprietary by the applicant) as being pertinent to the health claim. In these studies, the consumption of Nutriose[®]06 was shown to induce a significant reduction of post-prandial glycaemic and insulinaemic responses when compared with glucose.

A claim on non-digestible carbohydrates and reduction of post-prandial glycaemic responses has already been assessed by the Panel with a favourable outcome (EFSA NDA Panel, 2014). The Panel took into account that consumption of non-digestible carbohydrates results in reduced post-prandial blood glucose (and insulinaemic) responses compared with the consumption of sugars on a weight-by-weight basis owing to the non-digestibility in the small intestine and to a decrease in the amount of available carbohydrates, and that the consumption of foods/drinks in which non-digestible carbohydrates replaced sugars induced lower post-prandial glycaemic and insulinaemic responses than sugar-containing foods/drinks.

The Panel considers that the outcome, including the proposed wording and the conditions of use, of the previous evaluation on the replacement of sugars with non-digestible carbohydrates applies to the replacement of all glycaemic carbohydrates with non-digestible carbohydrates.

The Panel concludes that a cause and effect relationship has been established between the consumption of foods/beverages containing non-digestible carbohydrates and a reduction of post-prandial glycaemic responses as compared with foods/beverages containing glycaemic carbohydrates. The Panel notes that non-digestible carbohydrates have a neutral taste and cannot substitute for the sweet taste of sugars.

The Panel could have reached this conclusion without the human studies (Donazzolo and Latreille-Barbier, 2000; GI labs, 2007; Thondre and Lightowler, 2012; Yuexin et al., 2012; Gendre, 2013; Salvi, 2013) claimed as proprietary by the applicant.

CONCLUSIONS

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

- The food constituent, non-digestible carbohydrates (including resistant dextrin in Nutriose[®]06), which is the subject of the health claim, and the food constituent (i.e. glycaemic carbohydrates) that non-digestible carbohydrates should replace in foods or beverages, are both sufficiently characterised in relation to the claimed effect.
- The claimed effect proposed by the applicant relates to the reduction of post-prandial blood glucose responses. The target population proposed by the applicant is individuals wishing to reduce their post-prandial glycaemic responses. 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 foods/beverages containing non-digestible carbohydrates and a reduction of post-prandial glycaemic responses as compared with foods/beverages containing glycaemic carbohydrates.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on Nutriose®06 and reduction of post-prandial glycaemic responses pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0410_IT). January 2014. Submitted by Roquette Italia S.P.A.

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