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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to “non-fermentable” carbohydrates and maintenance of tooth mineralisation by decreasing tooth demineralisation 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 Roquette Frères, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, 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[®] which should replace “fermentable carbohydrates” in foods or beverages in order to obtain the claimed effect, i.e. maintenance of tooth mineralisation by reducing tooth demineralisation. From the information provided, the Panel noted that the main characteristic of carbohydrates which is relevant to the claimed effect is the rate and amount of acid production resulting from their fermentation by saccharolytic bacteria in the oral cavity. This Opinion applies to “non-fermentable” carbohydrates, which should replace “fermentable” carbohydrates in foods or beverages in order to obtain the claimed effect. The Panel considers that maintaining tooth mineralisation by reducing tooth demineralisation resulting from acid production in plaque caused by the fermentation of carbohydrates is a beneficial physiological effect. The Panel concludes that a cause and effect relationship has been established between the consumption of foods/beverages containing “fermentable” carbohydrates at an exposure frequency of four or more times daily and an increased tooth demineralisation, and that the consumption of foods/beverages containing “non-fermentable” carbohydrates instead of “fermentable” carbohydrates may maintain tooth mineralisation by decreasing tooth demineralisation. In order to bear the claim, “fermentable” carbohydrates should be replaced in foods or beverages by “non-fermentable” carbohydrates, so that consumption of such foods or beverages does not lower plaque pH below 5.7 during and up to 30 minutes after consumption, and does not lead to dental erosion.

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¹ On request from the Competent Authority of France following an application by Roquette Frères, Question No EFSA-Q-2013-00040, adopted on 10 July 2013.

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KEY WORDS

Nutriose[®], dietary fibre, non-fermentable carbohydrates, tooth mineralisation, tooth demineralisation, enamel, health claims

SUMMARY

Following an application from Roquette Frères, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, 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[®] and maintenance of tooth mineralisation by reducing tooth demineralisation.

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 applicant stated that the food that is the subject of the health claim is Nutriose[®], which should replace “fermentable carbohydrates” (i.e. sugars and starches) in foods or beverages in order to obtain the claimed effect (i.e. “maintenance of tooth mineralisation by decreasing tooth demineralisation”).

From the information provided, the Panel notes that the main characteristic of carbohydrates which is relevant to the claimed effect is the rate and amount of acid production resulting from their fermentation by saccharolytic bacteria in the oral cavity, and that this characteristic can be measured *in vivo* or *in situ* by plaque pH-telemetry under standard conditions.

In this context, and for the purpose of this Opinion, “fermentable” carbohydrates are defined as carbohydrates or carbohydrate mixtures as consumed in foods or beverages that lower plaque pH, as determined *in vivo* or *in situ* by plaque pH telemetry tests, below a conservative value of 5.7 by bacterial fermentation during and up to 30 minutes after consumption. Also, for the purpose of this Opinion, the term “non-fermentable” carbohydrates denotes carbohydrates or carbohydrate mixtures as consumed in foods or beverages that do not lower plaque pH below 5.7 under the same test conditions.

This Opinion applies to “non-fermentable” carbohydrates, which should replace “fermentable” carbohydrates in foods or beverages in order to obtain the claimed effect. The Panel notes that “non-fermentable” carbohydrates which have a neutral taste cannot substitute for the sweet taste of sugar.

The Panel considers that the food constituent, “non-fermentable” carbohydrates, which is the subject of the health claim, and the food constituent (i.e. “fermentable” carbohydrates) that “non-fermentable” carbohydrates should replace in foods or drinks are sufficiently characterised in relation to the claimed effect.

The claimed effect is “maintenance of tooth mineralisation by decreasing tooth demineralisation”. The target population proposed by the applicant is the general population. The Panel considers that maintaining tooth mineralisation by reducing tooth demineralisation resulting from acid production in plaque caused by the fermentation of carbohydrates is a beneficial physiological effect.

The evidence available from consensus opinions, reports from authoritative bodies and reviews shows that an increased risk of dental caries in children is associated with a high frequency of intake of “cariogenic” sugars, and that frequent consumption of sweets, confectionery products and sugar-containing drinks is associated with a higher risk of caries. Foods rich in starch, especially when the starch molecule is easily available to degradation by amylase, may also contribute to the higher risk of caries.

The evidence available from consensus opinions, reports from authoritative bodies and reviews indicates that the decrease in pH in plaque as a consequence of metabolic acid production by saccharolytic bacteria when exposed to fermentable carbohydrates (i.e. sugars and starches) may promote demineralisation and prevent remineralisation of hydroxyapatite crystals. Tooth hydroxyapatite crystals are very resistant to dissolution at neutral pH, but their solubility drastically

increases as pH drops. The Panel considers that foods lowering plaque pH, as determined *in vivo* or *in situ* by pH telemetry, below a conservative value of 5.7 by bacterial fermentation during and up to 30 minutes after consumption may promote demineralisation and prevent remineralisation of hydroxyapatite crystals.

A claim on a number of sugar replacers and maintenance of tooth mineralisation by decreasing tooth demineralisation has already been assessed with a favourable outcome. The Panel considers that the scientific substantiation and proposed conditions of use for the above-mentioned claim on sugar replacers also apply to “non-fermentable” carbohydrates, which should replace “fermentable carbohydrates” in foods and beverages in order to obtain the claimed effect.

The Panel concludes that a cause and effect relationship has been established between the consumption of foods/beverages containing “fermentable” carbohydrates at an exposure frequency of four or more times daily and an increased tooth demineralisation, and that the consumption of foods/beverages containing “non-fermentable” carbohydrates instead of “fermentable” carbohydrates may maintain tooth mineralisation by decreasing tooth demineralisation, provided that such foods/beverages do not lead to dental erosion.

The Panel considers that in order to bear the claim, “fermentable” carbohydrates should be replaced in foods or beverages by “non-fermentable” carbohydrates, so that consumption of such foods or beverages does not lower plaque pH below 5.7 during and up to 30 minutes after consumption, and does not lead to dental erosion.

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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 14/01/2013.
- 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 14/02/2013, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 19/03/2013, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 08/04/2013.
- On 25/04/2013, 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 02/05/2013 and restarted on 17/05/2013, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 21/05/2013, EFSA received the requested information (which was made available to EFSA in electronic format on 17/05/2013).
- During its meeting on 10/07/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to “non-fermentable” carbohydrates and maintenance of tooth mineralisation by reducing tooth demineralisation.

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-fermentable” carbohydrates and maintenance of tooth mineralisation by reducing tooth demineralisation.

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 “non-fermentable” carbohydrates, a positive assessment of their safety, nor a decision on whether “non-fermentable” 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.

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: Roquettes Frères, FR-62136 Lestrem, France.

The application includes a request for the protection of proprietary data for three unpublished studies (Imfeld, 2002, 2010a, 2010b), in accordance with Article 21 of Regulation (EC) No 1924/2006.

Food/constituent as stated by the applicant

According to the applicant, the food/constituent is Nutriose[®], which is derived from wheat or maize, and which contains on average 85 % resistant dextrin.

Health relationship as claimed by the applicant

According to the applicant, a decrease of pH in plaque as a consequence of acid production by metabolically active saccharolytic bacteria exposed to fermentable carbohydrates (i.e. sugars and starches) may promote demineralisation and prevent remineralisation of the hydroxyapatite crystals in tooth enamel.

The intake of Nutriose[®] is claimed by the applicant not to lower the pH in plaque to a critical level (typically around pH 5.5) associated with tooth enamel dissolution.

Hence, according to the applicant, the consumption of food/drinks containing Nutriose[®] instead of sugar may help maintain tooth mineralisation by decreasing tooth demineralisation.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “Frequent consumption of sugars contributes to tooth demineralisation. Consumption of food/drinks containing Nutriose[®] instead of sugar may help maintain tooth mineralisation by decreasing tooth demineralisation”.

Specific conditions of use as proposed by the applicant

The applicant has proposed to use Nutriose[®] as a substitute for “sugar”, sucrose or starch in foods and beverages. Up to 45 g (for adults) or 20 g (for children) of Nutriose[®] may be consumed per day. The target population is the general population.

ASSESSMENT

1. Characterisation of the food/constituent

The applicant states that the food that is the subject of the health claim is Nutriose[®], which should replace “fermentable carbohydrates” (i.e. sugars and starches) in foods or beverages in order to obtain the claimed effect (i.e. “maintenance of tooth mineralisation by decreasing tooth demineralisation”).

Nutriose[®] is produced from wheat or maize starch by dry roasting under acidic conditions (i.e. dextrinisation). The ensuing dextrin is treated enzymatically with α -amylase and then purified by chromatographic partitioning in order to minimise the content of mono- and disaccharides. During the manufacturing process, linear and/or branched glucosidic 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 polymerization

from 12 to 25, and less than 0.5 % of mono- and disaccharides. An overview of the manufacturing process, batch to batch variability, stability and microbiological analysis was provided.

The taste of Nutriose[®] is described by the applicant as neutral. According to the applicant, Nutriose[®] can be used to replace “fermentable carbohydrates” in a variety of foods, such as cereals, dairy products, confectionery and beverages.

Tooth hydroxyapatite crystals are very resistant to dissolution at neutral pH, but their solubility drastically increases as pH drops. Typically, the critical pH for dental enamel is around 5.5 (FDA, 1996; EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011). The applicant claims that the decrease in pH in plaque as a consequence of metabolic acid production by saccharolytic bacteria when exposed to fermentable carbohydrates (i.e. sugars and starches) may promote demineralisation and prevent remineralisation of the hydroxyapatite crystals. The applicant also claims that the intake of Nutriose[®] does not lower the pH in plaque to a critical level (typically around pH 5.5) associated with tooth enamel dissolution, as shown in three provided studies (Imfeld, 2002, 2010a, 2010b, unpublished, claimed as proprietary by the applicant) which included 18 plaque pH-telemetry tests carried out with 10 % solutions of Nutriose[®].

From the information provided, the Panel notes that the main characteristic of carbohydrates which is relevant to the claimed effect is the rate and amount of acid production resulting from their fermentation by saccharolytic bacteria in the oral cavity, and that this characteristic can be measured *in vivo* or *in situ* by plaque pH-telemetry under standard conditions. The Panel also notes that the rate, and the extent to which, carbohydrates are fermented by saccharolytic bacteria in the oral cavity depends on the structure of carbohydrates (e.g. chain length and type of glycosidic bonds), on other characteristics (e.g. accessibility of carbohydrates to bacterial/human enzymes, and other food constituents present) of the food or beverage in which carbohydrates are consumed, and to individual factors (e.g. oral microbiota) (Moynihan, 1998).

In this context, and for the purpose of this Opinion, “fermentable” carbohydrates are defined as carbohydrates or carbohydrate mixtures as consumed in foods or beverages that lower plaque pH, as determined *in vivo* or *in situ* by plaque pH telemetry tests, below a conservative value of 5.7 by bacterial fermentation during and up to 30 minutes after consumption (FDA, 1996). Also, for the purpose of this Opinion, the term “non-fermentable” carbohydrates denotes carbohydrates or carbohydrate mixtures as consumed in foods or beverages that do not lower plaque pH below 5.7 under the same test conditions.

EFSA noted that replacing “fermentable” carbohydrates with any “non-fermentable” carbohydrate would contribute to the claimed effect, and therefore requested the applicant to indicate which characteristics or properties of Nutriose[®] make Nutriose[®] unique as compared to other “non-fermentable” carbohydrates in relation to the claimed effect, and which could justify a product-specific claim. In response, the applicant indicated that Nutriose[®] is different from other non-viscous fibres on the market due to its low content of monosaccharides, disaccharides and low molecular weight oligosaccharides; that non-viscous soluble dietary fibres are highly fermented in the colon; and that non-viscous soluble dietary fibres other than Nutriose[®] are also fermented in the mouth because they contain disaccharides and monosaccharides at levels that promote fermentation by saccharolytic bacteria.

The Panel notes that the characteristic of Nutriose[®] which is relevant for the claimed effect (i.e. not lowering plaque pH below 5.7 during and up to 30 minutes after consumption) is not unique to Nutriose[®], but common to other “non-fermentable” carbohydrates (e.g. polyols, D-tagatose, isomaltulose, and polydextrose). A claim related to the “non-fermentable” carbohydrates xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose and maintenance of tooth mineralisation by decreasing tooth demineralisation has

already been assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011). The claim referred to the replacement of sugars in foods or drinks which reduce plaque pH below 5.7 by these food constituents (“non-fermentable” carbohydrates) or a combination, so that consumption of such foods or drinks does not lower plaque pH (as assessed by plaque pH telemetry) below 5.7 during and up to 30 minutes after consumption, and does not lead to dental erosion.

This Opinion applies to “non-fermentable” carbohydrates, which should replace “fermentable” carbohydrates in foods or beverages in order to obtain the claimed effect. The Panel notes that “non-fermentable” carbohydrates which have a neutral taste cannot substitute for the sweet taste of sugar.

The Panel considers that the food constituent, “non-fermentable” carbohydrates, which is the subject of the health claim, and the food constituent (i.e. “fermentable” carbohydrates) that “non-fermentable” carbohydrates should replace in foods or drinks are sufficiently characterised in relation to the claimed effect.

2. Relevance of the claimed effect to human health

The claimed effect is “maintenance of tooth mineralisation by decreasing tooth demineralisation”. The target population proposed by the applicant is the general population.

Demineralisation of tooth tissues can occur following acid production caused by the fermentation of carbohydrates by acid-producing bacteria in dental biofilms. The effect may be balanced by remineralisation when pH is neutralised and a state of calcium and phosphate supersaturation is achieved. If demineralisation is not balanced by remineralisation then net demineralisation of tooth tissues results which, if sustained, can lead to dental caries. Demineralisation of tooth tissues can also occur as a result of consumption of dietary acids in foods or beverages, and frequent consumption can lead to dental erosion. Dental caries and dental erosion are diseases with a high prevalence in the EU.

The Panel considers that maintaining tooth mineralisation by reducing tooth demineralisation resulting from acid production in plaque caused by the fermentation of carbohydrates is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The evidence available from consensus opinions, reports from authoritative bodies and reviews shows that an increased risk of dental caries in children is associated with a high frequency (more than about four times daily) of intake of “cariogenic” sugars (mainly sucrose, glucose and fructose), rather than with the total amount of dietary sugars, and that frequent consumption of sweets, confectionery products and sugar-containing drinks is associated with a higher risk of caries (DoH, 1991; Moynihan and Petersen, 2004; IoM, 2005; Anderson et al., 2009; EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2010). Foods rich in starch, especially when the starch molecule is easily available to degradation by amylase, may also contribute (FDA, 1996; EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2010).

The evidence available from consensus opinions, reports from authoritative bodies and reviews also indicates that the decrease in pH in plaque as a consequence of metabolic acid production by saccharolytic bacteria when exposed to fermentable carbohydrates (i.e. sugars and starches) may promote demineralisation and prevent remineralisation of hydroxyapatite crystals. Tooth hydroxyapatite crystals are very resistant to dissolution at neutral pH, but their solubility drastically increases as pH drops. Typically, the critical pH for dental enamel is around 5.5. The Panel considers that foods lowering plaque pH, as determined *in vivo* or *in situ* by pH telemetry, below a conservative value of 5.7 by bacterial fermentation during and up to 30 minutes after consumption may promote demineralisation and prevent remineralisation of hydroxyapatite crystals (FDA, 1996). The Panel

notes that demineralisation of tooth tissues can also occur as a result of consumption of dietary acids in foods or beverages, and that frequent consumption can lead to dental erosion.

A claim on the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose and maintenance of tooth mineralisation by decreasing tooth demineralisation has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011).

The Panel notes that the sugar replacers mentioned above are “non-fermentable” carbohydrates as defined in this Opinion. The Panel also notes that the food constituents to be replaced in order to obtain the claimed effect, sugars, are “fermentable” carbohydrates as defined in this Opinion.

The Panel considers that the scientific substantiation and proposed conditions of use for the above-mentioned claim on sugar replacers also apply to “non-fermentable” carbohydrates, which should replace “fermentable carbohydrates” in foods and beverages in order to obtain the claimed effect.

The Panel concludes that a cause and effect relationship has been established between the consumption of foods/beverages containing “fermentable” carbohydrates at an exposure frequency of four or more times daily and an increased tooth demineralisation, and that the consumption of foods/beverages containing “non-fermentable” carbohydrates instead of “fermentable” carbohydrates may maintain tooth mineralisation by decreasing tooth demineralisation, provided that such foods/beverages do not lead to dental erosion.

The Panel could have reached this conclusion without the human studies claimed as proprietary by the applicant (Imfeld, 2002, 2010a, 2010b, unpublished).

4. Panel’s comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: “Frequent consumption of “fermentable” carbohydrates contributes to tooth demineralisation. Consumption of foods/beverages containing “non-fermentable” carbohydrates instead of “fermentable” carbohydrates may help maintain tooth mineralisation by decreasing tooth demineralisation”.

5. Conditions and restrictions of use

The Panel considers that in order to bear the claim, “fermentable” carbohydrates should be replaced in foods or beverages (which reduce plaque pH below 5.7) by “non-fermentable” carbohydrates, so that consumption of such foods or beverages does not lower plaque pH below 5.7 during and up to 30 minutes after consumption, and does not lead to dental erosion.

The Panel notes that “non-fermentable” carbohydrates which have a neutral taste cannot substitute for the sweet taste of sugar.

CONCLUSIONS

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

- The food constituent, “non-fermentable” carbohydrates, which is the subject of the health claim, and the food constituent (i.e. “fermentable” carbohydrates) that “non-fermentable” carbohydrates should replace in foods or drinks are sufficiently characterised in relation to the claimed effect
- The claimed effect proposed by the applicant is “maintenance of tooth mineralisation by decreasing tooth demineralisation”. The target population proposed by the applicant is the

general population. Maintaining tooth mineralisation by reducing tooth demineralisation resulting from acid production in plaque caused by the fermentation of carbohydrates is a beneficial physiological effect.

- A cause and effect relationship has been established between the consumption of foods/beverages containing “fermentable” carbohydrates at an exposure frequency of four or more times daily and an increased tooth demineralisation; consumption of foods/beverages containing “non-fermentable” carbohydrates instead of “fermentable” carbohydrates may maintain tooth mineralisation by decreasing tooth demineralisation, provided that such foods/beverages do not lead to dental erosion.
- The following wording reflects the scientific evidence: “Frequent consumption of “fermentable” carbohydrates contributes to tooth demineralisation. Consumption of foods/beverages containing “non-fermentable” carbohydrates instead of “fermentable” carbohydrates may help maintain tooth mineralisation by decreasing tooth demineralisation”.
- In order to bear the claim, “fermentable” carbohydrates should be replaced in foods or beverages (which reduce plaque pH below 5.7) by “non-fermentable” carbohydrates, so that consumption of such foods or beverages does not lower plaque pH below 5.7 during and up to 30 minutes after consumption, and does not lead to dental erosion.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on Nutriose[®] and maintenance of tooth mineralisation by decreasing tooth demineralisation pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0374_FR). January 2013. Submitted by Roquette Frères.

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