



**EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to AlphaGOS® 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 AlphaGOS<sup>®</sup> and a reduction of post-prandial glycaemic responses pursuant to Article 13(5) of Regulation (EC) No 1924/2006<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

Following an application from Olygose, 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 AlphaGOS<sup>®</sup> and a reduction of post-prandial glycaemic responses. Non-digestible carbohydrates, including  $\alpha$ -galacto-oligosaccharides in AlphaGOS<sup>®</sup>, 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 sugars 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. sugars) 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 sugar-containing foods/beverages.

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#### KEY WORDS

$\alpha$ -galacto-oligosaccharides,  $\alpha$ -GOS, AlphaGOS<sup>®</sup>, non-digestible carbohydrates, post-prandial glycaemic responses, health claims

<sup>1</sup> On request from the Competent Authority of France following an application by Olygose, Question No EFSA-Q-2014-00044, adopted on 18 September 2014.

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<sup>3</sup> 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.

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## SUMMARY

Following an application from Olygose, 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 AlphaGOS<sup>®</sup> 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  $\alpha$ -GOS in AlphaGOS<sup>®</sup>, which should replace sugars 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  $\alpha$ -GOS in AlphaGOS<sup>®</sup> but common to other non-digestible carbohydrates (e.g. non-starch polysaccharides, resistant starch) because, similar to  $\alpha$ -GOS, 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 sugars (i.e. monosaccharides and disaccharides) 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. sugars) 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 identified one unpublished human study 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, 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 sugar-containing foods/beverages.

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## BACKGROUND

Regulation (EC) No 1924/2006<sup>4</sup> 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 21/01/2014.
- 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.
- The scientific evaluation procedure started on 18/03/2014.
- 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 16/05/2014 and was restarted on 31/05/2014, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 04/06/2014, EFSA received the requested information (which was made available to EFSA in electronic format on 28/05/2014).
- 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  $\alpha$ -GOS in AlphaGOS<sup>®</sup>) 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.

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<sup>4</sup> 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:** Olygose, Parc technologique des Rives de l'Oise, BP 50149, 60201 Compiègne Cedex, France.

The application includes a request for the protection of proprietary data for one unpublished study (Zair et al., 2011), 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 AlphaGOS<sup>®</sup> which contains a mix of  $\alpha$ -galacto-oligosaccharides ( $\alpha$ -GOS) with a degree of polymerisation of mainly three and four. AlphaGOS<sup>®</sup> is commercialised in syrup and in powder form.

### Health relationship as claimed by the applicant

According to the applicant, the consumption of foods/drinks containing AlphaGOS<sup>®</sup> instead of sugars leads to a reduced blood glucose rise. The applicant claims that this effect is a result of the  $\alpha$ -galacto-oligosaccharides in AlphaGOS<sup>®</sup> constituting non-digestible carbohydrates. Contrary to digestible carbohydrates, the  $\alpha$ -galacto-oligosaccharides in AlphaGOS<sup>®</sup> are resistant to gastrointestinal digestive enzymes, are not absorbed in the small intestine and therefore do not lead to a rise in blood glucose.

### Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "Consumption of foods or drinks containing AlphaGOS<sup>®</sup> instead of sugar induces a lower blood glucose rise after their consumption compared to sugar-containing foods or drinks".

### Specific conditions of use as proposed by the applicant

According to the applicant, sugars in foods or drinks should be replaced by AlphaGOS<sup>®</sup> so that amounts of sugars in foods or drinks are reduced by at least the amount referred to in the Annex of Regulation (EC) No 1924/2006. The proposed target population is individuals 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 AlphaGOS<sup>®</sup>, which should replace sugars in foods or beverages in order to obtain the claimed effect (i.e. reduction of post-prandial glycaemic responses).

AlphaGOS<sup>®</sup> contains a mixture of  $\alpha$ -GOS with a degree of polymerisation (DP) of mainly three and four. The  $\alpha$ -GOS in AlphaGOS<sup>®</sup> consist of  $\alpha$ -1,6-linked chains of D-galactose linked to the 6-position of D-glucose. AlphaGOS<sup>®</sup>, which contains at least 95 % of  $\alpha$ -GOS, is obtained by acid or enzymatic hydrolysis of raffinose family oligosaccharides (i.e. raffinose, stachyose and verbascose) extracted and purified from pea (*Pisum sativum*). AlphaGOS<sup>®</sup> is commercialised in syrup and in powder form. An overview of the manufacturing process, stability data and batch-to-batch variability were provided.

The applicant proposes to replace sugars in a range of foods and drinks (e.g. in hard candies, beverages, jams, fruit and cereal bars) with AlphaGOS<sup>®</sup>.

From the information provided, the Panel notes that the main characteristic of AlphaGOS<sup>®</sup> which contributes to the claimed effect is the non-digestibility of the  $\alpha$ -GOS contained in AlphaGOS<sup>®</sup> in the small intestine, and that replacing digestible (glycaemic) carbohydrates (e.g. sugars) by any non-digestible carbohydrate would contribute to the claimed effect. The applicant was requested to indicate which characteristics or properties of the  $\alpha$ -GOS in AlphaGOS<sup>®</sup> make the  $\alpha$ -GOS in AlphaGOS<sup>®</sup> unique as compared with other non-digestible carbohydrates (e.g. non-starch polysaccharides and resistant starch) in relation to the claimed effect. In reply, the applicant indicated that the  $\alpha$ -GOS in AlphaGOS<sup>®</sup> do not have specific characteristics or properties which make them unique as compared with other non-digestible carbohydrates in relation to the claimed effect.

The Panel notes that the characteristic which is most relevant to the claimed effect (i.e. reduction of post-prandial glycaemic responses by replacing sugars in foods and beverages) is not unique to  $\alpha$ -GOS but is common to other non-digestible carbohydrates (e.g. non-starch polysaccharides, resistant starch) because, similar to  $\alpha$ -GOS, 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 sugars (i.e. monosaccharides and disaccharides) in foods or beverages in order to obtain the claimed effect. The Panel notes that non-digestible carbohydrates have a neutral taste and cannot substitute for the sweet taste of sugars.

The Panel considers that the food constituent, non-digestible carbohydrates (including  $\alpha$ -GOS in AlphaGOS<sup>®</sup>), which is the subject of the health claim, and the food constituent (i.e. sugars) 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 PubMed, Science Direct, Wiley Interscience and Google Scholar, using the search string (“galactooligosaccharides” OR “GOS” OR “oligogalactose” OR “AlphaGOS”) AND (“glycaemia” OR “glycemia” OR “insulinaemia” OR “insulinemia” OR “blood glucose” OR “blood sugar”), and looking for published and unpublished literature in English or French. Studies were included if they were carried out with AlphaGOS<sup>®</sup>, had as primary outcome post-prandial glycaemic responses, and were performed with healthy adults or subjects with impaired glucose tolerance. Studies were excluded if they were carried out with a food constituent whose



specifications were different from those of AlphaGOS<sup>®</sup> (e.g.  $\beta$ -galacto-oligosaccharides produced by enzymatic conversion of lactose).

The applicant identified one unpublished human study (Zair et al., 2011, claimed as proprietary by the applicant) as being pertinent to the health claim. In this study, the consumption of AlphaGOS<sup>®</sup> 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 non-digestible carbohydrates and reduction of post-prandial glycaemic responses 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 sugar-containing foods/beverages. 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 study (Zair et al., 2011) 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  $\alpha$ -GOS in AlphaGOS<sup>®</sup>), which is the subject of the health claim, and the food constituent (i.e. sugars) 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 sugar-containing foods/beverages.

## DOCUMENTATION PROVIDED TO EFSA

Health claim application on AlphaGOS<sup>®</sup> and reduction of post-prandial glycaemic responses pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0407\_FR). January 2014. Submitted by Olygose.

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- Zair Y, Pichelin M, Desmars M, Prevel J-M and Housez B, 2011 (unpublished, claimed as proprietary by the applicant). Evaluation of the glycaemic and insulinaemic response of OLY GOS 570. Protocol No PEC10591, 45 pp.

## ABBREVIATIONS

$\alpha$ -GOS             $\alpha$ -galacto-oligosaccharides

DP                    degree of polymerisation