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EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on the substantiation of a health claim related to Bimuno® GOS and reducing gastro - intestinal discomfort 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 Bimuno[®] GOS and reducing gastro-intestinal discomfort 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 Clasado Limited, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Malta, 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 Bimuno[®] GOS and reducing gastro-intestinal discomfort. The food constituent, Bimuno[®] GOS, a mixture of β -galacto-oligosaccharides, which is the subject of the health claim, is sufficiently characterised. The claimed effect proposed by the applicant is “reduce bloating, flatulence and abdominal pain. These effects can be described collectively as abdominal discomfort” and the target population proposed by the applicant is the general adult population. Reducing gastro-intestinal discomfort is a beneficial physiological effect. A health claim on Bimuno[®] GOS and reducing gastro-intestinal discomfort has already been assessed by the Panel with an unfavourable outcome. The supplementary information submitted by the applicant in this application did not provide evidence that could be used for the scientific substantiation of this claim.

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KEY WORDS

Bimuno[®], GOS, β -galacto-oligosaccharides, gastro-intestinal discomfort, health claims

¹ On request from the Competent Authority of Malta following an application by Clasado Limited, Question No EFSA-Q-2012-01007, adopted on 30 May 2013.

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SUMMARY

Following an application from Clasado Limited, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Malta, 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 Bimuno[®] GOS and reducing gastro-intestinal discomfort.

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 constituent that is the subject of the health claim is Bimuno[®] GOS, a mixture of β -galacto-oligosaccharides, which is produced through conversion of lactose by enzymes from *Bifidobacterium bifidum* NCIMB 41171. The Panel considers that Bimuno[®] GOS is sufficiently characterised.

The claimed effect proposed by the applicant is “reduce bloating, flatulence and abdominal pain. These effects can be described collectively as abdominal discomfort”. The target population proposed by the applicant is the general adult population. The Panel considers that reducing gastro-intestinal discomfort is a beneficial physiological effect.

The applicant identified five human intervention studies, three non-human studies and one review publication as being pertinent to the health claim.

A health claim on Bimuno[®] GOS and reducing gastro-intestinal discomfort has already been assessed by the Panel with an unfavourable outcome.

All the references, except for the review publication, provided by the applicant for the scientific substantiation of this claim were already considered in the previous assessment. The Panel notes that the narrative review does not provide original data in addition to the individual studies submitted for substantiation. Additional information in relation to two human intervention studies was also provided. The Panel notes that the additional information provided on these studies did not address important methodological limitations which were identified by the Panel in its previous Opinion. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

A health claim on Bimuno[®] GOS and reducing gastro-intestinal discomfort has already been assessed by the Panel with an unfavourable outcome. The supplementary information submitted by the applicant did not provide evidence that could be used for the scientific substantiation of this claim.

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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 12/12/2012.
- 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 21/01/2013, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 07/02/2013, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 20/02/2013.
- 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 and the clock was stopped on 03/05/2013, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 15/05/2013, EFSA received the requested information (which was made available to EFSA in electronic format on 13/05/2013) and the clock was restarted, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- During its meeting on 30/05/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to Bimuno[®] GOS and reducing gastro-intestinal discomfort.

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: Bimuno[®] GOS and reducing gastro-intestinal discomfort.

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 Bimuno[®] GOS, a positive assessment of its safety, nor a decision on whether Bimuno[®] GOS 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: Clasado Limited, Regent House, Office 25, Bisazza Street, Sliema, SLM 1641, Malta.

The application includes a request for the protection of proprietary data in accordance with Article 21 of Regulation (EC) No 1924/2006 for seven published studies (Tzortzis et al., 2005a, b; Goulas et al., 2007; Depeint et al., 2008; Vulevic et al., 2008; Silk et al., 2009; Drakoularakou et al., 2010) and one unpublished study by Vulevic et al. The application also includes a request for protection of proprietary data for analytical and stability data pertaining to the manufacturing process.

Food/constituent as stated by the applicant

According to the applicant, the food constituents that are the subject of the health claim are galacto-oligosaccharides from Bimuno[®] (Bimuno[®] GOS), which are a mixture of β -linked galacto-oligosaccharides (β -1 \rightarrow 3, β -1 \rightarrow 4, β -1 \rightarrow 6) with a degree of polymerisation ranging between 2 and 5, and α -linked galacto-oligosaccharides (α -1 \rightarrow 6) with a degree of polymerisation of 2.

Health relationship as claimed by the applicant

According to the applicant, Bimuno[®] GOS acts to reduce bloating, flatulence and abdominal pain. These effects can be described collectively as "abdominal discomfort".

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "Regular daily consumption of 1.37 g galacto-oligosaccharides from Bimuno[®] may reduce abdominal discomfort".

Specific conditions of use as proposed by the applicant

According to the applicant, 1.37 g of galacto-oligosaccharides from Bimuno[®] should be consumed once daily for a minimum of 7 days.

The target population as proposed by the applicant is the general male and female adult population.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is Bimuno[®] GOS, a mixture of β -galacto-oligosaccharides, which is produced through conversion of lactose by enzymes from *Bifidobacterium bifidum* NCIMB 41171.

Based on chemical analyses that were provided on five batches, the Bimuno[®] powder contains a mixture of β -galacto-oligosaccharides (Bimuno[®] GOS, 47-53 %), lactose (25-35 %), glucose (6-10 %) and galactose (4-7 %).

Bimuno[®] GOS comprises a mixture of β -linked galacto-oligosaccharides (β -1 \rightarrow 3, β -1 \rightarrow 4, β -1 \rightarrow 6) and α -linked galacto-oligosaccharides (α -1 \rightarrow 6). The ratio of β -linked galacto-oligosaccharides to α -linked galacto-oligosaccharides is 93:7.

The results from the stability tests showed that the Bimuno[®] powder was stable for up to two years.

The Panel considers that the food constituent, Bimuno[®] GOS, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is “reduce bloating, flatulence and abdominal pain. These effects can be described collectively as abdominal discomfort”. The target population proposed by the applicant is the general adult population.

Reducing gastro-intestinal discomfort is considered an indicator of improved gastro-intestinal function. Appropriate outcome measures of the claimed effect in human studies include validated questionnaire(s) on severity and frequency of symptoms (e.g. abdominal pain, cramp, bloating, straining, borborygmi [rumbling] and sensation of incomplete evacuation).

The Panel considers that reducing gastro-intestinal discomfort is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed with the following key words: abdominal pain prebiotic, bloating prebiotic, flatulence prebiotic, IBS prebiotic, galactooligosaccharide bloating, galactooligosaccharide digestion, galactooligosaccharide gastrointestinal, bloating colonic microbiota, galactooligosaccharide, trans galactooligosaccharide, transgalactooligosaccharide, transgalactooligosaccharide. No restrictions were applied. Hand searches were also performed by the applicant.

The applicant identified through the literature search four human intervention studies (Depeint et al. 2008; Vulevic et al., 2008; Silk et al., 2009; Drakoularakou et al., 2010) and one review publication (Tzortzis, 2009) as being pertinent to the health claim. The applicant also provided one unpublished human intervention study (Vulevic et al., unpublished) and three non-human studies (Tzortzis et al., 2005a; Searle et al., 2009, 2010) for the scientific substantiation of the claim.

All of these human and non-human studies were already submitted by the applicant in a previous application for the same claim, which was assessed by the Panel with an unfavourable outcome (EFSA NDA Panel, 2011) and where the study by Vulevic et al. (unpublished) was referred to as Clasado Ltd. (unpublished, claimed as proprietary by the applicant). The present application contains, in addition, a non pre-planned intention-to-treat analysis (ITT) of data for the study by Vulevic et al. (unpublished), weekly results for secondary outcomes (e.g. defecation, stool consistency, flatulence, abdominal pain, bloating, and a composite score of symptoms) in the population of completers of the study by Silk et al. (2009), and the narrative review by Tzortzis (2009).

The Panel notes that in providing a non pre-planned ITT analysis for the study by Vulevic et al. (unpublished), the applicant did not address the important methodological limitations (e.g. short duration of the intervention, and inappropriateness of the original statistical analysis for the cross-over design of the study) of the study. These important methodological limitations of the study were identified by the Panel in its previous Opinion. The Panel considers that no conclusions can be drawn from the study by Vulevic et al. (unpublished) for the scientific substantiation of the claim.

The additional information provided by the applicant for the study by Silk et al. (2009) consists of weekly values for some secondary outcomes which were only reported and analysed for the baseline, end-of-placebo, and end-of-treatment time points in the original study. The Panel notes that in providing this additional information, the applicant did not address the important methodological limitations (e.g. high dropout rate, multiplicity of outcomes not taken into account in the data analysis, statistical methods and results insufficiently described, and no ITT analysis) of the study that were identified by the Panel in its previous Opinion. The Panel considers that no conclusions can be drawn from the study by Silk et al. (2009) for the scientific substantiation of the claim.

The Panel also notes that the narrative review by Tzortzis (2009) does not provide original data in addition to the individual studies already submitted by the applicant in this and the previous application for the scientific substantiation of the claim.

A health claim on Bimuno® GOS and reducing gastro-intestinal discomfort pursuant to Article 13(5) of Regulation (EC) No 1924/2006 has already been assessed by the Panel with an unfavourable outcome (EFSA NDA Panel, 2011). The supplementary information submitted by the applicant did not provide evidence that could be used for the scientific substantiation of this claim.

CONCLUSIONS

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

- The food constituent, Bimuno® GOS, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is “reduce bloating, flatulence and intestinal pain. These effects can be described collectively as intestinal discomfort”. The target population as proposed by the applicant is the general adult population. Reducing gastro-intestinal discomfort is a beneficial physiological effect.
- A health claim on Bimuno® GOS and reducing gastro-intestinal discomfort has already been assessed with an unfavourable outcome. The supplementary information submitted by the applicant did not provide evidence that could be used for the scientific substantiation of this claim.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on Bimuno® GOS and reducing gastro-intestinal discomfort pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0371_MT). December 2012. Submitted by Clasado Limited.

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GLOSSARY/ABBREVIATIONS

ITT Intention-to-treat

NCIMB National Collections of Industrial, Marine and Food Bacteria