

## SCIENTIFIC OPINION

### **Bimuno<sup>TM</sup> and support of the immune system**

### **Scientific substantiation of a health claim related to Bimuno<sup>TM</sup> and support of the immune system pursuant to Article 13(5) of Regulation (EC) No 1924/2006<sup>1</sup>**

### **Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies**

(Question No EFSA-Q-2009-00230)

**Adopted on 15 May 2009**

#### **PANEL MEMBERS**

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#### **SUMMARY**

Following an application from Clasado Limited submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of the United Kingdom, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to Bimuno<sup>TM</sup> and support of the immune system.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.

The food supplement, Bimuno<sup>TM</sup>, a  $\beta$ -galacto-oligosaccharide mixture, that is the subject of the health claim is sufficiently characterised.

The claimed effect is “supports the immune system by helping to increase the natural killer cell and phagocyte activity”. The target population is elderly people. From the evidence provided, it has not been established that changes in natural killer cells and phagocytes are beneficial to human health. The Panel considers that supporting the immune system is beneficial to human health.

The applicant identified one randomised, double-blind, placebo-controlled, crossover study in 44 elderly healthy subjects as being pertinent to the health claim. Primary outcomes were counts of faecal bifidobacteria that were found to be increased significantly in the Bimuno<sup>TM</sup>

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<sup>1</sup> For citation purposes: Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from Clasado Limited on the scientific substantiation of a health claim related to Bimuno<sup>TM</sup> and support of the immune system. *The EFSA Journal* (2009) 1106, 1-8

group. Immune parameters such as phagocytosis, natural killer (NK) cell activity and cytokine production were secondary outcomes. The applicant did not provide any evidence that the observed changes in counts of faecal bifidobacteria, NK cell activity, production of inflammatory cytokines and phagocytosis activity constitute beneficial changes in the immune system. The Panel considers this study as having limited relevance for the substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of Bimuno™ and support of the immune system

**Key words:** Bimuno™,  $\beta$ -galacto-oligosaccharide, immune system

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## **BACKGROUND**

Regulation (EC) No 1924/2006<sup>2</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 that Regulation and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of that Regulation lays down provisions for 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 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 that Regulation, an application for inclusion in the Community list of permitted claims referred to in Art 13(3) shall be submitted by the applicant to the national competent authority of a Member State, who will make the application and any supplementary information supplied by the applicant available to European Food Safety Authority (EFSA).

### **Steps taken by EFSA:**

- The application was received on 30/01/2009.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- The scientific evaluation procedure started on 30/01/2009.
- During the meeting on 15/05/2009, the NDA Panel, after having evaluated the overall data submitted, adopted an opinion on the scientific substantiation of a health claim related to Bimuno™ and support of the immune system.

## **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™ and support of the immune system.

## **EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of Bimuno™, a positive assessment of its safety, nor a decision on whether Bimuno™ 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.

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<sup>2</sup> European Parliament and Council (2006). 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. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

## **ACKNOWLEDGEMENTS**

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## 1. Information provided by the applicant

**Applicant's name and address:** Clasado Limited, 5 Canon Hartnett Court, Wolverton Mill, Milton Keynes, MK12 5NF, United Kingdom.

### 1.1. Food/constituent as stated by the applicant

Bimuno (BGOS) Prebiotic.

### 1.2. Health relationship as claimed by the applicant

Bimuno (BGOS) Prebiotic supports the immune system by helping to increase the natural killer cell and phagocyte activity in regular consumers. Natural killer cell activity and leukocyte phagocyte activity both play a key role in the function of the immune system.

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

Supports your natural defences.

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

The health claim is intended for elderly people. The recommended consumption is 5.5 g of Bimuno (BGOS) Prebiotic per day for at least 10 weeks.

## 2. Assessment

### 2.1. Characterisation of the food/constituent

The food supplement that is the subject of the claim is a “prebiotic”  $\beta$ -galacto-oligosaccharide mixture produced through conversion of lactose by exposure to enzymes from permeabilised *Bifidobacterium bifidum* NCIMB 41171.

Bimuno™ powder contains monosaccharide 15–17%, lactose 22%, disaccharides 18–25%, trisaccharides 20–25%, tetrasaccharides 8–12% and pentasaccharides 7–10%.

The composition of the constituent has been sufficiently characterised (source, origin, purity, chemical composition).

Stability was tested in one batch:

- 1) syrup stored at 4°C: tested six times in three samples per time point during a 12 month period;
- 2) powder (stored at 25°C): tested eight times in three samples per time point during a 2 year period;
- 3) in fruit juice (room temperature): tested five times in one sample per time point for 6 months.

The powder was found to be stable up to two years.

Data on batch to batch variability in composition and stability are not provided. It is unclear if monitoring of stability is included in a standardised way during the manufacturing process.

The Panel considers that the food supplement, Bimuno™, which is the subject of the health claim is sufficiently characterised.

## **2.2. Relevance of the claimed effect to human health**

The claimed effect is “supports the immune system by helping to increase the natural killer cell and phagocyte activity”. The target population is elderly people. A well functioning innate immune system that includes natural killer cells and phagocytes is crucial for the defence against pathogens and for the initiation of adaptive immune responses.

Even though it is possible to modulate several functional aspects of the immune system quantitatively, such modulation does not necessarily constitute a beneficial health effect. The Panel notes that the applicant has not provided any evidence showing that the changes in natural killer cells and phagocytes are beneficial to human health.

The Panel considers that supporting the immune system is beneficial to human health.

## **2.3. Scientific substantiation of the claimed effect**

The applicant performed a literature search through PubMed [MEDLINE] with the following key words: galacto-oligosaccharides, natural killer cells, neutrophils, monocytes, phagocytosis and immune. Only English language papers were included. A time frame for the search is not reported.

The applicant identified one human randomised controlled study (Vulevic et al., 2008) and one review (Cummings et al., 2004) as being pertinent to the health claim.

The Panel considers that the review by Cummings et al. (2004) is not pertinent to the health claim as it provides general information on claims on gut health and immunity and on methods for the assessment of gut function, gut flora and immunity, without any specific information related to Bimuno™.

The study by Vulevic et al. (2008), a double-blind, placebo-controlled, crossover study, was performed in 44 elderly, healthy subjects who were randomly assigned to receive 5.5 g Bimuno™ or 5.5 g maltodextrin daily for 10 weeks. Primary outcomes were counts of faecal bifidobacteria that were found to be increased significantly in the Bimuno™ group. Immune parameters such as phagocytosis, natural killer (NK) cell activity and cytokine production were secondary outcomes

The applicant did not provide any evidence that the observed changes in counts of faecal bifidobacteria, NK cell activity, production of inflammatory cytokines and phagocytosis activity constitute beneficial changes in the immune system. The Panel considers this study as having limited relevance for the substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Bimuno™ and support of the immune system.

## **CONCLUSIONS**

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

- The food supplement which is the subject of the claim, Bimuno™, a  $\beta$ -galacto-oligosaccharide mixture, is sufficiently characterised.
- The claimed effect “supports the immune system” is beneficial to human health. The target population is elderly people.
- A cause and effect relationship has not been established between the consumption of Bimuno™ and support of the immune system.

## **DOCUMENTATION PROVIDED TO EFSA**

Health claim application on Bimuno™ and support of the immune system pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0237\_UK). January 2009. Submitted by Clasado Limited.

## **REFERENCES**

Cummings JH, Antoine JM, Azpiroz F, Bourdet-Sicard R, Brandtzaeg P, Calder PC, Gibson GR, Guarner F, Isolauri E, Pannemans D, Shortt C, Tuijelaars S, Watzl B, 2004. European Journal of Nutrition 43 Supplement II, pp. S118–S173.

Vulevic J, Drakoularakou A, Yaqoob P, Tzortzis G, Gibson GR, 2008. Modulation of the fecal microflora profile and immune function by a novel trans-galactooligosaccharide mixture (B-GOS) in healthy elderly volunteers. American Journal of Clinical Nutrition 88(5), pp. 1438–1446.

## **GLOSSARY / ABBREVIATIONS**

NK

Natural killer