EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to Bifidobacterium animalis subsp. lactis LMG P-21384 and changes in bowel function (ID 2940, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to *Bifidobacterium animalis* subsp. *lactis* LMG P-21384 and changes in bowel function (ID 2940, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide a scientific opinion on a health claim pursuant to Article 13 of Regulation (EC) No 1924/2006 in the framework of further assessment in relation to *Bifidobacterium animalis* subsp. *lactis* LMG P-21384 and changes in bowel function. The food constituent that is the subject of the health claim, *B. animalis* subsp. *lactis* LMG P-21384, is sufficiently characterised. The claimed effect, changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be a beneficial physiological effect, provided that it does not result in diarrhoea. No human intervention studies were provided from which conclusions could be drawn for the scientific substantiation of the claim. On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of *B. animalis* subsp. *lactis* LMG P-21384 and changes in bowel function.

KEY WORDS

Bifidobacterium animalis subsp. *lactis* LMG P-21384, bowel function, health claims.

[1] On request from the European Commission, Question No EFSA-Q-2012-00176, adopted on 28 June 2012.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

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SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. The Commission has agreed with EU Member States that a certain number of Article 13 health claims would be eligible for further assessment by EFSA in order to be able to take a final decision on whether or not to include these claims in the list of permitted health claims. This opinion addresses the scientific substantiation of a health claim in relation to *Bifidobacterium animalis* subsp. *lactis* LMG P-21384 and changes in bowel function. The scientific substantiation is based on the information provided by the competent Authority of Italy for further assessment of this claim.

The food constituent that is the subject of the health claim is *B. lactis* LMG P-21384 (BS 01). The Panel considers that *B. animalis* subsp. *lactis* LMG P-21384 is sufficiently characterised.

The claimed effect, which is proposed for further assessment, relates to changes in bowel function. The proposed target population is adults or the elderly reporting mild to moderately decreased intestinal motility and evacuation disorders. The Panel considers that changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be a beneficial physiological effect, provided that it does not result in diarrhoea.

Two human intervention studies were provided for the scientific substantiation of the claim. No conclusions could be drawn from these studies for the scientific substantiation of the claim, because of insufficient information on the randomisation and blinding, the absence of information on the validation of the scale used to score subjective symptoms related to bowel function, and weaknesses in the statistical analyses in both studies.

No human intervention studies were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of *B. animalis* subsp. *lactis* LMG P-21384 and changes in bowel function.

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INTRODUCTION

The Commission has agreed with EU Member States that a certain number of Article 13 health claims would be eligible for further assessment by EFSA in order to be able to take a final decision on whether or not to include these claims in the list of permitted health claims. These claims include already assessed claims related to micro-organisms which the Panel considered to be not sufficiently characterised and claims for which the NDA Panel concluded that there was insufficient evidence to establish a cause and effect relationship between the consumption of the food and the claimed effect.

Following an opinion of the NDA Panel pursuant to Article 13 of Regulation (EC) No 1924/2006[4] in which the Panel concluded that the data available were not sufficient to characterise *Bifidobacterium lactis* LMG P-21384 (BS 01) (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010), EFSA received additional information from the competent Authority of Italy for further assessment of this claim. The information provided in the framework of further assessment for the health claim which is the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent (ID 2940)

The food constituent that is the subject of the health claim is *Bifidobacterium lactis* LMG P-21384 (BS 01), hereafter *B. animalis* subsp. *lactis* LMG P-21384, since the species *B. lactis* has been reclassified as *B. animalis* subsp. *lactis* (Masco et al., 2004).

A culture collection number from the Belgian Co-ordinated Collections of Microorganisms (BCCM/LMG) was provided (LMG P-21384). The BCCM/LMG is an internationally recognised culture collection which has the status of an International Depositary Authority under the Budapest Treaty. In the LMG, cultures can be deposited in a restricted-access collection for safe deposit or for patent purposes. Data on the identification and characterisation of *B. animalis* subsp. *lactis* LMG P-21384 at species and strain level, by using both phenotypic (enzymatic activity pattern, carbohydrate fermentation profile, PAGE, antibiotic resistance profiles) and genotypic (Rep-PCR, species-specific PCR, MLST, genome sequencing [publicly available at genbank, Project ID 59607]) methods, were provided in the application for further assessment and in the accompanying references (Del Piano et al., 2010).

The Panel considers that the food constituent, *B. animalis* subsp. *lactis* LMG P-21384, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health (ID 2940)

The claimed effect, which is proposed for further assessment, is "able to help restore and maintain a physiological intestinal motility by reducing the transit time in healthy adult subjects with mild to moderately decreased peristalsis (number of weekly evacuations less than 7) and evacuation disorders as straining and anal itching, burning, or pain during or after defecation". The proposed target population is adults or the elderly reporting mild to moderately decreased intestinal motility and evacuation disorders.

The Panel considers that changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be a beneficial physiological effect, provided that it does not result in diarrhoea.

[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.

3. Scientific substantiation of the claimed effect (ID 2940)

In a randomised double-blind, placebo-controlled study, Del Piano et al. (2005) evaluated the effects of seven bacterial strains in the treatment of chronic constipation. Eighty subjects (59 females; 65-80 years) with a mean number of weekly evacuations less than 7 and not under antibiotic treatment were allocated to eight groups (10 subjects per group) to consume either placebo (maltodextrin) or one of the following bacterial strains at concentrations of $10x10^9$ CFU: *B. animalis* subsp. *lactis* LMG P-21384 (*B. lactis* BS01), *L. plantarum* LP01, *B. longum* BL03, *L. rhamnosus* LR05, *B. adolescentis* BA02, *L. paracasei* LPC07, or *B. breve* BR03 for 15 days with a 15-day follow-up period. Almost all subjects were under medical treatment with, for example, anti-hypertensive medication, vasodilators, hypercholesterolaemic drugs or proton pump inhibitors. Subjects recorded the number of weekly defecations; consistency of faeces, ease of expulsion, sense of complete emptying, anal itching, and burning or pain during or after defecation were scored by the subjects on a three-point scale. Wilcoxon signed-rank test was used to compare results within groups. The Panel notes the insufficient information given on the randomisation and blinding of the study, that no information was provided on the validation of the scale used to score subjective symptoms, and that no between-group comparisons were reported. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

In another randomised double-blind, placebo-controlled study (Del Piano et al., 2010), 300 volunteers (recruited between 2003 and 2008) with evacuation disorders and hard stools (149 females; 24-71 years) were assigned to receive daily either placebo (n=80; maltodextrin), *B. animalis* subsp. *lactis* LMG P-21384 (*B. lactis* BS01) (n=110; $5x10^9$ CFU) or a combination of *L. plantarum* LP01 (LMG P-21021) and *B. breve* BR03 (DSM 16604) (n=110; $2.5x10^9$ CFU of each strain) for 30 days with a 15-day follow-up period. Subjects were asked to record in the week before each visit the number of weekly defecations; consistency of faeces, ease of expulsion, sensation of complete emptying, anal itching, burning and pain, and abdominal bloating were scored by the subjects on a three-point scale. Around 10 % of subjects dropped out from the study. Data were analysed by the independent Student *t* test. The Panel notes the insufficient information given on the randomisation and blinding of the study, that no information was provided on the validation of the scale used to score subjective symptoms, and that repeated measures, missing data and baseline values were not taken into account in the analysis. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no human intervention studies were provided from which conclusions could be drawn for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of *B. animalis* subsp. *lactis* LMG P-21384 and changes in bowel function.

CONCLUSIONS

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

- The food constituent, *B. animalis* subsp. *lactis* LMG P-21384, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed for further assessment relates to changes in bowel function. The proposed target population is adults or the elderly reporting mild to moderately decreased intestinal motility and evacuation disorders. Changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be a beneficial physiological effect, provided that it does not result in diarrhoea.
- A cause and effect relationship has not been established between the consumption of *B. animalis* subsp. *lactis* LMG P-21384 and changes in bowel function.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 for further assessment (No: EFSA-Q-2012-00176). The scientific substantiation is based on the information provided by the competent Authority of Italy for further assessment of this claim (available at: http://www.efsa.europa.eu/en/topics/topic/article13.htm).

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[5] (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

a) the role of a nutrient or other substance in growth, development and the functions of the body; or

b) psychological and behavioural functions; or

c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[6]

Foods are commonly involved in many different functions[7] of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

[5] OJ L12, 18/01/2007

[6] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

[7] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

(a) the claimed effect of the food is beneficial for human health,

(b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

(c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. 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 wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Health claims related to *Bifidobacterium animalis* subsp. *lactis* LMG P-21384, including conditions of use, as proposed in the framework of further assessment.

ID	Food or Food constituent	Health Relationship	Proposed wording
2940	*Bifidobacterium lactis* BS 01 (LMG P-21384)	Able to help restore and maintain a physiological intestinal motility by reducing the transit time in healthy adult subjects with mild to moderately decreased peristalsis (number of weekly evacuations less than 7) and evacuation disorders as straining and anal itching, burning, or pain during or after defecation. Able to decrease abdominal bloating in subjects with a suboptimal intestinal motility, therefore helping to reduce the overall intestinal discomfort.	Contributes to restore and maintain a physiological intestinal transit and reduce abdominal bloating in adults or elderly reporting less than one bowel movement per day and evacuation disorders.
	Conditions of use The target population is represented by adults or elderly reporting mild to moderately decreased intestinal motility and evacuation disorders as hard stool or anal itching, burning, and pain during or after defecation, also if associated with abdominal bloating. The microorganism *Bifidobacterium lactis* BS 01, which is the subject of the present claim, should be consumed for at least 15 days at a concentration of 5 to 10 billion viable cells/day in order to achieve the positive health effect.		

GLOSSARY AND ABBREVIATIONS

BCCM/LMG	Belgian Co-ordinated Collections of Microorganisms/Laboratorium voor Microbiologie, Universiteit Gent
CFU	Colony forming unit
MLST	Multi-locus sequence typing
PAGE	Polyacrylamide gel electrophoresis
PCR	Polymerase chain reaction
Rep-PCR	Repetitive extragenomic palindromic – PCR