

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C and defence against vaginal pathogens (ID 934, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

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ABSTRACT

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies 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 related to a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C and defence against vaginal pathogens. The food constituent that is the subject of the claim, a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C, is sufficiently characterised. The claimed effect, defence against vaginal pathogens, is a beneficial physiological effect. The target population is the female population. 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 *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C and defence against vaginal pathogens.

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KEY WORDS

Lactobacillus fermentum, 57A, *Lactobacillus plantarum*, 57B, *Lactobacillus gasseri*, 57C, vaginal pathogens, health claims.

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SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies 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 a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C and defence against vaginal pathogens. The scientific substantiation is based on the information provided by the competent Authority of Poland for further assessment of this claim.

The food constituent that is the subject of the health claim is a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C. The Panel considers that the combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C is sufficiently characterised.

The claimed effect, which is proposed for further assessment, is “a beneficial effect on vaginal bacterial flora increasing total number of *Lactobacillus* rods, colonisation with tested strains and decreasing pH value and Nugent score”. The proposed target population is “women with no symptoms of urogenital tract infections but with disturbed or abnormal vaginal flora”. The Panel notes that the claimed effect refers to defence against vaginal pathogens by increasing the number of lactobacilli and/or decreasing potentially pathogenic bacteria, and that the target population is the female population. The Panel considers that defence against vaginal pathogens is a beneficial physiological effect.

The only human intervention study provided which investigated the effect of a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C on defence against vaginal pathogens was an uncontrolled study. The Panel notes that no conclusions can be drawn from an uncontrolled 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 and animal and *in vitro* studies cannot predict the occurrence of an effect of a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C on defence against vaginal pathogens *in vivo* in humans.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C and defence against vaginal pathogens.

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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 on a health claim pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ in which the Panel concluded that a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C, which is the subject of the health claim, is not sufficiently characterised (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009), EFSA received additional information from the competent Authority of Poland for further assessment of this claim. The information provided in the framework of further assessment for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent (ID 934)

The food constituent that is the subject of the health claim is a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C.

For *Lactobacillus fermentum* 57A (hereafter *L. fermentum* 57A) a culture collection number from the Polish Collection of Microorganisms (PCM) (no. B/00007) was provided. The PCM has the status of International Depositary Authority under the Budapest Treaty. Data on the identification and characterisation of *L. fermentum* 57A at species and strain level using both phenotypic (colony morphology, carbohydrates fermentation and antibiotic resistance profiles) and genotypic (16S rRNA gene sequence analysis and 16S/23S intergenic spacer region sequence analysis, species-specific PCR, RAPD and PFGE) methods were provided in the application and accompanying references (Heczko, 2006, unpublished, 2008, unpublished; Pałucha, 2010, unpublished; Strus, 2010, unpublished). The Panel considers that *L. fermentum* 57A is sufficiently characterised.

For *Lactobacillus plantarum* 57B (hereafter *L. plantarum* 57B) a culture collection number from the PCM (no. B/00008) was provided. Data on the identification and characterisation of *L. plantarum* 57B at species and strain level using both phenotypic (colony morphology, carbohydrates fermentation and antibiotic resistance profiles) and genotypic (16S rRNA gene sequence analysis and 16S/23S intergenic spacer region sequence analysis, species-specific PCR, RAPD, PFGE and MLST) methods were provided in the application and accompanying references (Heczko, 2006, unpublished, 2008, unpublished; Pałucha, 2010, unpublished; Strus, 2010, unpublished). The Panel considers that *L. plantarum* 57B is sufficiently characterised.

For *Lactobacillus gasseri* 57C (hereafter *L. gasseri* 57C) a culture collection number from the PCM (no. B/00009) was provided. Data on the identification and characterisation of *L. gasseri* 57C at species and strain level using both phenotypic (colony morphology, carbohydrates fermentation and antibiotic resistance profiles) and genotypic (16S rRNA gene sequence analysis and 16S/23S intergenic spacer region sequence analysis, species-specific PCR, RAPD and PFGE) methods were provided in the application and accompanying references (Heczko, 2006, unpublished, 2008, unpublished; Pałucha, 2010, unpublished; Strus, 2010, unpublished). The Panel considers that *L. gasseri* 57C is sufficiently characterised.

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.

The formulation, which is the subject of the claim, is the three bacterial strains in a ratio of *L. gasseri* 57C 50 %, *L. fermentum* 57A 25 %, and *L. plantarum* 57B 25 %.

The Panel considers that the food constituent, a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health (ID 934)

The claimed effect, which is proposed for further assessment, is “a beneficial effect on vaginal bacterial flora increasing total number of *Lactobacillus* rods, colonisation with tested strains and decreasing pH value and Nugent score”. The proposed target population is “women with no symptoms of urogenital tract infections but with disturbed or abnormal vaginal flora”.

The Panel notes that the claimed effect refers to defence against vaginal pathogens by increasing the number of lactobacilli and/or decreasing potentially pathogenic bacteria, and that the target population is the female population.

Unlike any other anatomical site of the body, most vaginal vaults are dominated by one or more species of *Lactobacillus*. In over 70 % of women, vaginal microbiota are dominated by lactobacilli (>50 %) (Ling et al., 2010; Ravel et al., 2010; Yamamoto et al., 2009). This microbiota is different from the more complex gut microbiota, where lactobacilli represent less than 3 % of the bacterial population (Franks et al., 1998; Lay et al., 2005; Sghir et al., 2000). The diagnosis of bacterial vaginosis (BV) can be based on, for example, the Nugent score (microscopic examination of Gram stained smear or vaginal discharge for bacteria and ‘clue’ cells). The Panel notes that appropriate outcome measures of the claimed effect include assessment of the changes in the Nugent scores. Nugent scores are estimated by measuring the relative amounts of lactobacilli and bacterial pathogens present in the vagina. A Nugent score of 0-3 is classified as normal (lactobacilli are present, but not *Gardnerella/Bacteroides* or curved Gram-negative bacilli), a score of 4-6 as intermediate (colonisation by *Gardnerella/Bacteroides* and curved Gram-variable rods (*Mobiluncus*)), and a score of 7-10 is indicative of BV (with domination of *Gardnerella/Bacteroides* or curved Gram-negative bacilli and absence of lactobacilli).

The Panel considers that defence against vaginal pathogens is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect (ID 934)

The references provided for the scientific substantiation of the claim included textbooks, narrative reviews, industrial certifications and consensus documents that did not provide original data for the scientific substantiation of the claim. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Among six human studies provided, four did not use the combination of bacterial strains which is the subject of the claim (Caillouette et al., 1997; Priestley et al., 1997; Samet et al., 2003; Vasquez et al., 2002). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Two references described the same human study (Strus et al., 2008; Strus et al., 2011, unpublished). In an open-label, not randomised, uncontrolled study the combination of the three bacterial strains which is the subject of the claim, was administered orally (1×10^9 CFU/day of lactic acid bacteria in the ratio: *L. gasseri* 57C 50 %, *L. fermentum* 57A 25 %, *L. plantarum* 57B 25 %) for 60 days to a group of outpatient women with intermediate Nugent score and increased vaginal pH but without clinical symptoms of urogenital infection to evaluate the colonisation of the vaginal epithelium by at least one of the given strains. The secondary endpoints included measurement of numbers of total lactobacilli in the vagina and rectum, vaginal pH, and Nugent score values. The Panel notes that this study was a

preliminary, open-label, uncontrolled study and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The animal and *in vitro* studies provided evaluated bacterial adhesion properties, bacterial binding to cell surfaces, production of hydrogen peroxide by bacteria, bacterial resistance to gastric acid and bile salts, and bactericidal activity. 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 notes that animal and *in vitro* studies cannot predict the occurrence of an effect of a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C on defence against vaginal pathogens *in vivo* in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C and defence against vaginal pathogens.

CONCLUSIONS

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

- The food constituent, a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed for further assessment is “a beneficial effect on vaginal bacterial flora increasing total number of *Lactobacillus* rods, colonisation with tested strains and decreasing pH value and Nugent score”. The target population is the female population. Defence against vaginal pathogens is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C and defence against vaginal pathogens.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 for further assessment (No: EFSA-Q-2012-00129). The scientific substantiation is based on the information provided by the competent Authority of Poland 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 foods⁵ (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 FOOD⁶

Foods are commonly involved in many different functions⁷ 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 a combination of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C, including conditions of use, as proposed in the framework of further assessment.

ID	Food or Food constituent	Health Relationship	Proposed wording
934	A combination of 3 bacterial strains: <i>Lactobacillus fermentum</i> 57A, <i>Lactobacillus plantarum</i> 57B and <i>Lactobacillus gasseri</i> 57C	A beneficial effect on vaginal bacterial flora increasing total number of <i>Lactobacillus</i> rods, colonization with tested strains and decreasing pH value and Nugent score.	Exerts a beneficial effect on vaginal bacterial flora increasing total number of <i>Lactobacillus</i> rods and decreasing pH value.
	<p>Conditions of use</p> <p>Once daily for at least 20 days, 1 capsule of the product contains not less than 10⁸ CFU of the combination of strains: <i>Lactobacillus fermentum</i> 57A, <i>Lactobacillus plantarum</i> 57B and <i>Lactobacillus gasseri</i> 57C and excipients.</p> <p>Intended for women with no symptoms of urogenital tract infections but with disturbed or abnormal vaginal flora i.e. in situations which are characterised by increased vaginal pH and Nugent score as well as a decreased number of lactobacilli.</p>		

GLOSSARY AND ABBREVIATIONS

BV	Bacterial vaginosis
CFU	Colony forming units
DNA	Deoxyribonucleic acid
MLST	Multilocus sequence typing
PCM	Polish Collection of Microorganisms
PCR	Polymerase chain reaction
PFGE	Pulsed field gel electrophoresis
RAPD	Random amplification of polymorphic DNA
rRNA	Ribosomal ribonucleic acid