EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to a combination of Lactobacillus gasseri PA 16/8, Bifidobacterium bifidum M 20/5 and Bifidobacterium longum SP 07/3 and maintenance of upper respiratory tract defence against pathogens (ID 931, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

EFSA-Q-2012-00128

EFSA Publication

Link to article, DOI:
10.2903/j.efsa.2012.2718

Publication date:
2012

Document Version
Publisher's PDF, also known as Version of record

European Food Safety Authority

EFSA Journal 2012;10(6):2718

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to a combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3 and maintenance of upper respiratory tract defence against pathogens (ID 931, 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 was asked to provide a scientific opinion on a health claim pursuant to Article 13.1 of Regulation (EC) No 1924/2006 in the framework of further assessment related to a combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3 and maintenance of upper respiratory tract defence against pathogens. The food constituent that is the subject of the claim, a combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3, is sufficiently characterised. The claimed effect, maintenance of upper respiratory tract defence against pathogens, is a beneficial physiological effect. The proposed target population is the general adult population. The Panel notes that the only human intervention study provided did not show an effect of consumption of a combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3 on defence against pathogens in the upper respiratory tract. 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 gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3 and maintenance of upper respiratory tract defence against pathogens.

KEY WORDS

Lactobacillus gasseri, PA 16/8, *Bifidobacterium bifidum*, M 20/5, *Bifidobacterium longum*, SP 07/3, pathogens, upper respiratory tract, health claims.

---

[1] On request from the European Commission, Question No EFSA-Q-2012-00128, adopted on 26 April 2012.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[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.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to a combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3 and maintenance of upper respiratory tract defence against pathogens (ID 931, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2012;10(6):2718. [15 pp.]. doi:10.2903/j.efsa.2012.2718. Available online: www.efsa.europa.eu/efsajournal

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 gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP and maintenance of upper respiratory tract defence against pathogens. The scientific substantiation is based on the information provided by the competent Authority of Germany for further assessment of this claim.

The food constituent that is the subject of the health claim is a combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3. The Panel considers that the combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3 is sufficiently characterised.

The claimed effect, which is proposed for further assessment, is "supports the defence against pathogens in the upper respiratory tract resulting in a decrease in duration and severity of common cold symptoms". The proposed target population is the general adult population. The Panel considers that maintenance of upper respiratory defence against pathogens is a beneficial physiological effect.

In the only human intervention study provided, the effect of consumption of the bacterial preparation on the incidence, severity and duration of common colds was assessed in healthy adults. The Panel notes that no information is provided about the validity of the questionnaire used to assess the incidence, severity or duration of respiratory tract infections, that the symptoms used for the diagnosis of common cold episodes are non-specific, and that the presence of one or more of these symptoms is not an appropriate measure of respiratory tract infections in the study population. The Panel also notes that no information has been provided in the publication about the use of rescue medication, which may have confounded the results. 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 have been provided from which conclusions could be drawn for the scientific substantiation of the claim, and that the animal and *in vitro* studies which were provided cannot be used for the scientific substantiation of the claim as their results cannot predict the occurrence of an effect of a combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3 *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 gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3 and maintenance of upper respiratory tract defence against pathogens.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

EFSA DISCLAIMER

See Appendix B

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 1924/2006[4] in which the Panel concluded that the data available were not sufficient to characterise a combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* MF 20/5, *Bifidobacterium longum* SP 07/3 (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009), EFSA received additional information from the competent Authority of Germany 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 931)

The food constituent that is the subject of the health claim is a combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3.

Lactobacillus gasseri PA 16/8 (hereafter *L. gasseri* PA 16/8) is also named *L. gasseri* KS-13 (previously known as *Lactobacillus acidophilus* KS-13). A culture collection number from the National Institute of Technology and Evaluation (NITE) Patent Microorganisms Depositary (NITE BP-819) was provided. The NITE Patent Microorganisms Depositary is an International Depositary Authority under the Budapest Treaty. Data on the identification and characterisation of the strain *L. gasseri* PA 16/8 at species and strain level using both phenotypic (cell morphology, colony morphology, carbohydrate fermentation profiles and antibiotic resistance patterns) and genotypic (16S rRNA gene sequence analysis, ARDRA, AFLP and PFGE) methods were provided in the application for further assessment. The Panel considers that *L. gasseri* PA 16/8 is sufficiently characterised.

Bifidobacterium bifidum MF 20/5 (hereafter *B. bifidum* MF 20/5) is also known as *B. bifidum* G9-1. A culture collection number from the NITE Patent Microorganisms Depositary (NITE BP-817) was provided. Data on the identification and characterisation of the strain *B. bifidum* MF 20/5 at species and strain level using both phenotypic (cell morphology, colony morphology, carbohydrate fermentation profiles and antibiotic resistance patterns) and genotypic (16S rRNA gene sequence analysis, ARDRA, AFLP and PFGE) methods were provided in the application for further assessment. The Panel considers that the strain *B. bifidum* MF 20/5 is sufficiently characterised.

Bifidobacterium longum SP 07/3 (hereafter *B. longum* SP 07/3) is also known as *B. longum* MM-2. A culture collection number from the NITE Patent Microorganisms Depositary (NITE BP-818) was provided. Data on the identification and characterisation of *B. longum* SP 07/3 at species and strain level using both phenotypic (cell morphology, colony morphology, carbohydrate fermentation profiles and antibiotic resistance patterns) and genotypic (16S rRNA gene sequence analysis, ARDRA, AFLP and PFGE) methods were provided in the application for further assessment. The Panel considers that the strain *B. longum* SP 07/3 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 Panel considers that the food constituent, a combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health (ID 931)

The claimed effect, which is proposed for further assessment, is "supports the defence against pathogens in the upper respiratory tract resulting in a decrease in duration and severity of common cold symptoms". The proposed target population is the general adult population.

The Panel considers that the claimed effect refers to defence against pathogens in the upper respiratory tract.

The Panel considers that maintenance of upper respiratory tract defence against pathogens is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect (ID 931)

Five studies were provided as being pertinent for the scientific substantiation of the claim. These studies included one human intervention study (de Vrese et al., 2005), one animal study (Ohno et al., 2005) and three *in vitro* studies (Ghadimi et al., 2008; 2010a; 2010b).

In a randomised, double-blind, placebo-controlled parallel study, de Vrese et al. (2005) assessed the effect of consumption of the bacterial preparation on the incidence, severity and duration of common colds in 479 healthy adults (294 women aged 18-67 years). A total of 242 subjects were completed in a three-month study (from January to May 2001; 121 test group, 121 control group, 8 withdrawals) and 237 subjects participated in a 5.5 month study (from December 2001 to June 2002; 117 test group, 120 control group, 17 withdrawals). The Panel notes that these are two different studies with independent randomisation and different duration of the intervention, and that the reasons to combine data from these two cohorts are unclear. Cellular immune response was assessed in a subgroup of 122 subjects before and after 14 days of intervention in the first study. Volunteers were randomly assigned to take one tablet daily of either a bacterial preparation (containing *L. gasseri* PA 16/8, *B. longum* SP 07/3and *B. bifidum* MF 20/5 ($5x10^7$ CFU) with vitamins and minerals) or a control preparation (containing the same amount of vitamins and minerals only). Subjects were asked to record daily in a questionnaire the occurrence and severity of a number of symptoms, including nasal, pharyngeal, and bronchial symptoms, headache, myalgia, conjunctivitis, fatigue, loss of appetite, and fever (oral temperature >37.7°C). Common cold episodes were defined as the appearance of at least one nasal, pharyngeal or bronchial symptom, which include running nose, stuffed nose, blowing the nose, yellow secretion, bloody secretion, sneezing, scratchy throat, sore throat, hoarseness and cough. Total symptom severity scores were calculated by combining individual symptom scores over the study period. The Panel notes that no information is provided about the validity of the questionnaire used to assess the incidence, severity or duration of respiratory tract infections, that the symptoms used for the diagnosis of common cold episodes are non-specific, and that the presence of one or more of these symptoms is not an appropriate measure of respiratory tract infections in the study population. The Panel also notes that no information has been provided in the publication about the use of rescue medication, which may have confounded the results. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

In the information provided, it is acknowledged that the mechanism by which the combination of *L. gasseri* PA 16/8, *B. bifidum* MF 20/5 and *B. longum* SP 07/3 could exert the claimed effect is not well understood. One animal study (Ohno et al., 2005) and three *in vitro* studies (Ghadimi et al., 2008; 2010a; 2010b) explored the effects of the microorganisms on the immune response to allergens/antigens. Three of these studies examined the effects of a single strain and only the *in vitro*

study by Ghadimi et al. (2008) assessed the effects of the combination. The Panel considers that, in the absence of evidence for an effect of the combination of *L. gasseri* PA 16/8, *B. bifidum* MF 20/5 and *B. longum* SP 07/3 on defence against pathogens in the upper respiratory tract in humans, these animal and *in vitro* studies cannot be used for the scientific substantiation of the claim as their results cannot predict the occurrence of an effect of a combination of *L. gasseri* PA 16/8, *B. bifidum* MF 20/5 and *B. longum* SP 07/3 *in vivo* in humans.

The Panel notes that no human intervention studies have been 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 a combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3 and maintenance of upper respiratory tract defence against pathogens.

CONCLUSIONS

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

- The food constituent, a combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed for further assessment is "supports the defence against pathogens in the upper respiratory tract resulting in a decrease in duration and severity of common cold symptoms". The proposed target population is the general adult population. Maintenance of upper respiratory tract defence against pathogens is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of a combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3 and maintenance of upper respiratory tract defence against pathogens.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 for further assessment (No: EFSA-Q-2012-00128). The scientific substantiation is based on the information provided by the competent Authority of Germany for further assessment of this (available at: http://www.efsa.europa.eu/en/topics/topic/article13.htm).

REFERENCES

de Vrese M, Winkler P, Rautenberg P, Harder T, Noah C, Laue C, Ott S, Hampe J, Schreiber S, Heller K and Schrezenmeir J, 2005. Effect of Lactobacillus gasseri PA 16/8, Bifidobacterium longum SP 07/3, B. bifidum MF 20/5 on common cold episodes: a double blind, randomized, controlled trial. Clinical Nutrition, 24, 481-491.

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009. Scientific Opinion on the substantiation of health claims related to non characterised microorganisms pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 7(9):1247.

Ghadimi D, Folster-Holst R, de Vrese M, Winkler P, Heller KJ and Schrezenmeir J, 2008. Effects of probiotic bacteria and their genomic DNA on TH1/TH2-cytokine production by peripheral blood mononuclear cells (PBMCs) of healthy and allergic subjects. Immunobiology, 213, 677-692.

Ghadimi D, de Vrese M, Heller KJ and Schrezenmeir J, 2010a. Lactic acid bacteria enhance autophagic ability of mononuclear phagocytes by increasing Th1 autophagy-promoting cytokine (IFN-gamma) and nitric oxide (NO) levels and reducing Th2 autophagy-restraining cytokines (IL-4 and IL-13) in response to Mycobacterium tuberculosis antigen. International Immunopharmacology, 10, 694-706.

Ghadimi D, Vrese M, Heller KJ and Schrezenmeir J, 2010b. Effect of natural commensal-origin DNA on toll-like receptor 9 (TLR9) signaling cascade, chemokine IL-8 expression, and barrier integritiy of polarized intestinal epithelial cells. Inflammatory Bowel Diseases, 16, 410-427.

Ohno H, Tsunemine S, Isa Y, Shimakawa M and Yamamura H, 2005. Oral administration of Bifidobacterium bifidum G9-1 suppresses total and antigen specific immunoglobulin E production in mice. Biological and Pharmaceutical Bulletin, 28, 1462-1466.

APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation (EC) No 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.

[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).

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

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 gasseri* PA 16/8, *Bifidobacterium bifidum* MF 2/5 and *Bifidobacterium longum* SP 7/3, including conditions of use, as proposed in the framework of further assessment.

ID	Food or Food constituent	Health Relationship	Proposed wording
931	*Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* MF 2/5 and *Bifidobacterium longum* SP 7/3	Supports the defence against pathogens in the upper respiratory tract resulting in a decrease in duration and severity of common cold symptoms.	"The probiotic combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/3 contributes to the maintenance of the defence in the upper respiratory tract".
	Conditions of use To obtain the claimed effect, a minimum daily intake of 1×10^7 cfu of the combination "*L. gasseri* PA 16/8, *B. bifidum* MF 20/5 *and B. longum* SP 07/3" in tablet form is recommended for at least 3 months. This combination shall provide: $\geq 1\times10^7$ cfu/day of *L. gasseri* PA 16/8, $\geq 1\times10^5$ cfu/day of *B. bifidum* MF 20/5, $\geq 1\times10^5$ cfu/day p *B. longum* SP 07/3. The indicated daily amount can reasonably be consumed as part of a balanced diet The intended health claim relates to the general healthy adult population, whatever the age and the gender.		

GLOSSARY AND ABBREVIATIONS

AFLP	Amplified Fragment Length Polymorphism
ARDRA	Amplified rDNA Restriction analysis
CFU	Colony Forming Units
DNA	Deoxyribonucleic acid
NITE	National Institute of Technology and Evaluation
PFGE	Pulsed Field Gel Electrophoresis
rRNA	Ribosomal ribonucleic acid