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EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to Lactobacillus casei DG CNCM I-1572 and decreasing potentially pathogenic gastro-intestinal microorganisms (ID 2949, 3061, 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 health claims related to *Lactobacillus casei* DG CNCM I-1572 and decreasing potentially pathogenic gastro-intestinal microorganisms (ID 2949, 3061, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following 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 in the framework of further assessment related to *Lactobacillus casei* DG CNCM I-1572 and decreasing potentially pathogenic gastro-intestinal microorganisms. The food constituent that is the subject of the health claim, *Lactobacillus casei* DG CNCM I-1572, is sufficiently characterised. The claimed effect, decreasing potentially pathogenic gastro-intestinal microorganisms, might be a beneficial physiological effect. The proposed target population is the general population. No human 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 casei* DG CNCM I-1572 and decreasing potentially pathogenic gastro-intestinal microorganisms.

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KEY WORDS

Lactobacillus casei, DG CNCM I-1572, gastro-intestinal, microorganisms, health claims.

¹ On request from the European Commission, Question No EFSA-Q-2012-00182 and EFSA-Q-2012-00211, adopted on 26 April 2012.

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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 *Lactobacillus casei* DG CNCM I-1572 and decreasing potentially pathogenic gastro-intestinal microorganisms. 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 *Lactobacillus casei* DG CNCM I-1572. The Panel considers that *Lactobacillus casei* DG CNCM I-1572 is sufficiently characterised.

The claimed effects, which are proposed for further assessment, relate to “contributes to the rebalancing of intestinal microflora” and “reducing the content of potentially pathogenic microorganism”. The proposed target population is the general population. The Panel considers that decreasing potentially pathogenic gastro-intestinal microorganisms might be a beneficial physiological effect.

Four human intervention studies provided did not assess outcomes related to decreasing potentially pathogenic gastro-intestinal microorganisms. The Panel notes that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

One human intervention study investigated the effect of *Lactobacillus casei* added as co-adjuvant to quadruple therapy for *Helicobacter pylori* eradication. The Panel notes that no evidence was provided that results obtained in patients with *Helicobacter pylori* infection under antibiotics with respect to the treatment of the disease can be extrapolated to healthy subjects with respect to the development of *Helicobacter pylori* infection. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of a claim on defence against pathogenic gastro-intestinal microorganisms targeted to the general population (i.e. subjects without infections).

The Panel notes that no human 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 casei* DG CNCM I-1572 and decreasing potentially pathogenic gastro-intestinal microorganisms.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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EFSA DISCLAIMER

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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 the data available were not sufficient to characterise *Lactobacillus casei* CNCM I-1572 (ID 2949, 3061) (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009, 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 claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent (ID 2949, 3061)

The food constituent that is the subject of the health claims is *Lactobacillus casei* DG CNCM I-1572 (hereafter *L. casei* DG CNCM I-1572).

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM I-1572) was provided. The CNCM is a restricted-access non-public collection which has the status of an International Depository Authority under the Budapest Treaty. Data on the identification and characterisation of *L. casei* DG CNCM I-1572 at species and strain level using both phenotypic (cell morphology, carbohydrate fermentation pattern) and genotypic (16S/23S rRNA intergenic spacer region sequence analysis and ribotyping) methods were provided in the application.

The Panel considers that the food constituent, *Lactobacillus casei* DG CNCM I-1572, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health (ID 2949, 3061)

The claimed effects, which are proposed for further assessment, relate to “contributes to the rebalancing of intestinal microflora” and “reducing the content of potentially pathogenic microorganism”. The proposed target population is the general population.

The Panel considers that decreasing potentially pathogenic gastro-intestinal microorganisms might be a beneficial physiological effect.

3. Scientific substantiation of the claimed effect (ID 2949, 3061)

The references provided comprised five human intervention studies. One study evaluated *L. casei* DG CNCM I-1572 recovery in faeces after oral administration (Drago et al., 2002). In two studies, the effectiveness of *L. casei* DG CNCM I-1572, taken together with mesalazine, in preventing recurrence of symptomatic diverticular disease of the colon was investigated (Tursi et al., 2006; 2008) and in another study, D’Inca et al. (2011) evaluated the effect of three types of intervention (oral 5-

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.

aminosalicylic acid (5-ASA) alone, oral 5-ASA+*L. casei* DG, and oral 5-ASA+rectal *L. casei* DG) on intestinal microbiota adhering to the sigmoid colon mucosa, on the intestinal mucosal cytokines level, and on toll-like receptor expression in a group of 26 patients with ulcerative colitis. In these studies, no outcomes on reduction of gastro-intestinal pathogens were reported. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

Tursi et al. (2004) studied the effect of *L. casei* DG CNCM I-1572 added to quadruple therapy (proton-pump inhibitor + ranitidine bismuth citrate + amoxicillin + tinidazole given for 10 days) vs. quadruple therapy alone as co-adjuvant therapy for *Helicobacter pylori* eradication. The Panel notes that no evidence was provided that results obtained in patients with *H. pylori* infection under antibiotics with respect to the treatment of the disease can be extrapolated to healthy subjects with respect to the development of *H. pylori* infection. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of a claim on defence against pathogenic gastro-intestinal microorganisms targeted to the general population (i.e. subjects without infections).

The Panel notes that no human 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 *Lactobacillus casei* DG CNCM I-1572 and decreasing potentially pathogenic gastro-intestinal microorganisms.

CONCLUSIONS

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

- The food constituent, *Lactobacillus casei* DG CNCM I-1572, which is the subject of the health claims, is sufficiently characterised.
- The claimed effects proposed for further assessment relate to “contributes to the rebalancing of intestinal microflora” and to “reducing the content of potentially pathogenic microorganism”. The proposed target population is the general population. Decreasing potentially pathogenic gastro-intestinal microorganisms might be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of *Lactobacillus casei* DG CNCM I-1572 and decreasing potentially pathogenic gastro-intestinal microorganisms.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 for further assessment (No: EFSA-Q-2012-00182, EFSA-Q-2012-00211). 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 (EC) No 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.

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 *Lactobacillus casei* DG CNCM I-1572, including conditions of use, as proposed in the framework of further assessment.

ID	Food or Food constituent	Health Relationship	Proposed wording
2949	<i>Lactobacillus casei</i> DG CNCM I-1572	Lactobacillus casei DG, CNCM I-1572 contributes to the rebalancing of intestinal microflora doubling the <i>lactobacilli</i> content in the feces as demonstrating by Drago et. Al. (2002). The bowel colonization by <i>L.casei</i> DG did not significantly influenced other <i>lactobacilli</i> strains content in the feces. Furthermore <i>L.casei</i> DG is able to reducing the content of potentially pathogenic microorganism like <i>Enterobacteriaceae</i> . This effects was determined indirectly by Tursi et. Al. (2006-2008) as <i>L.casei</i> DG administration prevents the recurrence of symptomatic uncomplicated diverticular disease of the colon for 36 months and directly by D’Inca et al. (2011) on sigmoid region mucosal-associated microbes culture obtained after biopsy. <i>L. casei</i> DG had a marked effect on the colonic microflora, with a significant increase of the <i>Lactobacillus</i> spp., and significant decrease of <i>Enterobacteriacee</i> spp. (effect obtained after rectal administration of 8 million/day a 10 fold lower dose of oral dose).	Helps balance the intestinal flora
<p>Conditions of use</p> <p>At least 8 billion/day for adult, the food supplement is specifically formulated in order to provide this minimum quantities.</p> <p>General population; there’re several condition that can lead to transient intestinal microbiota alteration (i.e. improper diet, antibiotics therapy, stress or bacterial overgrowth) and are independent from age or sex. Those alteration can cause intestinal discomfort and are mainly do to an increase of the potentially pathogenetic microorganisms.</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
3061	<i>Lactobacillus casei</i> DG CNCM I-1572	Lactobacillus casei DG, CNCM I-1572 contributes to the rebalancing of intestinal microflora doubling the <i>lactobacilli</i> content in the feces as demonstrating by Drago et al. (2002). The bowel colonization by <i>L.casei</i> DG did not significantly influenced other <i>lactobacilli</i> strains content in the feces. Furthermore <i>L.casei</i> DG is able to reducing the content of potentially pathogenic microorganism like <i>Enterobacteriaceae</i> . This effects was determined indirectly by Tursi et. Al.	Contributes to decrease potentially pathogenic gastro-intestinal microorganism

		<p>(2006-2008) as <i>L.casei</i> DG administration prevents the recurrence of symptomatic uncomplicated diverticular disease of the colon for 36 months and directly by D’Inca et al. (2011) on sigmoid region mucosal-associated microbes culture obtained after biopsy. <i>L. casei</i> DG had a marked effect on the colonic microflora, with a significant increase of the <i>Lactobacillus</i> spp., and significant decrease of <i>Enterobacteriaceae</i> spp. (effect obtained after rectal administration of 8 million/day a 10 fold lower dose of oral dose).</p>	
<p>Conditions of use</p> <p>At least 8 billion/day for adult, the food supplement is specifically formulated in order to provide this minimum quantities.</p> <p>General population; there’re several condition that can lead to transient intestinal microbiota alteration (i.e. improper diet, antibiotics therapy, stress or bacterial overgrowth) and are independent from age or sex. Those alteration can cause intestinal discomfort and are mainly do to an increase of the potentially pathogenetic microorganisms.</p>			

GLOSSARY AND ABBREVIATIONS

5-ASA	5-Aminosalicylic acid
CNCM	Collection Nationale de Cultures de Microorganismes
rRNA	Ribosomal ribonucleic acid