SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to fermented dairy products and decreasing potentially pathogenic intestinal microorganisms (ID 1376) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

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

European Food Safety Authority (EFSA), Parma, Italy

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 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to fermented dairy products and "healthy digestion". The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claim is *Bifidobacterium* Bb-12 and soluble fibre in fermented dairy products. The Panel considers that the strain *Bifidobacterium animalis* ssp. *lactis* Bb-12 is sufficiently characterised. The Panel considers that the soluble fibre is not sufficiently characterised.

The claimed effect "healthy digestion" is not sufficiently defined but in the context of the proposed wording, the Panel assumes that the claimed effect relates to aspects of promoting the growth of "beneficial" bacteria and decreasing potentially pathogenic intestinal microorganisms. The Panel considers that decreasing potentially pathogenic intestinal microorganisms might be beneficial to human health.

As the information provided in the list is insufficient to characterise the soluble fibre in the fermented dairy products and the references cited did not provide any scientific data that could be used to substantiate the claimed effect, the Panel concludes that a cause and effect relationship has not been established between the consumption of "*Bifidobacterium animalis* ssp. *lactis* Bb-12 and soluble fibre in fermented dairy products" and decreasing potentially pathogenic intestinal microorganisms.

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1 On request from the European Commission, Question No EFSA-Q-2008-2113, adopted on 02 July 2009.

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KEY WORDS

Bifidobacterium animalis ssp. *lactis* Bb-12, soluble fibre, fermented dairy products, potentially pathogenic microorganisms, health claims

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

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The members of the Working Group on claims: Jean-Louis Bresson, Albert Flynn, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Sean (J.J.) Strain, Inge Tetens, Henk van den Berg, Hendrik van Loveren and Hans Verhagen.

The members of the Claims/Sub-Working Group Gut/Immune: Maria Carmen Collado, Miguel Gueimonde, Daisy Jonkers, Martinus Løvik, Bevan Moseley, Maria Saarela, Stephan Strobel and Hendrik van Loveren.

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation 1924/2006[3] submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims. The information provided in the consolidated list for the health claims subject to this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is *Bifidobacterium* Bb-12 and soluble fibre in fermented dairy products.

The bacterial strain, which is the subject of the health claim, is assumed to be *Bifidobacterium animalis* ssp. *lactis* Bb-12 (hereafter *B. animalis* ssp. *lactis* Bb-12). The strain *B. animalis* ssp. *lactis* Bb-12, previously known as *B. lactis* Bb-12, is subjected to reclassification (Masco et al., 2004). The species identity as well as the strain identity and characteristics have been determined using different genotypic methods (Yimin et al., unpublished; Garrigues et al., 2005; Mayer et al., 2007; Ventura et al., 2001a). It is important to point out that it may not be possible to differentiate commercially available *B. animalis* ssp. *lactis* strains from each other on the basis of traditional genetic methods (e.g. PFGE (Pulsed Field Gel Electrophoresis)) (Engel et al., 2003; Gueimonde et al., 2004) and that it may be necessary to use multi-locus sequencing or genome-wide approaches. In this regard the genome of *B. animalis* ssp. *lactis* Bb-12 although sequenced (Yimin et al., unpublished) is not publicly available.

The deposit of the strain in the German culture collection DSMZ (Deutsche Sammlung von Mikroorganismen und Zellkulturen) under number DSM 15954 was reported in the literature (Kajander et al., 2008). In addition several authors consider the strain Bb-12 to be also equal to the strain DSMZ 10140 (Ventura et al., 2001b). This is owing to the fact that, although the strain owner did not deposit the strain under the Bb-12 name, strain DSMZ 10140 was isolated from a yoghurt containing Bb-12 and deposited by Meile et al. (1997).

The Panel considers that the strain *Bifidobacterium animalis* ssp. *lactis* Bb-12, which is the subject of the health claim, is sufficiently characterised.

There is a wide variety of soluble fibres. The Panel considers that the soluble fibre, which is the subject of the health claim, is not sufficiently characterised in the information provided.

2. Relevance of the claimed effect to human health

The claimed effect is "healthy digestion". The Panel assumes that the target population is the general population.

"Healthy digestion" is not sufficiently defined. In the context of the proposed wording, the Panel assumes that the claimed effect relates to aspects of promoting the growth of "beneficial" bacteria and decreasing potentially pathogenic intestinal microorganisms.

[3] 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 numbers/proportions of bacterial groups that would constitute a "beneficial" gut microbiota have not been established. Increasing the number of any groups of bacteria is not in itself considered as beneficial. The Panel considers that no evidence has been provided that promoting the growth of "beneficial" bacteria is beneficial to human health.

The Panel considers that decreasing potentially pathogenic intestinal microorganisms might be beneficial to human health.

3. Scientific substantiation of the claimed effect

Seventy-nine references were cited to substantiate the claimed effect.

Sixteen references were human studies where a Bifidobacterium strain alone or in combination with lactic acid bacteria (yoghurt or probiotic bacteria) were added into milk before fermentation or administered in form of capsules. In one study (Chouraqui et al., 2004), *Bifidobacterium* Bb-12 was the only bacterial strain added to an acidified infant formula but no soluble fibre was added. Three studies addressed the effect of *Bifidobacterium* Bb-12 added to yogurt (without soluble fibre) in subject with *Helicobacter pylori* infections (Wang et al. 2004; Sheu at al., 2002; Sheu et al. 2006). The Panel notes that these studies did not use the indicated conditions of use for the claimed effect applied (fermented dairy products containing 10^9 CFU *B. animalis* ssp. *lactis* Bb-12 and 6 grams soluble fibre).

The other references were not related to fermented dairy products or dealt with different outcomes, such as lactose intolerance, lactose maldigestion, low-lactose milk, oligofructose or inulin intake or "probiotic" containing capsules.

The Panel notes the references cited did not provide any scientific data that could be used to substantiate the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of *Bifidobacterium animalis* ssp. *lactis* Bb-12 and soluble fibre in fermented dairy products and decreasing potentially pathogenic intestinal microorganisms.

CONCLUSIONS

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

- The food constituent that is the subject of the health claim is *Bifidobacterium* Bb-12 and soluble fibre in fermented dairy products. The strain *Bifidobacterium animalis* ssp. *lactis* Bb-12 is sufficiently characterised. The soluble fibre is not sufficiently characterised.
- The claimed effect is "healthy digestion". The target population is assumed to be the general population. Decreasing potentially pathogenic intestinal microorganisms might be beneficial to human health.
- A cause and effect relationship has not been established between the consumption of *Bifidobacterium animalis* ssp. *lactis* Bb-12 and soluble fibre in fermented dairy products and decreasing potentially pathogenic intestinal microorganisms.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2113). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/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[4] (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[5]

Foods are commonly involved in many different functions[6] 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.

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:

[4] OJ L12, 18/01/2007
[5] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[6] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

(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. Main entry health claims related to fermented dairy products, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food component	Health Relationship	Proposed wording
1376	Fermented dairy products	Healthy Digestion	Healthy Digestion A concentrated boost of probiotics and soluble fibre which provides double strength support for a healthy gut Yoplait Essence Healthy Digestion is a concentrated boost of probiotics and soluble fibres which work together to provide double strength support, to help maintain a healthy gut. Help your body's digestive system's performance Provide support for a healthy gut Work to ensure healthy functioning of your digestive system Help your body's digestive system's performance thereby maintaining a healthy gut Work in the gut, by promoting the growth of more beneficial bacteria and thereby outnumbering the growth of harmful bacteria Improved bowel function and colonic health The essence of healthy digestion Ensures healthy functioning of your digestive system Helps boost your digestive system A source of energy for the good probiotic Bifidobacterium BB-12
	Conditions of use - Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 900000 grams probiotics Weight of average daily food serving: 250 gram(s) Daily amount to be consumed to produce claimed effect: 250 gram(s) Number of food portions this equates to in everyday food portions: 1 Are there factors that could interfere with bioavailability: Yes Please give reason: Ex Vivo May be destroyed by oxygen. Potential losses in bacterial viability if stored at ambient temperature for long periods. in Vivo These 2 particular strains are relatively stable to stomach acid and moderate temperature changes during storage However more stable in cool temperatures. *Lactobacillus* species sensitive to non antibiotic therapy Length of time after consumption for claimed effect to become apparent: It is apparent after a period of		

	regular use. Number of days: 14 Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No Where applicable outline nutritional composition (g per 100g) of food: Total Fat: 1.30 Saturated Fat: .90 Trans Fat: .00 Sugar: 9.80 Salt: .00 Sodium: .00 Other conditions for use: Regular consumption or a 'daily dose' of at least 10 million bacteria is necessary in order to support healthy digestion. - Number of nutrients/other substances that are essential to claimed effect: 2 Names of nutrient and Quantity in Average daily serving: 1,000,000,000 CFU's *Bifidobacterium* BB12, 6grams soluble fibre Weight of average daily food serving: 60 gram(s) Daily amount to be consumed to produce claimed effect: 60 gram(s) Number of food portions this equates to in everyday food portions: 1 Are there factors that could interfere with bioavailability: No Length of time after consumption for claimed effect to become apparent: It is dependent on the individual's fibre intake status Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No more than 10g of soluble fibre is recommended per day for an adult