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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to various microorganisms and reduction of gastro-intestinal discomfort (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970), decreasing potentially pathogenic gastro-intestinal microorganisms (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970), improved lactose digestion (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970), “intestinal flora/digestive health” (ID 4231), defence against vaginal pathogens (ID 2950, 2957, 2967) and increasing IL-10 production and/or enhancing the activity of natural killer cells (ID 2960, 2962, 2971) (further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide a scientific opinion on health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 in the framework of further assessment related to various microorganisms and reduction of gastro-intestinal discomfort, decreasing potentially pathogenic gastro-intestinal microorganisms, improved lactose digestion, “intestinal flora/digestive health”, defence against vaginal pathogens and increasing IL-10 production and/or enhancing the activity of natural killer cells. The food constituents *Lactobacillus crispatus* BCCM/LMG P-17631, *Lactobacillus gasseri* BCCM/LMG P-17632, *Lactobacillus gasseri* BCCM/LMG P-18137, *Lactobacillus paracasei* CNCM I-1687, *Lactobacillus paracasei* CNCM I-1688, *Lactobacillus plantarum* BCCM/LMG P-17630, *Lactobacillus salivarius* CNCM I-1794 and a combination of *Bifidobacterium animalis* ssp. *lactis* Bi-6 and *Lactobacillus johnsonii* La-1 (ACD-1)(CLbA22) are sufficiently characterised. The evidence provided did not establish that the proposed claimed effect, increasing IL-10 production and/or enhancing the activity of natural killer cells, is a beneficial physiological effect. The claimed effect “intestinal flora/digestive health” is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006. The references provided in relation to the claims evaluated in this opinion


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included studies which assessed the effects of food constituents other than the food constituents which are the subject of the claims and/or investigated health outcomes unrelated to the claimed effects. No human studies which investigated the effects of the food constituents on appropriate measures of the claimed effects were provided. On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituents and the claimed effects evaluated in this opinion.

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**KEY WORDS**

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. The Commission has agreed with EU Member States that a certain number of Article 13 health claims would be eligible for further assessment by EFSA in order to be able to take a final decision on whether or not to include these claims in the list of permitted health claims. This opinion addresses the scientific substantiation of health claims in relation to various microorganisms and reduction of gastro-intestinal discomfort, decreasing potentially pathogenic gastro-intestinal microorganisms, improved lactose digestion, “intestinal flora/digestive health”, defence against vaginal pathogens and increasing IL-10 production and/or enhancing the activity of natural killer cells. The scientific substantiation is based on the information provided by the competent Authority of Italy for further assessment of these claims.

The following food constituents are sufficiently characterised:

- Lactobacillus crispatus BCCM/LMG P-17631 (ID1030, 2950),
- Lactobacillus gasseri BCCM/LMG P-17632 (ID 2956),
- Lactobacillus gasseri BCCM/LMG P-18137 (ID 2957, 2958),
- Lactobacillus paracasei CNCM I-1687 (ID 2960, 2961),
- Lactobacillus paracasei CNCM I-1688 (ID 2962, 2963),
- Lactobacillus plantarum BCCM/LMG P-17630 (ID 2966, 2967),
- Lactobacillus salivarius CNCM I-1794 (ID 2970, 2971),
- A combination of Bifidobacterium animalis ssp. lactis Bf-6 and Lactobacillus johnsonii La-1 (ACD-1)(CLbA22) (ID 4231).

Reduction of gastro-intestinal discomfort (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970)

The claimed effect which is proposed for further assessment relates to reduction of gastro-intestinal discomfort. The proposed target population is the general population. Reduction of gastro-intestinal discomfort is a beneficial physiological effect.

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 the food constituents which are the subject of the claims and reduction of gastro-intestinal discomfort.

Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970)

The claimed effect which is proposed for further assessment relates to a decrease in potentially pathogenic gastro-intestinal microorganisms. The proposed target population is the general population. Decreasing potentially pathogenic gastro-intestinal microorganisms might be a beneficial physiological effect.

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 the food constituents which are the subject of the claims and decreasing potentially pathogenic gastro-intestinal microorganisms.
Health claims related to various microorganisms (further assessment)

Improved lactose digestion (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970)

The claimed effect which is proposed for further assessment relates to improved lactose digestion. Improved lactose digestion is a beneficial physiological effect for individuals with lactose maldigestion.

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 the food constituents which are the subject of the claims and improved lactose digestion.

“Intestinal flora/digestive health” (ID 4231)

No health relationship is proposed for further assessment. The health relationship submitted in the consolidated list for the initial assessment was “intestinal flora/digestive health”. The target population is assumed to be the general population.

On the basis of the data presented, the Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

Defence against vaginal pathogens (ID 2950, 2957, 2967)

The claimed effect which is proposed for further assessment relates to defence against vaginal pathogens by increasing the number of lactobacilli and/or decreasing potentially pathogenic bacteria. The target population is the female population. Defence against vaginal pathogens is a beneficial physiological effect.

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 the food constituents which are the subject of the claims and defence against vaginal pathogens.

Increasing IL-10 production and/or enhancing the activity of natural killer cells (ID 2960, 2962, 2971)

The claimed effect which is proposed for further assessment relates to increasing IL-10 production and/or enhancing the activity of natural killer cells. The proposed target population is the general population. The Panel notes that increasing IL-10 production and/or enhancing the activity of natural killer cells is not a beneficial physiological effect per se, but needs to be linked to a beneficial physiological or clinical outcome.

The Panel considers that the evidence provided did not establish that increasing IL-10 production and/or enhancing the activity of natural killer cells is a beneficial physiological effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituents which are the subject of the health claims and a beneficial physiological effect related to an increase in IL-10 production and/or an enhancement of the lytic activity of natural killer cells.
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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 microorganisms which the Panel considered to be not sufficiently characterised and claims for which the NDA Panel concluded that there was insufficient evidence to establish a cause and effect relationship between the consumption of the food and the claimed effect.

Following an opinion of the NDA Panel pursuant to Article 13 of Regulation (EC) No 1924/2006 in which the Panel concluded that the data available were not sufficient to characterise *Lactobacillus crispatus* P-17631 (ID 1030, 2950), *Lactobacillus gasseri* P-17632 (ID 2956), *Lactobacillus gasseri* P-18137 (ID 2957, 2958), *Lactobacillus paracasei* I-1687 (ID 2960, 2961), *Lactobacillus paracasei* I-1688 (ID 2962, 2963), *Lactobacillus plantarum* P-17630 (ID 2966, 2967), *Lactobacillus salivarius* I-1794 (ID 2970, 2971) and a combination of *Bifidobacterium animalis* ssp. lactis Bf-6/Bif-6/CB111 and *Lactobacillus johnsonii* La-1/ACD-1/CLbA22 (A/B-61) (ID 4231) (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 these claims. 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

1.1. *Lactobacillus crispatus* BCCM/LMG P-17631 (ID1030, 2950)

The food constituent that is the subject of the proposed health claims is *Lactobacillus crispatus* BCCM/LMG P-17631.

For *L. crispatus* BCCM/LMG P-17631, a culture collection number from the Belgian Co-ordinated Collections of Microorganisms (BCCM/LMG P-17631) was provided. The BCCM/LMG is an internationally recognised culture collection which has the status of an International Depositary Authority under the Budapest Treaty. In the LMG, cultures can be deposited in a restricted-access collection for safe deposit or for patent purposes. Data on the identification and characterisation of *L. crispatus* BCCM/LMG P-17631 at species and strain level, by different phenotypic (carbohydrate fermentation profiles, PAGE) and genotypic (16S rRNA gene sequence analyses, plasmidic profile, ARDRA, Rep-PCR, AFLP) methods, were provided in the applications for further assessment and in the accompanying references (AAT, 2011a, unpublished, 2011b, unpublished; BCCM/LMG, 1997, unpublished; Dondi and Morelli, 1999, 2002; Morelli, 1997, unpublished).

The Panel considers that the food constituent that is the subject of the proposed health claims, *L. crispatus* BCCM/LMG P-17631, is sufficiently characterised.

1.2. *Lactobacillus gasseri* BCCM/LMG P-17632 (ID 2956)

The food constituent that is the subject of the proposed health claims is *Lactobacillus gasseri* BCCM/LMG P-17632.

For *L. gasseri* BCCM/LMG P-17632, a culture collection number from the BCCM/LMG, P-17632, was provided. Data on the identification and characterisation of *L. gasseri* BCCM/LMG P-17632 at species and strain level, by different phenotypic (carbohydrate fermentation profiles, PAGE) and genotypic (16S rRNA gene sequence analyses, ARDRA, Rep-PCR, PFGE) methods, were provided in

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The Panel considers that the food constituent that is the subject of the proposed health claims, \textit{L. gasseri} BCCM/LMG P-17632, is sufficiently characterised.

1.3. \textit{Lactobacillus gasseri} BCCM/LMG P-18137 (ID 2957, 2958)

The food constituent that is the subject of the proposed health claims is \textit{Lactobacillus gasseri} BCCM/LMG P-18137.

For \textit{L. gasseri} BCCM/LMG P-18137, a culture collection number from the BCCM/LMG, P-18137, was provided. Data on the identification and characterisation of \textit{L. gasseri} BCCM/LMG P-18137 at species and strain level, by different phenotypic (carbohydrate fermentation profiles) and genotypic (16S rRNA gene sequence analyses, ARDRA, Rep-PCR, PFGE) methods, were provided in the applications for further assessment and in the accompanying references (AAT, 2011d, unpublished; BCCM/LMG, 1998, unpublished; Dondi and Morelli, 1999, 2002).

The Panel considers that the food constituent that is the subject of the proposed health claims, \textit{L. gasseri} BCCM/LMG P-18137, is sufficiently characterised.

1.4. \textit{Lactobacillus paracasei} CNCM I-1687 (ID 2960, 2961)

The food constituent that is the subject of the proposed health claims is \textit{Lactobacillus paracasei} CNCM I-1687.

For \textit{L. paracasei} CNCM I-1687, a culture collection number from the French National Collection of Cultures of Microorganisms (CNCM I-1687) was provided. The CNCM is a restricted-access non-public collection which has the status of an International Depositary Authority under the Budapest Treaty. Data on the identification and characterisation of \textit{L. paracasei} CNCM I-1687 at species and strain level, by different phenotypic (carbohydrate fermentation profiles) and genotypic (16S rRNA gene sequence analyses, plasmidic profile, ARDRA, Rep-PCR, AFLP) methods, were provided in the applications for further assessment and in the accompanying references (AAT, 2011b, unpublished, 2011e, unpublished; Morelli, 1996, unpublished; Morelli, 1997, unpublished).

The Panel considers that the food constituent that is the subject of the proposed health claims, \textit{L. paracasei} CNCM I-1687, is sufficiently characterised.

1.5. \textit{Lactobacillus paracasei} CNCM I-1688 (ID 2962, 2963)

The food constituent that is the subject of the proposed health claims is \textit{Lactobacillus paracasei} CNCM I-1688.

For \textit{L. paracasei} CNCM I-1688, a culture collection number from the CNCM, I-1688, was provided. Data on the identification and characterisation of \textit{L. paracasei} CNCM I-1688 at species and strain level, by different phenotypic (carbohydrate fermentation profiles) and genotypic (16S rRNA gene sequence analyses, plasmidic profile, ARDRA, RAPD, Rep-PCR, PFGE) methods, were provided in the applications for further assessment and in the accompanying references (AAT, 2011f, unpublished; Bonetti et al., 2002; Morelli, 1996, unpublished; Morelli, 1997, unpublished).

The Panel considers that the food constituent that is the subject of the proposed health claims, \textit{L. paracasei} CNCM I-1688, is sufficiently characterised.
1.6. **Lactobacillus plantarum** BCCM/LMG P-17630 (ID 2966, 2967)

The food constituent that is the subject of the proposed health claims is *Lactobacillus plantarum* BCCM/LMG P-17630.

For *L. plantarum* BCCM/LMG P-17630, a culture collection number from the BCCM/LMG, P-17630, was provided. Data on the identification and characterisation of *L. plantarum* BCCM/LMG P-17630 at species and strain level, by different phenotypic (carbohydrate fermentation profile, antibiotic resistance pattern, PAGE) and genotypic (16S rRNA gene sequence analyses, ARDRA, Rep-PCR, PFGE, genome sequencing) methods, were provided in the applications and in the accompanying references (AAT, 2011g, unpublished; BCCM/LMG, 1997, unpublished; Dho et al., 2003; Dondi, 2000; Escorsell, 2007; Morelli, 1997, unpublished; Semiautomatic Genome Annotation, 2010, unpublished).

The Panel considers that the food constituent that is the subject of the proposed health claims, *L. plantarum* BCCM/LMG P-17630, is sufficiently characterised.

1.7. **Lactobacillus salivarius** CNCM I-1794 (ID 2970, 2971)

The food constituent that is the subject of the proposed health claims is *Lactobacillus salivarius* CNCM I-1794.

For *L. salivarius* CNCM I-1794, a culture collection number from the CNCM, I-1794, was provided. Data on the identification and characterisation of *L. salivarius* CNCM I-1794 at species and strain level, by different phenotypic (carbohydrate fermentation profiles, antibiotic resistance pattern) and genotypic (16S rRNA gene sequence analyses, plasmidic profile, ARDRA, RAPD, Rep-PCR, PFGE) methods, were provided in the applications for further assessment and in the accompanying references (AAT, 2011h, unpublished; Bonetti et al., 2002; Morelli, 1997, unpublished; Pedraglio, 2004).

The Panel considers that the food constituent that is the subject of the proposed health claims, *L. salivarius* CNCM I-1794, is sufficiently characterised.

1.8. A combination of *Bifidobacterium animalis* ssp. *lactis* Bf-6 and *Lactobacillus johnsonii* La-1 (ACD-1)(CLbA22) (ID 4231)

The food constituent that is the subject of the proposed health claim is a combination of *Bifidobacterium animalis* ssp. *lactis* Bf-6 and *Lactobacillus johnsonii* La-1 (ACD-1)(CLbA22).

The strain *B. animalis* ssp. *lactis* Bf-6 is also known as *Bifidobacterium animalis* ssp. *lactis* CB1111. A culture collection number from the BCCM/LMG, LMG 24384, was provided. Data on the identification and characterisation of *B. animalis* ssp. *lactis* Bf-6 at species and strain level, by different genotypic (16S rRNA gene sequence analysis, RAPD, Rep-PCR, genome sequencing) methods, were provided in the application for further assessment and in the accompanying references (Cargill, 2011a, unpublished; Ehrmann, 2006, unpublished; Integrated Genomics, 2011, unpublished; MIDI Labs, 2011a, unpublished, 2011b, unpublished). The Panel considers that *B. animalis* ssp. *lactis* Bf-6 is sufficient characterised.

For *L. johnsonii* La-1 (ACD-1)(CLbA22), a culture collection number from the BCCM/LMG, LMG 24394, was provided. Data on the identification and characterisation of *L. johnsonii* La-1 (ACD-1)(CLbA22) at species and strain level, by different genotypic (16S rRNA gene sequence analysis, RAPD, Rep-PCR) methods, were provided in the application for further assessment and in the accompanying references (Cargill, 2011b, unpublished, 2011c, unpublished; Ehrmann, 2006, unpublished). The Panel considers that *L. johnsonii* La-1 (ACD-1)(CLbA22) is sufficiently characterised.
The Panel considers that the food constituent that is the subject of the proposed health claims, a combination of *B. animalis* ssp. *lactis* Bf-6 and *L. johnsonii* La-1 (ACD-1)(CLbA22), is sufficiently characterised.

2. **Relevance of the claimed effect to human health**

2.1. **Reduction of gastro-intestinal discomfort (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970)**

The claimed effect which is proposed for further assessment is: “Is a probiotic; Contributes to a healthy digestive system by supporting the gut flora through an increased number of positive lactobacillus in the intestine; useful to maintain a healthy intestinal flora by adhering to the mucosa; Improves intestinal barrier function by competing (steric encumbrance) against pathogens; Reduces gastro-intestinal discomfort; Necessary to maintain a healthy digestive system by production of specific enzymes (e.g. beta-galactosidase).” The proposed target population is the general population.

The Panel considers that reduction of gastro-intestinal discomfort is a beneficial physiological effect.

2.2. **Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970)**

The claimed effect which is proposed for further assessment is: “Is a probiotic; Contributes to a healthy digestive system by supporting the gut flora through an increased number of positive lactobacillus in the intestine; useful to maintain a healthy intestinal flora by adhering to the mucosa; Improves intestinal barrier function by competing (steric encumbrance) against pathogens; Reduces gastro-intestinal discomfort; Necessary to maintain a healthy digestive system by production of specific enzymes (e.g. beta-galactosidase).” The proposed target population is the general adult population.

The Panel notes that it is not possible to define the exact number of the different microbial groups which constitute a normal microbiota. Increasing the number of any groups of microorganisms, including lactobacilli, is not in itself considered to be a beneficial physiological effect.

The Panel assumes that the claimed effect refers to decreasing potentially pathogenic gastro-intestinal microorganisms. The Panel considers that decreasing potentially pathogenic gastro-intestinal microorganisms might be a beneficial physiological effect.

2.3. **Improved lactose digestion (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970)**

The claimed effect which is proposed for further assessment is: “Is a probiotic; Contributes to a healthy digestive system by supporting the gut flora through an increased number of positive lactobacillus in the intestine; useful to maintain a healthy intestinal flora by adhering to the mucosa; Improves intestinal barrier function by competing (steric encumbrance) against pathogens; Reduces gastro-intestinal discomfort; Necessary to maintain a healthy digestive system by production of specific enzymes (e.g. beta-galactosidase).” The proposed target population is the general population.

The Panel assumes that the claimed effect refers to improved lactose digestion, and that the target population is individuals with lactose maldigestion. Lactose maldigestion is a common condition caused by reduced levels of intestinal lactase.

The Panel considers that improved lactose digestion is a beneficial physiological effect for individuals with lactose maldigestion.

2.4. **“Intestinal flora/digestive health” (ID 4231)**

In the application submitted for further assessment of the health claim, no health relationship, wording or references for the substantiation of the health effect have been provided. The health relationship
submitted in the consolidated list for the initial assessment was “intestinal flora/digestive health”. The Panel assumes that the target population is the general population.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

2.5. Defence against vaginal pathogens (ID 2950, 2957, 2967)

The claimed effect which is proposed for further assessment is: “Helps in maintaining balanced vaginal flora and pH; Contributes to a healthy colonization of the lactobacilli on the vagina; Helps to redress the healthy balanced vaginal microflora during and after the treatment of vaginal disorders”. The proposed target population is the female population.

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.

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, the vaginal microbiota is dominated by lactobacilli (> 50%) (Ling et al., 2010; Ravel et al., 2011; 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 for example on 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 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.

2.6. Increasing IL-10 production and/or enhancing the activity of natural killer cells (ID 2960, 2962, 2971)

The claimed effects which are proposed for further assessment are: “Supports your natural (immune) defence system by increasing the IL-10 production and enhancing NK cell activity in peripheral blood mononuclear cells (PBMC); Necessary to maintain the natural defences/helps to maintain a balanced immune system (increasing the IL-10 production and enhancing NK cell activity)”, and “Supports your natural (immune) defence system by increasing the IL-10 production in peripheral blood mononuclear cells (PBMC); Necessary to maintain the natural defences/helps to maintain a balanced immune system (increasing the IL-10 production)”. The proposed target population is the general population.

The Panel notes that the claimed effect “supports your natural (immune) defence system /necessary to maintain the natural defences /helps to maintain a balanced immune system” is not sufficiently defined, and assumes that the claimed effect relates to increasing IL-10 production by peripheral blood mononuclear cells and/or enhancing the lytic activity of natural killer cells.

The Panel notes that increasing IL-10 production by peripheral blood mononuclear cells and/or enhancing the lytic activity of natural killer cells is not a beneficial physiological effect per se, but needs to be linked to a beneficial physiological or clinical outcome.

Most of the references provided in relation to these claims were on methodologies for bacterial strain identification; in vitro studies on immunomodulatory properties (i.e. lymphocyte proliferation,
phenotype of the lymphocytic subpopulations, cytokine production) (Castellazzi, 2007a, unpublished; Castellazzi et al., 2007b; Castellazzi, 2007c, unpublished); and a patent (Dondi and Malfa, 2007) which reported the results of the in vitro study by Castellazzi et al. (2007a, unpublished).

In relation to ID 2962 and 2971, two references reported on the same single-arm (no control group) human intervention study (Castellazzi, 2007a, unpublished; Valsecchi et al., 2008) which investigated the effects of two strains in combination, while the single strains are the subject of the claims, on allergy symptoms (atopic dermatitis, rhino-conjunctivitis, urticaria, contact dermatitis, oral allergy syndrome and food allergies) and immunological parameters (i.e. lymphocyte population, natural killer activity and cytokine production) in 20 children with atopic disorders. The Panel notes that this single-arm study was not controlled and investigated a combination of strains rather than the single strains which are the subject of the claim, and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel considers that the evidence provided does not establish that increasing IL-10 production by peripheral blood mononuclear cells and/or enhancing the lytic activity of natural killer cells is a beneficial physiological effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituents which are the subject of the health claims and a beneficial physiological effect related to an increase in IL-10 production and/or an enhancement of the lytic activity of natural killer cells.

3. Scientific substantiation of the claimed effect

3.1. Reduction of gastro-intestinal discomfort (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970)

Most of the references provided in relation to these claims were on methodologies for bacterial strain identification (Jensen et al., 1993; Ventura et al., 2000), abstracts from a congress on the isolation of specific bacterial strains (Pietronave et al., 2003) or on the properties of a strain (Pietronave et al., 2004), which were unrelated to the claimed effect.

Patents on methods for the selection of Lactobacillus strains (e.g. L. crispatus P-17631, L. gasseri P-17632 and L. gasseri P-18137) with antimicrobial activity (Dondi and Morelli, 1999, 2002); patents on methods for selection of Lactobacillus strains (e.g. L. paracasei CNCM I-1687 and L. paracasei CNCM I-1688) indicated to be useful for the treatment of various disorders of the gastro-intestinal tract because of their capability to produce lactic acid (Pedraglio, 2004), or with high ability to adhere to human mucosa (e.g. L. plantarum LMG P-17630) (Dondi, 2000), or patents for the use of two bacterial strains (L. gasseri P-17632 and L. salivarius CNCM I-1794) against Candida albicans (Dondi, 2004, 2007), were also provided. One human intervention study on the viability of the strains through the human intestinal tract (Bonetti et al., 2002) and one in vitro study on the properties of the bacterial strain (i.e. growth at different temperatures and pH levels (Dho et al., 2003)) were also provided. The Panel notes that these references were unrelated to the claimed effect, and considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

The Panel notes that no human studies were provided from which conclusions could be drawn for the scientific substantiation of the claims evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituents which are the subject of the claims evaluated in this section and reduction of gastro-intestinal discomfort.
3.2. Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970)

Most of the references provided in relation to these claims were on methodologies for bacterial strain identification (Jensen et al., 1993; Ventura et al., 2000), abstracts from a congress on the isolation of specific bacterial strains (Pietronave et al., 2003) or on the properties of a strain (Pietronave et al., 2004), which were unrelated to the claimed effect.

Patents on methods for the selection of Lactobacillus strains (e.g. L. crispatus P-17631, L. gasseri P-17632 and L. gasseri P-18137) with antimicrobial activity, in which the in vitro inhibitory activity of the strain that is the subject of the claim against Candida albicans and Streptococcus β-haemolyticus was mentioned (Dondi and Morelli, 1999, 2002) were provided. Also patents on methods for the selection of Lactobacillus strains (e.g. L. paracasei CNCM I-1687 and L. paracasei CNCM I-1688) indicated to be useful for the treatment of various disorders of the gastro-intestinal tract because of their capability to produce lactic acid (Pedraglio, 2004)), or with high ability to adhere to human mucosa (e.g. L. plantarum LMG P-17630) (Dondi, 2000) were provided. Two patents for the use of L. gasseri P-17632 and L. salivarius CNCM I-1794, alone or in combination, against Candida albicans (Dondi, 2004, 2007) were also provided. The Panel notes that no primary data were provided in these patents that could be used for the substantiation of the claim. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One human intervention study on the viability of the strains through the human intestinal tract (Bonetti et al., 2002) and one in vitro study on the properties of the bacterial strain (i.e. growth at different temperatures and pH levels (Dho et al., 2003)) were also provided. The Panel notes that these studies did not address outcome measures related to the claimed effect, and considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

The Panel notes that no human studies were provided from which conclusions could be drawn for the scientific substantiation of the claims evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituents which are the subject of the claims evaluated in this section and decreasing potentially pathogenic gastro-intestinal microorganisms.

3.3. Improved lactose digestion (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970)

Patents on methods for the selection of Lactobacillus strains (e.g. L. crispatus P-17631, L. gasseri P-17632 and L. gasseri P-18137) with antimicrobial activity (Dondi and Morelli, 1999, 2002); patents on methods for selection of lactobacilli strains (e.g. L. paracasei CNCM I-1687 and L. paracasei CNCM I-1688) indicated to be useful for the treatment of various disorders of the gastro-intestinal tract because of their capability to produce lactic acid (Pedraglio, 2004)), or with high ability to adhere to human mucosa (e.g. L. plantarum LMG P-17630) (Dondi, 2000), or patents for the use of two bacterial strains (e.g. L. gasseri P-17632 and L. salivarius CNCM I-1794) against Candida albicans (Dondi, 2004, 2007), were also provided. One human intervention study on the viability of the strains through the human intestinal tract (Bonetti et al., 2002) and one in vitro study on the properties of the bacterial strain (i.e. growth at different temperatures and pH levels (Dho et al., 2003)) were also provided. The Panel notes that these references were unrelated to the claimed effect, and considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

The Panel notes that no human studies were provided from which conclusions could be drawn for the scientific substantiation of the claims evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituents which are the subject of the claims evaluated in this section and improved lactose digestion.
3.4. Defence against vaginal pathogens (ID 2950, 2957, 2967)

Most of the references provided in relation to these claims were on methodologies for bacterial strain identification (Jensen et al., 1993; Ventura et al., 2000); an abstract from a congress on the isolation of specific bacterial strains (Petronave et al., 2003); patents on methods for selection of Lactobacillus strains (e.g. L. plantarum LMG P-17630) with high ability to adhere to human mucosa (Dondi, 2000), in vitro studies which reported on properties of the strains (e.g. adherence to vaginal epithelial cells (Bonetti et al., 2003; Culici et al., 2004; Escorsell, 2007), or on viability at different pH (Morelli, 2000)). The Panel notes that these references did not address outcome measures related to the claimed effect.

Patents on methods for the selection of Lactobacillus strains (e.g. L. crispatus P-17631, L. gasseri P-17632 and L. gasseri P-18137) with antimicrobial activity, in which the in vitro inhibitory activity of the strain that is the subject of the claim against Candida albicans and Streptococcus β-haemolyticus was mentioned (Dondi and Morelli, 1999, 2002) were provided. Patents for the use of two bacterial strains (i.e. L. gasseri P-17632 and L. salivarius CNCM I-1794) against Candida albicans (Dondi, 2004, 2007), were also provided. The Panel notes that no primary data which could be used for the scientific substantiation of the claim were provided in these patents. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

A number of human intervention studies investigated the effects of the specific strain which is the subject of the claim when the strain was administered intravaginally (Carriero et al., 2007; Escorsell, 2007; Gianella, 2003; Nava et al., 2002). The Panel considers that studies made on substances which are not administered orally cannot be used to substantiate a claim on a food constituent.

The Panel notes that no human studies were provided from which conclusions could be drawn for the scientific substantiation of the claims evaluated in this section.

In relation to ID 2967, in vitro studies which addressed the effects of the strain that is the subject of the claim on the adhesion properties of Candida albicans to vaginal epithelia cells (Culici et al., 2004; Escorsell, 2007) were provided. The Panel considers that in the absence of evidence for an effect on defence against vaginal pathogens in humans, evidence provided in in vitro studies cannot be used alone for the scientific substantiation of a claim on defence against vaginal pathogens.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituents which are the subject of the claims evaluated in this section and defence against vaginal pathogens.

CONCLUSIONS

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

- The following food constituents are sufficiently characterised:
  - Lactobacillus crispatus BCCM/LMG P-17631 (ID 1030, 2950),
  - Lactobacillus gasseri BCCM/LMG P-17632 (ID 2956),
  - Lactobacillus gasseri BCCM/LMG P-18137 (ID 2957, 2958),
  - Lactobacillus paracasei CNCM I-1687 (ID 2960, 2961),
  - Lactobacillus paracasei CNCM I-1688 (ID 2962, 2963),
  - Lactobacillus plantarum BCCM/LMG P-17630 (ID 2966, 2967),
  - Lactobacillus salivarius CNCM I-1794 (ID 2970, 2971),
a combination of *Bifidobacterium animalis* ssp. *lactis* Bf-6 and *Lactobacillus johnsonii* La-1 (ACD-1)(CLbA22) (ID 4231).

**Reduction of gastro-intestinal discomfort (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970)**

- The claimed effect proposed for further assessment relates to reduction of gastro-intestinal discomfort. The proposed target population is the general population. Reduction of gastro-intestinal discomfort is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of the food constituents which are the subject of the claims and reduction of gastro-intestinal discomfort.

**Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970)**

- The claimed effect proposed for further assessment relates to decreasing potentially pathogenic gastro-intestinal microorganisms. 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 the food constituents which are the subject of the claims and decreasing potentially pathogenic gastro-intestinal microorganisms.

**Improved lactose digestion (ID 1030, 2956, 2958, 2961, 2963, 2966, 2970)**

- The claimed effect proposed for further assessment relates to improved lactose digestion. Improved lactose digestion is a beneficial physiological effect for individuals with lactose maldigestion.
- A cause and effect relationship has not been established between the consumption of the food constituents which are the subject of the claims and improved lactose digestion.

**“Intestinal flora/digestive health” (ID 4231)**

- No health relationship is proposed for further assessment. The health relationship submitted in the consolidated list for the initial assessment was “intestinal flora/digestive health”. The target population is assumed to be the general population.
- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

**Defence against vaginal pathogens (ID 2950, 2957, 2967)**

- The claimed effect proposed for further assessment relates to defence against vaginal pathogens by increasing the number of lactobacilli and/or decreasing potentially pathogenic bacteria. 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 the food constituents which are the subject of the claims and defence against vaginal pathogens.
Increasing IL-10 production and/or enhancing the activity of natural killer cells (ID 2960, 2962, 2971)

- The claimed effect proposed for further assessment relates to increasing the IL-10 production and/or enhancing the activity of natural killer cells. The proposed target population is the general population. The evidence provided did not establish that increasing IL-10 production in peripheral blood mononuclear cells and/or enhancing the activity of natural killer cells is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of the food constituents, which are the subject of the health claims, and a beneficial physiological effect related to an increase in IL-10 production and/or an enhancement of the lytic activity of natural killer cells.

DOCUMENTATION PROVIDED TO EFSA


REFERENCES


Cargill, 2011a, unpublished. Report on Rep-PCR of Bf-6 compared to other commercial bifidobacteria strains.

Cargill, 2011b, unpublished. Report on Rep-PCR of L. johnsonii La-a (ACD-1) compared to other Cargill thermophilic rod strains.


Health claims related to various microorganisms (further assessment)


APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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

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

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

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

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

b) psychological and behavioural functions; or

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

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

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

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

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD\(^6\)

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

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

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\(^5\) 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".

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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 various microorganisms, including conditions of use, as proposed in the framework of further assessment.

<table>
<thead>
<tr>
<th>ID</th>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>1030</td>
<td><em>Lactobacillus crispatus</em> BCCM/LMG P-17631</td>
<td>Is a probiotic; Contributes to a healthy digestive system by supporting the gut flora through an increased number of positive lactobacillus in the intestine; useful to maintain a healthy intestinal flora by adhering to the mucosa; Improves intestinal barrier function by competing (steric encumbrance) against pathogens; Reduces gastro-intestinal discomfort; Necessary to maintain a healthy digestive system by production of specific enzymes (eg: beta-galactosidase).</td>
<td>Is a probiotic that maintains the balance of healthy intestinal microflora and regulates intestinal functionality by replacing normal, natural microflora (especially after antibiotic/antimycotic treatment) which contributes to reducing gastro-intestinal discomfort which, for example, could be due to problems in lactose digestion.</td>
</tr>
</tbody>
</table>

**Conditions of use**

Being 'Generally Recognized as Safe' (GRAS) by the Food and Drug Administration, this health claim is destined for the general population.

The advised condition of use of this constituent is of at least $1 \times 10^8$ ufc per day

Since this product's release on the market, there have not been any reported cases of undesirable side effects due to this nutrient, however, Italian national law imposes the use of these precautions on the product label: Do not exceed the indicated dosage; Keep out of reach of children under three years of age; The intake of this supplement is not meant as a substitute to a balanced diet and healthy lifestyle; This product does not substitute antibiotic or chemotherapeutic therapy.

This product is presented in a soluble powder form. Dissolve the content of one sachet in water or warm milk, and drink immediately. Should be consumed, preferably, on an empty stomach.

<table>
<thead>
<tr>
<th>2950</th>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>Lactobacillus crispatus</em> BCCM/LMG P-17631</td>
<td>Helps in maintaining balanced vaginal flora and pH; Contributes to a healthy colonization of the lactobacilli on the vagina; Helps to redress the healthy balanced vaginal microflora during and after treatment of vaginal disorders.</td>
<td>Is a probiotic that helps to maintain normal vaginal microflora and vaginal pH at physiological levels (acid pH) playing a part in the inhibition of pathogen growth, and also aids in replacing the vaginal ecosystem when modified after antibiotic/antimycotic treatment</td>
</tr>
</tbody>
</table>
### Conditions of use

This health claim is destined for the female population, due to the product's specific vaginal use.

The advised condition of use of this constituent is of at least $1 \times 10^8$ ufc per day.

Since this product's release on the market, there have not been any reported cases of undesirable side effects due to this nutrient, however, Italian national law imposes the use of these precautions on the product label:

- Do not exceed the indicated dosage;
- Keep out of reach of children under three years of age;
- The intake of this supplement is not meant as a substitute to a balanced diet and healthy lifestyle;
- This product does not substitute antibiotic or chemotherapeutic therapy.

This product is presented in a soluble powder form. Dissolve the content of one sachet in water or warm milk, and drink immediately. Should be consumed, preferably, on an empty stomach.

### Food or Food constituent

<table>
<thead>
<tr>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Lactobacillus gasseri</em> BCCM/LMG P-17632</td>
<td>Is a probiotic; Contributes to a healthy digestive system by supporting the gut flora through an increased number of positive lactobacillus in the intestine; useful to maintain a healthy intestinal flora by adhering to the mucosa; Improves intestinal barrier function by competing (steric encumbrance) against pathogens; Reduces gastro-intestinal discomfort; Necessary to maintain a healthy digestive system by production of specific enzymes (eg: betagalactosidase).</td>
<td>Is a probiotic that maintains the balance of healthy intestinal microflora and regulates intestinal functionality by replacing normal, natural microflora (especially after antibiotic/antimycotic treatment) which contributes to reducing gastro-intestinal discomfort which, for example, could be due to problems in lactose digestion.</td>
</tr>
</tbody>
</table>

### Conditions of use

Being 'Generally Recognized as Safe' (GRAS) by the Food and Drug Administration, this health claim is destined for the general population.

The advised condition of use of this constituent is of at least $1 \times 10^8$ ufc per day.

Since this product's release on the market, there have not been any reported cases of undesirable side effects due to this nutrient, however, Italian national law imposes the use of these precautions on the product label: Do not exceed the indicated dosage; Keep out of reach of children under three years of age; The intake of this supplement is not meant as a substitute to a balanced diet and healthy lifestyle; This product does not substitute antibiotic or chemotherapeutic therapy.

This product is presented in a soluble powder form. Dissolve the content of one sachet in water or warm milk, and drink immediately. Should be consumed, preferably, on an empty stomach.
<table>
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<th><strong>Food or Food constituent</strong></th>
<th><strong>Health Relationship</strong></th>
<th><strong>Proposed wording</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lactobacillus gasseri BCCM/LMG P-18137</td>
<td>Helps in maintaining balanced vaginal flora and pH; Contributes to a healthy colonization of the lactobacilli on the vagina; Helps to redress the healthy balanced vaginal microflora during and after treatment of vaginal disorders.</td>
<td>Is a probiotic that helps to maintain normal vaginal microflora and vaginal pH at physiological levels (acid pH) playing a part in the inhibition of pathogen growth, and also aids in replacing the vaginal ecosystem when modified after antibiotic/antimycotic treatment.</td>
<td></td>
</tr>
<tr>
<td><strong>Conditions of use</strong></td>
<td></td>
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<tr>
<td></td>
<td>This health claim is destined for the female population, due to the product's specific vaginal use The advised condition of use of this constituent is of at least $1 \times 10^8$ ufc per day. Since this product's release on the market, there have not been any reported cases of undesirable side effects due to this nutrient, however, italian national law imposes the use of these precautions on the product label: Do not exceed the indicated dosage; Keep out of reach of children under three years of age; The intake of this supplement is not meant as a substitute to a balanced diet and healthy lifestyle; This product does not substitute antibiotic or chemotherapeutic therapy. This product is presented in a soluble powder form. Dissolve the content of one sachet in water or warm milk, and drink immediately. Should be consumed, preferably, on an empty stomach.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lactobacillus gasseri BCCM/LMG P-18137</td>
<td>Is a probiotic; Contributes to a healthy digestive system by supporting the gut flora through an increased number of positive lactobacillus in the intestine; useful to maintain a healthy intestinal flora by adhering to the mucosa; Improves intestinal barrier function by competing (steric encumbrance) against pathogens; Reduces gastro-intestinal discomfort; Necessary to maintain a healthy digestive system by production of specific enzymes (eg: beta-galactosidase).</td>
<td>Is a probiotic that maintains the balance of healthy intestinal microflora and regulates intestinal functionality by replacing normal, natural microflora (especially after antibiotic/antimycotic treatment) which contributes to reducing gastro-intestinal discomfort which, for example, could be due to problems in lactose digestion.</td>
<td></td>
</tr>
<tr>
<td><strong>Conditions of use</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Being 'Generally Recognized as Safe' (GRAS) by the Food and Drug Administration, this health claim is destined for the general population.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The advised condition of use of this constituent is of at least $1 \times 10^8$ ufc per day.

Since this product's release on the market, there have not been any reported cases of undesirable side effects due to this nutrient, however, Italian national law imposes the use of these precautions on the product label: Do not exceed the indicated dosage; Keep out of reach of children under three years of age; The intake of this supplement is not meant as a substitute to a balanced diet and healthy lifestyle.

This product is presented in a soluble powder form. Dissolve the content of one sachet in water or warm milk, and drink immediately. Should be consumed, preferably, on an empty stomach.

<table>
<thead>
<tr>
<th>2960</th>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactobacillus paracasei CNCM I-1687</td>
<td>Supports your natural (immune) defence system by increasing the IL-10 production and enhancing NK cell activity in peripheral blood mononuclear cells (PBMC); Necessary to maintain the natural defences/helps to maintain a balanced immune system (increasing the IL-10 production and enhancing NK cell activity).</td>
<td>Is a probiotic that helps to support body’s natural defence by modulating and regulating the immune response (especially in subjects prone to inflammatory reactions), which aids in supporting the development of the immune system.</td>
<td></td>
</tr>
</tbody>
</table>

**Conditions of use**

Being 'Generally Recognized as Safe' (GRAS) by the Food and Drug Administration, this health claim is destined for the general population.

The advised condition of use of this constituent is of at least $1 \times 10^9$ ufc per day.

Since this product's release on the market, there have not been any reported cases of undesirable side effects due to this nutrient, however, Italian national law imposes the use of these precautions on the product label: Do not exceed the indicated dosage; Keep out of reach of children under three years of age; The intake of this supplement is not meant as a substitute to a balanced diet and healthy lifestyle.

This product is presented in a soluble powder form. Dissolve the content of one sachet in water or warm milk, and drink immediately. Should be consumed, preferably, on an empty stomach.

<table>
<thead>
<tr>
<th>2961</th>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactobacillus paracasei CNCM I-1687</td>
<td>Is a probiotic; Contributes to a healthy digestive system by supporting the gut flora through an increased number of positive lactobacillus in the intestine; useful to maintain a healthy intestinal flora by adhering to the mucosa; Improves intestinal barrier function by competing (steric encumbrance) against pathogens;</td>
<td>Is a probiotic that maintains the balance of healthy intestinal microflora and regulates intestinal functionality by replacing normal, natural microflora (especially after antibiotic/antimycotic treatment) which contributes to reducing gastro-intestinal discomfort which, for example, could be due to</td>
<td></td>
</tr>
</tbody>
</table>
Reduces gastro-intestinal discomfort; Necessary to maintain a healthy digestive system by production of specific enzymes (eg: betagalactosidase).

### Conditions of use

Being ‘Generally Recognized as Safe’ (GRAS) by the Food and Drug Administration, this health claim is destined for the general population. The advised condition of use of this constituent is of at least $1 \times 10^9$ ufc per day.

Since this product's release on the market, there have not been any reported cases of undesirable side effects due to this nutrient, however, italian national law imposes the use of these precautions on the product label: Do not exceed the indicated dosage; Keep out of reach of children under three years of age; The intake of this supplement is not meant as a substitute to a balanced diet and healthy lifestyle.

This product is presented in a soluble powder form. Dissolve the content of one sachet in water or warm milk, and drink immediately. Should be consumed, preferably, on an empty stomach.

<table>
<thead>
<tr>
<th>2962</th>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>Lactobacillus paracasei</em></td>
<td>Supports your natural (immune) defence system by increasing the IL-10 production in peripheral blood mononuclear cells (PBMC); As recommended by PASSCLAIM, the functional capacity of the immune system has been assessed by: - measuring specific cell functions ex vivo - measuring specific cell function in vivo e.g. production of cytokines or response to antigens and determining the incidence and severity of infection; Necessary to maintain the natural defences/helps to maintain a balanced immune system (increasing the IL-10 production)</td>
<td>A probiotic that helps to support the body’s natural defence by modulating and regulating the immune response (especially in subjects prone to inflammatory reactions), which aids in supporting the development of the immune system</td>
</tr>
</tbody>
</table>

### Conditions of use

Being ‘Generally Recognized as Safe’ (GRAS) by the Food and Drug Administration, this health claim is destined for the general population. The advised condition of use of this constituent is of at least $1 \times 10^{10}$ ufc per day.

Since this product's release on the market, there have not been any reported cases of undesirable side effects due to this nutrient, however, italian national law imposes the use of these precautions on the product label: Do not exceed the indicated dosage; Keep out of reach of children under three years of age; The intake of this supplement is not meant as a substitute to a balanced diet and healthy lifestyle.

This product is presented in a soluble powder form. Dissolve the content of one sachet in water or warm milk, and drink immediately. Should be consumed, preferably, on an empty stomach.
<table>
<thead>
<tr>
<th>2963</th>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lactobacillus paracasei</td>
<td>Is a probiotic;</td>
<td>Is a probiotic that maintains the balance of healthy intestinal microflora and regulates intestinal functionality by replacing normal, natural microflora (especially after antibiotic/antimycotic treatment) which contributes to reducing gastro-intestinal discomfort which, for example, could be due to problems in lactose digestion.</td>
</tr>
<tr>
<td></td>
<td>CNCM I-1688</td>
<td>Contributes to a healthy digestive system by supporting the gut flora through an increased number of positive lactobacillus in the intestine; useful to maintain a healthy intestinal flora by adhering to the mucosa; Improves intestinal barrier function by competing (steric encumbrance) against pathogens; Reduces gastro-intestinal discomfort; Necessary to maintain a healthy digestive system by production of specific enzymes (eg: betagalactosidase).</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Conditions of use</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Being 'Generally Recognized as Safe' (GRAS) by the Food and Drug Administration, this health claim is destined for the general population. The advised condition of use of this constituent is of at least $1 \times 10^9$ ufc per day. Since this product's release on the market, there have not been any reported cases of undesirable side effects due to this nutrient, however, italian national law imposes the use of these precautions on the product label: Do not exceed the indicated dosage; Keep out of reach of children under three years of age; The intake of this supplement is not meant as a substitute to a balanced diet and healthy lifestyle. This product is presented in a soluble powder form. Dissolve the content of one sachet in water or warm milk, and drink immediately. Should be consumed, preferably, on an empty stomach.</td>
<td></td>
</tr>
<tr>
<td>2966</td>
<td>Food or Food constituent</td>
<td>Health Relationship</td>
<td>Proposed wording</td>
</tr>
<tr>
<td></td>
<td>Lactobacillus plantarum</td>
<td>Is a probiotic;</td>
<td>Is a probiotic that defends intestinal ecosystem inhibiting the growth of pathogenic microorganisms or contributes to reducing gastro-intestinal discomfort; Replaces natural intestinal microflora after antibiotics/antimycotic treatment; Influences positively well-being of body; Is useful for lactose digestion.</td>
</tr>
<tr>
<td></td>
<td>BCCM/LMG P-17630</td>
<td>Contributes to a healthy digestive system by supporting the gut flora through an increased number of positive lactobacillus in the intestine; useful to maintain a healthy intestinal flora by adhering to the mucosa; Improves intestinal barrier function by competing (steric encumbrance) against pathogens; Reduces gastro-intestinal discomfort; Necessary to maintain a healthy digestive system by production of specific enzymes (eg: betagalactosidase).</td>
<td></td>
</tr>
</tbody>
</table>
**Conditions of use**

Being 'Generally Recognized as Safe' (GRAS) by the Food and Drug Administration, this health claim is destined for the general population.

The advised condition of use of this constituent is of at least $1 \times 10^8$ UFC per day.

Since this product's release on the market, there have not been any reported cases of undesirable side effects due to this nutrient, however, Italian national law imposes the use of these precautions on the product label: Do not exceed the indicated dosage; Keep out of reach of children under three years of age; The intake of this supplement is not meant as a substitute to a balanced diet and healthy lifestyle.

This product is presented in a soluble powder form. Dissolve the content of one sachet in water or warm milk, and drink immediately. Should be consumed, preferably, on an empty stomach.

<table>
<thead>
<tr>
<th>2967</th>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>Lactobacillus plantarum</em>&lt;br&gt;BCCM/LMG P-17630</td>
<td>Helps in maintaining balanced vaginal flora and pH;&lt;br&gt;Contributes to a healthy colonization of the lactobacilli on the vagina;&lt;br&gt;Helps to redress the healthy balanced vaginal microflora during and after treatment of vaginal disorders.</td>
<td>Is a probiotic that helps to maintain normal vaginal microflora and vaginal pH at physiological levels (acid pH) playing a part in the inhibition of pathogen growth, and also aids in replacing the vaginal ecosystem when modified after antibiotic/antimycotic treatment.</td>
</tr>
</tbody>
</table>

**Conditions of use**

This health claim is destined for the female population, due to the product's specific vaginal use.

The advised condition of use of this constituent is of at least $1 \times 10^8$ UFC per day.

Since this product's release on the market, there have not been any reported cases of undesirable side effects due to this nutrient, however, Italian national law imposes the use of these precautions on the product label: Do not exceed the indicated dosage; Keep out of reach of children under three years of age; The intake of this supplement is not meant as a substitute to a balanced diet and healthy lifestyle; This product does not substitute antibiotic or chemotherapeutic therapy.

This product is presented in a soluble powder form. Dissolve the content of one sachet in water or warm milk, and drink immediately. Should be consumed, preferably, on an empty stomach.

<table>
<thead>
<tr>
<th>2970</th>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>Lactobacillus salivarius</em>&lt;br&gt;CNCM I-1794</td>
<td>Is a probiotic;&lt;br&gt;Contributes to a healthy digestive system by supporting the gut flora through an</td>
<td>Is a probiotic that maintain the balance of healthy intestinal microflora and regulates intestinal functionality by</td>
</tr>
</tbody>
</table>
increased number of positive lactobacillus in the intestine;
Useful to maintain an healthy intestinal flora adhering to the mucosa;
Improves intestinal barrier function by competion (steric encumbrance) against pathogens;
Reduces gastro-intestinal discomfort;
Necessary to maintain a healthy digestive system by production of specific enzymes (eg: betagalactosidase).

<table>
<thead>
<tr>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactobacillus salivarius CNCM I-1794</td>
<td>Supports your natural (immune) defence system by increasing the IL-10 production in peripheral blood mononuclear cells (PBMC); As recommended by PASSCLAIM, the functional capacity of the immune system has been assessed by: measuring specific cell functions ex vivo, measuring specific cell function in vivo e.g. production of cytokines or response to antigens, and determining the incidence and severity of infection; Necessary to maintain the natural defences/helps to maintain a balanced immune system (increasing the IL-10 production).</td>
<td>Is a probiotic that helps to support natural defences by modulating natural immunological responses, and helps to support the development of the immune system by regulating an immunological response in subjects with allergic reactions or by stimulating immunological response during viral infections.</td>
</tr>
</tbody>
</table>

**Conditions of use**

Being 'Generally Recognized as Safe' (GRAS) by the Food and Drug Administration, this health claim is destined for the general population.

The advised condition of use of this constituent is of at least $1 \times 10^8$ ufc per day.

Since this product's release on the market, there have not been any reported cases of undesirable side effects due to this nutrient, however, Italian national law imposes the use of these precautions on the product label: Do not exceed the indicated dosage; Keep out of reach of children under three years of age; The intake of this supplement is not meant as a substitute to a balanced diet and healthy lifestyle.

This product is presented in a soluble powder form. Dissolve the content of one sachet in water or warm milk, and drink immediately. Should be consumed, preferably, on an empty stomach.
intake of this supplement is not meant as a substitute to a balanced diet and healthy lifestyle. This product is presented in a soluble powder form. Dissolve the content of one sachet in water or warm milk, and drink immediately. Should be consumed, preferably, on an empty stomach.

<table>
<thead>
<tr>
<th>4231</th>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Bifidobacterium animalis ssp. lactis Bf-6 and Lactobacillus johnsonii La-1 (ACD-1)(CLbA22)</strong></td>
<td>NOT GIVEN</td>
<td>NOT GIVEN</td>
</tr>
</tbody>
</table>

**Conditions of use**

NOT GIVEN
GLOSSARY AND ABBREVIATIONS

AFLP Amplified fragment length polymorphism
ARDRA Amplified rDNA restriction analysis
BCCM/LMG Belgian Co-ordinated Collections of Microorganisms/Laboratorium voor Microbiologie, Universiteit Gent
BV Bacterial vaginosis
CNCM Collection Nationale de Cultures de Microorganismes, France
DNA Deoxyribonucleic acid
IL Interleukin
NK cells Natural killer cells
PAGE Polyacrylamide gel electrophoresis
PBMC Peripheral blood mononuclear cells
PCR Polymerase chain reaction
PFGE Pulsed field gel electrophoresis
RAPD Randomly amplified polymorphic DNA
Rep-PCR Repetitive extragenomic palindromic – PCR
RNA Ribonucleic acid