Consolidated list of Article 13 health claims

List of references received by EFSA in the framework of further assessment

BACKGROUND
The European Commission has agreed with EU Member States that a certain number of Article 13 health claims would be eligible for further assessment by EFSA in order to be able to take a final decision on whether or not to include these claims in the list of permitted health claims. These claims include already assessed claims related to micro-organisms which the Panel considered to be not sufficiently characterised and claims for which the NDA Panel concluded that there was insufficient evidence to establish a cause and effect relationship between the consumption of the food and the claimed effect.

LIST OF REFERENCES
The present document compiles the lists of references for the 91 claims (IDs), which were submitted for further assessment to EFSA.

For 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, this list contains the references indicated in the application for further assessment as being pertinent for the scientific substantiation of the claim (section A). As the assessment for this type of claims combines the evidence submitted originally and in the framework of further assessment, this document should be read in conjunction with the list of references originally submitted for scientific evaluation and which can be accessed under: http://www.efsa.europa.eu/en/topics/topic/article13.htm.

For claims related to micro-organisms which the Panel considered to be not sufficiently characterised, this list contains all references indicated in the application for further assessment as being pertinent to the claim for further assessment and those provided in support of the characterisation of the strain (section B).

In some cases, additional references not listed as directly pertinent to the claim in the application, for example, with respect to a possible mechanism by which the food/constituent could exert the claimed effect were mentioned in the application and have been considered by the NDA Panel but are not included in this list of references. The opinions of the NDA Panel should therefore be consulted for information on the totality of evidence which formed the basis of the Panel’s assessment.

The main health claim entries are sorted in ascending order of the ID number for claims related to microorganisms and by the food/constituent eligible for further assessment for claims for which there was insufficient evidence to establish a cause and effect relationship.
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SECTION A

Alpha-cyclodextrin and reduction of post-prandial glycaemic responses (ID 2926)


Isoleucine-proline-proline (IPP) and valine-proline-proline (VPP) and maintenance of normal blood pressure (ID 661, 1831, 1832, 2891)


**Lutein and maintenance of normal vision (ID 1603)**


Lutein and maintenance of normal vision (ID 1604)


Dried plums of ‘prune’ cultivars (Prunus domestica L.) and maintenance of normal bowel function (ID 1164)

Polyphenols in olive and maintenance of normal blood HDL-cholesterol concentrations (ID 1639)
2 EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011. Scientific Opinion on the substantiation of health claims related to polyphenols in olive and protection of LDL particles from oxidative damage (ID 1333, 1638, 1639, 1696, 2865), maintenance of normal blood HDL cholesterol concentrations (ID 1639), maintenance of normal blood pressure (ID 3781), “anti-inflammatory properties” (ID 1882), “contributes to the upper respiratory tract health” (ID 3468), “can help to maintain a normal function of gastrointestinal tract” (3779), and “contributes to body defences against external agents” (ID 3467) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 9(4):2033, 12 pp.


Soy isoflavones and maintenance of bone mineral density (ID 1655)


Turhan Ö, Boklan F, Duvan Cl, Ardiçoglu Y, 2008. The Effect of Isoflavones on Bone Mass and Bone Remodelling Markers in Postmenopausal Women. Turkish Journal of Medical Sciences, 38, 145-152.


Soy isoflavones and reduction of vasomotor symptoms associated with menopause (ID 1654, 1704, 2140, 3093, 3154, 3590)


**Vitamin K2 and contribution to the normal function of the heart and blood vessels (ID 125)**


**SECTION B**

**ID 913: Saccharomyces cerevisiae var boulardii CNCM I-1079**

1. Dossier submitted by the competent Authority of United Kingdom on Saccharomyces boulardii CNCM I-1079, ID 913. 2011.


34 van der Aa Kühle A and Jespersen L, 2003. The Taxonomic Position of Saccharomyces boulardii as Evaluated by Sequence Analysis of the D1/D2 Domain of 26S rDNA, the ITS1-5.8S rDNA-ITS2 Region and the Mitochondrial Cytochrome-c Oxidase II Gene. Systematic and Applied Microbiology, 26, 564-571.


ID 931: Lactobacillus gasseri PA 16/8, Bifidobacterium bifidum MF 20/5 and Bifidobacterium longum SP 07/3

1 Dossier submitted by the competent authority of Germany on "Combination of L. gasseri PA 16/8, B. bifidum MF 20/5 and B. longum SP 07/3" and "natural defence/immune system", ID 931 2011.


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


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Merck, 2010. 16S rRNA Sequence analysis - Bifidobacterium longum NITE BP-818.

Merck, 2010. 16S rRNA Sequence analysis - Bifidobacterium bifidum NITE BP-817.


ID 934: Lactobacillus gasseri 57C, Lactobacillus fermentum 57A, Lactobacillus plantarum 57B

1 Dossier submitted by the competent authority of Poland on "Combination of Lactobacillus fermentum 57A / Lactobacillus plantarum 57B / Lactobacillus gasseri 57C" and "vaginal flora", ID 934. 2011.


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20 Motyl I, 2010. Study on L(+) and D(-) lactic acid production by Lactobacillus probiotic bacteria in the presence of glycogen as the only source of carbon.


24 PROLAB, 2008, unpublished. The examination of inhibitory influence of nonoxynol-9 on chosen strains: Lactobacillus fermentum 57A, Lactobacillus plantarum 57B, Lactobacillus gasseri 57C after 5 and 24 hours.

25 PROLAB, 2008, unpublished. Erratum to The examination of inhibitory influence of nonoxynol-9 on chosen strains: Lactobacillus fermentum 57A, Lactobacillus plantarum 57B, Lactobacillus gasseri 57C after 5 and 24 hours.


TÜV Rheinland Cert GMBH, 2007. HACCP Certificate-IBSS biomed S.A.


**ID 938: Lactobacillus helveticus CNCM I-1722 and Bifidobacterium longum CNCM I-3470**

1. Dossier submitted by the competent Authority of United Kingdom on Combination of Lactobacillus helveticus CNCM I-1722 and Bifidobacterium longum CNCM I-3470, ID 938, 2011.


equilibrium as assessed by real-time polymerase chain reaction. Journal of Molecular Microbiology and Biotechnology, 14, 90-99.


ID 939: Lactobacillus helveticus CNCM I-1722 and Lactobacillus rhamnosus CNCM I-1720

1. Dossier submitted by the competent Authority of United Kingdom on Combination of Lactobacillus rhamnosus CNCM I-1720 and Lactobacillus helveticus CNCM I-1722, ID 939, 2011.


exopolysaccharide locus in strains of the Lactobacillus casei group. Applied and Environmental Microbiology, 69, 3299-3307.


ID 941: *Propionibacterium freudenreichii* SI 41 and *Propionibacterium freudenreichii* SI 26

1. Dossier submitted by the competent Authority of Germany on *Propionibacterium freudenreichii* SI 41 and *Propionibacterium freudenreichii* SI 26 Propio-Fidus®, ID 941. 2011.


**ID 960: Bifidobacterium animalis ssp. lactis THT 010801**

Dossier submitted by the competent authority of Belgium on Bifidobacterium animalis ssp lactis THT 010801 and digestive health/intestinal flora, ID 960. 2011.


Dossier submitted by the competent authority of Belgium on Bifidobacterium animalis ssp. lactis THT 010801 and intestinal transit, ID 961. 2011.


**ID 962: Bifidobacterium animalis ssp. lactis THT 010801**

1. Dossier submitted by the competent authority of Belgium on Bifidobacterium animalis ssp lactis THT 010801 and natural defences/immune system, ID 962. 2011.


10. Shu Q and Gill HS. 2001. A dietary probiotic (Bifidobacterium lactis HN019) reduces the severity of Escherichia coli O157:H7 infection in mice. Medical Microbiology and Immunology, 189, 147-152.


**ID 967: Bifidobacterium longum spp. infantis THT 010201**

1. Dossier submitted by the competent authority of Belgium on Bifidobacterium longum ssp infantis THT 010201 and digestive health/intestinal flora, ID 967. 2011.


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Bifidobacterium species in the upper human gastrointestinal tract. Journal of Applied Microbiology, 84, 759-768.


ID 968: *Bifidobacterium longum* bv *infantis* THT 010201

1 Dossier submitted by the competent Authority of Belgium on Bifidobacterium longum subsp infantis THT 010201 and natural defences/immune system, ID 968, 2011.


ID 969: *Bifidobacterium longum* THT 010301

1 Dossier submitted by the competent Authority of Belgium on Bifidobacterium longum subsp longum THT 010301 and digestive health/intestinal flora, ID 969, 2011.


ID 970: *Bifidobacterium longum* THT 010301

1 Dossier submitted by the competent Authority of Belgium on Bifidobacterium longum subsp longum THT 010301 and natural defences/immune system, ID 970, 2011.

ID 971: Bifidobacterium psuedolongum ssp psuedolongum THT 010501

Dossier submitted by the competent Authority of Belgium on Bifidobacterium psuedolongum subsp pseudolongum THT 010501 and digestive health/intestinal flora, ID 971. 2011.

ID 972: Bifidobacterium psuedolongum ssp psuedolongum THT 010501

Dossier submitted by the competent Authority of Belgium on Bifidobacterium psuedolongum subsp pseudolongum THT 010501 and natural defences/immune system, ID 972. 2011.


**ID 975: Lactobacillus casei THT 030401**

1. Dossier submitted by the competent Authority of Belgium on Lactobacillus casei THT 030401 and digestive health/intestinal flora, ID 975. 2011.
specific primers derived from the 16S-23S rRNA intergenic spacer region and its flanking 23S rRNA. FEMS Microbiology Letters, 187, 167-173.


ID 976: Lactobacillus casei THT 030401

1. Dossier submitted by the competent Authority of Belgium on Lactobacillus casei THT 030401 and natural defences/immune system, ID 976. 2011.
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ID 983: Lactobacillus gasseri THT 031301

1 Dossier submitted by the competent Authority of Belgium on Lactobacillus gasseri THT 031301 and digestive health/intestinal flora, ID 983. 2011.

ID 984: Lactobacillus gasseri THT 031301

1 Dossier submitted by the competent Authority of Belgium on Lactobacillus gasseri THT 031301 and natural defence/immune system, ID 984. 2011.


ID 985: Lactobacillus helveticus THT 031102

Dossier submitted by the competent Authority of Belgium on Lactobacillus helveticus THT 031102 and digestive health/intestinal flora, ID 985. 2011.


ID 986: Lactobacillus helveticus THT 031102

Dossier submitted by the competent Authority of Belgium on Lactobacillus helveticus THT 031102 and natural defences/immune system, ID 986. 2011.


ID 994: Lactobacillus plantarum THT 030701

Dossier submitted by the competent Authority of Belgium on Lactobacillus plantarum THT 030701 and digestive health/intestinal flora, ID 994. 2011.


ID 995: Lactobacillus plantarum THT 030701

Dossier submitted by the competent Authority of Belgium on Lactobacillus plantarum THT 030701 and natural defences/immune system, ID 995. 2011.


ID 996: Lactobacillus plantarum THT 030707

Dossier submitted by the competent Authority of Belgium on Lactobacillus plantarum THT 030707 and digestive health/intestinal flora, ID 996. 2011.


ID 997: Lactobacillus plantarum THT 030707

Dossier submitted by the competent Authority of Belgium on Lactobacillus plantarum THT 030707 and natural defences/immune system, ID 997, 2011.


ID 998: Lactobacillus reuteri THT 030802

Dossier submitted by the competent Authority of Belgium on Lactobacillus reuteri THT 030802 and digestive health/intestinal flora, ID 998, 2011.


19 Wolf BW, Wheeler KB, Ataya DG, Garleb KA, 1998. Safety and tolerance of Lactobacillus reuteri supplementation to a population infected with the human immunodeficiency virus. Food and Chemical Toxicology, 36, 1085-1094.

Dossier submitted by the competent Authority of Belgium on Lactobacillus reuteri THT 030802 and natural defences/immune system, ID 999, 2011.


Wolf BW, Wheeler KB, Ataya DG, Garleb KA, 1998. Safety and tolerance of Lactobacillus reuteri supplementation to a population infected with the human immunodeficiency virus. Food and Chemical Toxicology, 36, 1085-1094.

ID 1006: Lactobacillus salivarius THT 031001

1 Dossier submitted by the competent Authority of Belgium on Lactobacillus salivarius THT 031001 and digestive health/intestinal flora, ID 1006. 2011.


ID 1007: Lactobacillus salivarius THT 031001

1 Dossier submitted by the competent Authority of Belgium on Lactobacillus salivarius THT 031001 and natural defences/immune system, ID 1007. 2011.


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ID 1010: Saccharomyces boulardii ATY-SB-101 (BCCM/MUCL 53837)

1 Dossier submitted by the competent Authority of Belgium on claim Saccharomyces boulardii ATY-SB-101 (=MUCL 53837), ID 1010. 2011.


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ID 1011: Saccharomyces boulardii ATY-SB-101 (BCCM/MUCL 53837)

1. Dossier submitted by the competent Authority of Belgium on claim Saccharomyces boulardii ATY-SB-101 (=MUCL 53837), ID 1011. 2011.


11. van der Aa Kuhle A and Jespersen L. 2003. The taxonomic position of Saccharomyces boulardii as evaluated by sequence analysis of the D1/D2 domain of 26S rDNA, the ITS1-5.8S rDNA-ITS2 region and the mitochondrial cytochrome-c oxidase II gene. Systematic and Applied Microbiology, 26, 564-571.


ID 1014: Streptococcus thermophylus THT 070102

1. Dossier submitted by the competent Authority of Belgium on Streptococcus thermophilus THT 070102 and digestive health/intestinal flora, ID 1014. 2011.


ID 1015: Streptococcus thermophylus THT 070102

Dossier submitted by the competent Authority of Belgium on Streptococcus thermophilus THT 070102 and natural defences/immune system, ID 1015. 2011.


ID 1030: Lactobacillus crispatus P 17631

Dossier submitted by the competent Authority of Italy on Lactobacillus crispatus P17631, ID1030. 2011.


**ID 2936: Bifidobacterium breve BR 03 DSM 16604**

1. Dossier submitted by the competent Authority of Italy on Bifidobacterium breve BR 03 (DSM 16604) and Intestinal transit time, ID 2936. 2011.


**ID 2937: Bifidobacterium breve BR 03 DSM 16603**

1. Dossier submitted by the competent Authority of Italy on Bifidobacterium longum BL 03 (DSM 16603) and Intestinal transit time, ID 2937. 2011.


**ID 2938: Bifidobacterium breve BR 03 (DSM 16604) and Lactobacillus plantarum LP 01 (LMG P-21021)**

1. Dossier submitted by the competent Authority of Italy on Bifidobacterium breve BR 03 (DSM 16604) + Lactobacillus plantarium LP 01 (LMG P-21021) and Intestinal transit time, ID 2938. 2011.


ID 2940: Bifidobacterium lactis BS 01 (LMG P-21384)

1 Dossier submitted by the competent Authority of Italy on Bifidobacterium lactis BS 01 (LMG P-21384) and Intestinal transit time, ID 2940. 2011.


ID 2941: Bifidobacterium lactis BS 01 (LMG P-21384), Lactobacillus rhamnosus LR 04 (DSM 16605) and Lactobacillus plantarum LP 02 (LMG P-21020)

1 Dossier submitted by the competent Authority of Italy on Bifidobacterium lactis BS 01 (LMG P-21384) + Lactobacillus rhamnosus LR 04 (DSM 16605) + Lactobacillus plantarum LP 02 (LMG P-21020), ID 2941. 2011.


ID 2942: Lactobacillus acidophilus bar 13 (CNCM I-3857) and Bifidobacterium longum bar 33 (CNCM I-3858)

1 Dossier submitted by the competent Authority of Italy on Lactobacillus helveticus Bar13 + Bifidobacterium longum Bar33, ID 2942. 2011.


3 Identification from Lallemand Supply's Frame Agreement 956-2011U-07


**ID 2944: Lactobacillus acidophilus LA 02 (LMG P-21381) and Lactobacillus plantarum LP 01 (LMG P-21021)**

1. Dossier submitted by the competent Authority of Italy on Lactobacillus acidophilus LA 02 (DSM 21717) + Lactobacillus plantarum LP 01 (LMG P-21021), ID 2944. 2011.


**ID 2946: Lactobacillus acidophilus P 18806**

1. Dossier submitted by the competent Authority of Italy on Lactobacillus acidophilus P18806, ID 2946. 2011.


ID 2947: Lactobacillus acidophilus P 18806

1 Dossier submitted by the competent Authority of Italy on Lactobacillus acidophilus P18806, ID 2947. 2011.


ID 2949: Lactobacillus casei I-1572 DG

1 Dossier submitted by the competent Authority of Italy on Lactobacillus casei DG CNCM I-1572, ID 2949. 2011.


ID 2950: Lactobacillus crispatus P 17631

1 Dossier submitted by the competent Authority of Italy on Lactobacillus crispatus P17631, ID 2950. 2011.


ID 2951: Lactobacillus delbrueckii P 18805

Dossier submitted by the competent Authority of Italy on Lactobacillus delbrueckii P18805, ID 2951. 2011.


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<th>ID 2956: Lactobacillus gasseri P 17632</th>
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**ID 2957: Lactobacillus gasseri BCCM/LMG P 18137**

1  Dossier submitted by the competent Authority of Italy on Lactobacillus gasseri P18137, ID2957. 2011.


**ID 2958: Lactobacillus gasseri BCCM/LMG P 18137**

1  Dossier submitted by the competent Authority of Italy on Lactobacillus gasseri P18137, ID 2958. 2011.


**ID 2960: Lactobacillus paracasei CNCM I 1687**

1. Dossier submitted by the competent Authority of Italy on Lactobacillus paracasei II1687, ID 2960, 2011.

**ID 2961: Lactobacillus paracasei CNCM I 1687**

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ID 2962: Lactobacillus paracasei CNCM I 1688

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ID 2963: Lactobacillus paracasei CNCM I 1688

Dossier submitted by the competent Authority of Italy on Lactobacillus paracasei I1688, ID 2963. 2011.


ID 2965: Lactobacillus plantarum LP 01

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ID 2966: Lactobacillus plantarum BCCM/LMG P 17630

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Dossier submitted by the competent Authority of Italy on Lactobacillus plantarum P17630, ID 2966. 2011.


**ID 2967: Lactobacillus plantarum BCCM/LMG P 17630**

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1 Dossier submitted by the competent Authority of Italy on claim ID 2968 L.rhamnosus. 2011.


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ID 2970: Lactobacillus salivarius I 1794

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ID 2971: Lactobacillus salivarius I 1794

1 Dossier submitted by the competent Authority of Italy on Lactobacillus salivarius I1794, ID 2971. 2011.
ID 2972: Lactobacillus paracasei CNCM I 1688 and Lactobacillus salivarius CNCM I 1794

1. Dossier submitted by the competent Authority of Italy on PSMIX (Mix of L.paracasei I 1688 and L.salivarius I 1794), ID 2972. 2011.

ID 2973: Lactobacillus paracasei CNCM I 1688 and Lactobacillus salivarius CNCM I 1794

1. Dossier submitted by the competent Authority of Italy on PSMIX (Mix of L.paracasei I 1688 and L.salivarius I 1794), ID 2973. 2011.


ID 2974: Streptococcus thermophilus BCCM/LMG P 18807

Dossier submitted by the competent Authority of Italy on Streptococcus thermophilus P18807, ID2974. 2011.


ID 2975: Streptococcus thermophilus BCCM/LMG P 18807

Dossier submitted by the competent Authority of Italy on Streptococcus thermophilus P18807, ID 2975. 2011.


ID 3016: Lactobacillus helveticus CNCM I-1722, Bifidobacterium infantis CNCM I-3424, Bifidobacterium bifidum CNCM I-3426

Dossier submitted by the competent Authority of France on Lactobacillus helveticus CNCM I-1722, Bifidobacterium infantis CNCM I-3424, Bifidobacterium bifidum CNCM I-3426 and fructo-oligosaccharides, ID 3016. 2011.


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