

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.

Table of Contents

Table of Contents.....	2
SECTION A	4
Alpha-cyclodextrin and reduction of post-prandial glycaemic responses (ID 2926).....	4
Isoleucine-proline-proline (IPP) and valine-proline-proline (VPP) and maintenance of normal blood pressure (ID 661, 1831, 1832, 2891)	4
Lutein and maintenance of normal vision (ID 1603).....	6
Lutein and maintenance of normal vision (ID 1604).....	7
Dried plums of ‘prune’ cultivars (<i>Prunus domestica L.</i>) and maintenance of normal bowel function (ID 1164)	10
Polyphenols in olive and maintenance of normal blood HDL-cholesterol concentrations (ID 1639)	10
Soy isoflavones and maintenance of bone mineral density (ID 1655).....	12
Soy isoflavones and reduction of vasomotor symptoms associated with menopause (ID 1654, 1704, 2140, 3093, 3154, 3590)	16
Vitamin K2 and contribution to the normal function of the heart and blood vessels (ID 125).....	18
SECTION B.....	18
ID 913: <i>Saccharomyces cerevisiae</i> var <i>boulardii</i> CNCM I-1079.....	18
ID 931: <i>Lactobacillus gasseri</i> PA 16/8, <i>Bifidobacterium bifidum</i> MF 20/5 and <i>Bifidobacterium longum</i> SP 07/3.....	20
ID 934: <i>Lactobacillus gasseri</i> 57C, <i>Lactobacillus fermentum</i> 57A, <i>Lactobacillus plantarum</i> 57B	24
ID 938: <i>Lactobacillus helveticus</i> CNCM I-1722 and <i>Bifidobacterium longum</i> CNCM I-3470.....	26
ID 939: <i>Lactobacillus helveticus</i> CNCM I-1722 and <i>Lactobacillus rhamnosus</i> CNCM I-1720.....	28
ID 941: <i>Propionibacterium freudenreichii</i> SI 41 and <i>Propionibacterium freudenreichii</i> SI 26	29
ID 960: <i>Bifidobacterium animalis</i> ssp. <i>lactis</i> THT 010801	30
ID 961: <i>Bifidobacterium animalis</i> ssp. <i>lactis</i> THT 010801	31
ID 962: <i>Bifidobacterium animalis</i> ssp. <i>lactis</i> THT 010801	32
ID 967: <i>Bifidobacterium longum</i> spp. <i>infantis</i> THT 010201	32
ID 968: <i>Bifidobacterium longum</i> bv <i>infantis</i> THT 010201	33
ID 969: <i>Bifidobacterium longum</i> THT 010301	33
ID 970: <i>Bifidobacterium longum</i> THT 010301	33
ID 971: <i>Bifidobacterium psuedolongum</i> ssp <i>psuedolongum</i> THT 010501	34
ID 972: <i>Bifidobacterium psuedolongum</i> ssp <i>psuedolongum</i> THT 010501	34
ID 975: <i>Lactobacillus casei</i> THT 030401	35
ID 976: <i>Lactobacillus casei</i> THT 030401	36
ID 983: <i>Lactobacillus gasseri</i> THT 031301	37
ID 984: <i>Lactobacillus gasseri</i> THT 031301	37
ID 985: <i>Lactobacillus helveticus</i> THT 031102	38
ID 986: <i>Lactobacillus helveticus</i> THT 031102	38
ID 994: <i>Lactobacillus plantarum</i> THT 030701.....	39
ID 995: <i>Lactobacillus plantarum</i> THT 030701.....	39
ID 996: <i>Lactobacillus plantarum</i> THT 030707.....	39
ID 997: <i>Lactobacillus plantarum</i> THT 030707.....	40
ID 998: <i>Lactobacillus reuteri</i> THT 030802	40
ID 999: <i>Lactobacillus reuteri</i> THT 030802	42
ID 1006: <i>Lactobacillus salivarius</i> THT 031001.....	43
ID 1007: <i>Lactobacillus salivarius</i> THT 031001.....	43
ID 1010: <i>Saccharomyces boulardii</i> ATY-SB-101 (BCCM/MUCL 53837).....	44
ID 1011: <i>Saccharomyces boulardii</i> ATY-SB-101 (BCCM/MUCL 53837).....	46
ID 1014: <i>Streptococcus thermophilus</i> THT 070102	46

ID 1015: <i>Streptococcus thermophylus</i> THT 070102	47
ID 1030: <i>Lactobacillus crispatus</i> P 17631	47
ID 2936: <i>Bifidobacterium breve</i> BR 03 DSM 16604	48
ID 2937: <i>Bifidobacterium breve</i> BR 03 DSM 16603	48
ID 2938: <i>Bifidobacterium breve</i> BR 03 (DSM 16604) and <i>Lactobacillus plantarum</i> LP 01 (LMG P-21021).....	48
ID 2940: <i>Bifidobacterium lactis</i> BS 01 (LMG P-21384).....	49
ID 2941: <i>Bifidobacterium lactis</i> BS 01 (LMG P-21384), <i>Lactobacillus rhamnosus</i> LR 04 (DSM 16605) and <i>Lactobacillus plantarum</i> LP 02(LMG P-21020)	49
ID 2942: <i>Lactobacillus acidophilus</i> bar 13 (CNCM-I-3857) and <i>Bifidobacterium longum</i> bar 33 (CNCM-I-3858)..	49
ID 2944: <i>Lactobacillus acidophilus</i> LA 02 (LMG P-21381) and <i>Lactobacillus plantarum</i> LP 01 (LMG P-21021) ...	50
ID 2946: <i>Lactobacillus acidophilus</i> P 18806.....	50
ID 2947: <i>Lactobacillus acidophilus</i> P 18806.....	51
ID 2949: <i>Lactobacillus casei</i> I-1572 DG	51
ID 2950: <i>Lactobacillus crispatus</i> P 17631	51
ID 2951: <i>Lactobacillus delbrueckii</i> P 18805	52
ID 2952: <i>Lactobacillus delbrueckii</i> P 18805	53
ID 2956: <i>Lactobacillus gasseri</i> P 17632	53
ID 2957: <i>Lactobacillus gasseri</i> BCCM/LMG P 18137.....	54
ID 2958: <i>Lactobacillus gasseri</i> BCCM/LMG P 18137.....	54
ID 2960: <i>Lactobacillus paracasei</i> CNCM I 1687.....	55
ID 2961: <i>Lactobacillus paracasei</i> CNCM I 1687.....	55
ID 2962: <i>Lactobacillus paracasei</i> CNCM I 1688.....	56
ID 2963: <i>Lactobacillus paracasei</i> CNCM I 1688.....	56
ID 2965: <i>Lactobacillus plantarum</i> LP 01	57
ID 2966: <i>Lactobacillus plantarum</i> BCCM/LMG P 17630.....	57
ID 2967: <i>Lactobacillus plantarum</i> BCCM/LMG P 17630.....	58
ID 2968: <i>Lactobacillus rhamnosus</i> LR 04 (DSM 16605)	59
ID 2969: <i>Lactobacillus rhamnosus</i> LR 04	61
ID 2970: <i>Lactobacillus salivarius</i> I 1794	61
ID 2971: <i>Lactobacillus salivarius</i> I 1794	62
ID 2972: <i>Lactobacillus paracasei</i> CNCM I 1688 and <i>Lactobacillus salivarius</i> CNCM I 1794	63
ID 2973: <i>Lactobacillus paracasei</i> CNCM I 1688 and <i>Lactobacillus salivarius</i> CNCM I 1794	63
ID 2974: <i>Streptococcus thermophilus</i> BCCM/LMG P 18807	64
ID 2975: <i>Streptococcus thermophilus</i> BCCM/LMG P 18807	64
ID 3016: <i>Lactobacillus helveticus</i> CNCM I-1722, <i>Bifidobacterium infantis</i> CNCM I-3424, <i>Bifidobacterium bifidum</i> CNCM I-3426.....	65
ID 3017: <i>Lactobacillus rhamnosus</i> CNCM I-1720, <i>Lactobacillus helveticus</i> CNCM I-1722, <i>Bifidobacterium longum</i> subsp. <i>longum</i> CNCM I-3470 and <i>Saccharomyces boulardii</i> CNCM I-1079.....	66
ID 3035: <i>Bifidobacterium adolescentis</i> BA 02	70
ID 3047: <i>Bifidobacterium lactis</i> BS 01, <i>Lactobacillus rhamnosus</i> LR 04, <i>Lactobacillus rhamnosus</i> LR 05, <i>Lactobacillus plantarum</i> LP 01 and <i>Lactobacillus plantarum</i> LP 02.....	70
ID 3055: <i>Lactobacillus paracasei</i> LPC 01	70
ID 3056: <i>Bifidobacterium longum</i> W11	71
ID 3059: <i>Bifidobacterium lactis</i> BS 01, <i>Lactobacillus rhamnosus</i> LR 04 and <i>Lactobacillus plantarum</i> LP 02 and lactoferrin.....	72
ID 3061: <i>Lactobacillus casei</i> DG, CNCM I-1572	72
ID 4231: <i>Bifidobacterium animalis</i> ssp. <i>lactis</i> Bf-6 and <i>Lactobacillus johnsonii</i> La-1 (ACD-1)(CLbA22)	72

SECTION A

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

- 1 Comerford KB, Artiss JD, Jen KL, Karakas SE, 2011. The beneficial effects of alpha-cyclodextrin on blood lipids and weight loss in healthy humans. *Obesity (Silver Spring)*, 19, 1200-1204.
- 2 Diamantis I and Bär A, 2002. Effect of alpha-cyclodextrin on the glycaemic index (GI) and insulinaemic index (II) of starch in healthy human volunteers. Unpublished study report.
- 3 Gentilcore D, Vanis L, Teng JC, Wishart JM, Buckley JD, Rayner CK, Horowitz M, Jones KL, 2011. The oligosaccharide alpha-cyclodextrin has modest effects to slow gastric emptying and modify the glycaemic response to sucrose in healthy older adults. *British Journal of Nutrition*, 106, 583-587.
- 4 Grunberger G, Jen KL, Artiss JD, 2007. The benefits of early intervention in obese diabetic patients with FBCx: a new dietary fibre. *Diabetes/Metabolism Research and Reviews*, 23, 56-62.
- 5 Koukiekolo R, Desseaux V, Moreau Y, Marchis-Mouren G, Santimone M, 2001. Mechanism of porcine pancreatic alpha-amylase. Inhibition of amylose and maltopentaose hydrolysis by alpha-, beta- and gamma-cyclodextrins. *European Journal of Biochemistry*, 268, 841-848.
- 6 Li S, Shin HJ, Ding EL, van Dam RM, 2009. Adiponectin levels and risk of type 2 diabetes: a systematic review and meta-analysis. *JAMA*, 302, 179-188.
- 7 Ochiai H, Ooka H, Shida C, Ishikawa T, Inoue D, Okazaki R, 2008. Acarbose treatment increases serum total adiponectin levels in patients with type 2 diabetes. *Endocrine Journal*, 55, 549-556.
- 8 Oudjeriouat N, Moreau Y, Santimone M, Svensson B, Marchis-Mouren G, Desseaux V, 2003. On the mechanism of alpha-amylase. *European Journal of Biochemistry*, 270, 3871-3879.
- 9 Shimazu T, Inami N, Satoh D, Kajiura T, Yamada K, Iwasaka T, Nomura S, 2009. Effect of acarbose on platelet-derived microparticles, soluble selectins, and adiponectin in diabetic patients. *Journal of Thrombosis and Thrombolysis*, 28, 429-435.
- 10 Weyer C, Funahashi T, Tanaka S, Hotta K, Matsuzawa Y, Pratley RE, Tataranni PA, 2001. Hypoadiponectinemia in obesity and type 2 diabetes: close association with insulin resistance and hyperinsulinemia. *Journal of Clinical Endocrinology and Metabolism*, 86, 1930-1935.
- 11 Yun JE, Sull JW, Lee HY, Park E, Kim S, Jo J, Lee SJ, Kim SY, Choi YJ, Jee SH, Huh KB, 2009. Serum adiponectin as a useful marker for metabolic syndrome in type 2 diabetic patients. *Diabetes/Metabolism Research and Reviews*, 25, 259-265.

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

- 1 Aihara K, Kajimoto O, Hirata H, Takahashi R, Nakamura Y, 2005. Effect of powdered fermented milk with *Lactobacillus helveticus* on subjects with high-normal blood pressure or mild hypertension. *Journal of the American College of Nutrition*, 24, 257-265.
- 2 Aubin F, 2011, unpublished. Meta-analysis of studies on the effect of lactotriptides on blood pressure in European patients.
- 3 Cicero AF, Rosticci M, Veronesi M, Bacchelli S, Strocchi E, Melegari C, Grandi E, Borghi C, 2010. Hemodynamic effects of lactotriptides from casein hydrolysate in Mediterranean normotensive subjects and patients with high-normal blood pressure: a randomized, double-blind, crossover clinical trial. *Journal of Medicinal Food*, 13, 1363-1368.

- 4 Cicero AFG, Gerocarni B, Laghi L, Borghi C, 2011. Blood pressure lowering effect of lactotripeptides assumed as functional foods: a meta-analysis of current available clinical trials. *Journal of Human Hypertension*, 25, 425-436.
- 5 De Leeuw PW, Van der Zander K, Kroon AA, Rennenberg RM, Koning MM, 2009. Dose-dependent lowering of blood pressure by dairy peptides in mildly hypertensive subjects. *Blood Pressure*, 18, 44-50.
- 6 Engberink MF, Schouten EG, Kok FJ, van Mierlo LA, Brouwer IA, Geleijnse JM, 2008. Lactotripeptides show no effect on human blood pressure: results from a double-blind randomized controlled trial. *Hypertension*, 51, 399-405.
- 7 Hirata H, Nakamura Y, Yada H, Moriguchi S, Kajimoto O, Takahashi T, 2002. Clinical effects of new sour milk drink in mild or moderate hypertensive subjects. *Journal of New Remedies & Clinics*, 51, 61-69.
- 8 Ishida Y, Sagitani A, Kaneko K, Nakamura Y, Mizutani J, Watanabe M, Sato S, Nobuhiko S, Masuda1 O, 2007. Antihypertensive Effects of the Tablet Containing "Lactotripeptide (VPP, IPP)" in Subjects with High Normal Blood Pressure or Mild Hypertension. *Japanese Pharmacology & Therapeutics*, 35, 1249-1260.
- 9 Itakura H, Ikemoto S, Terada S, Kondo K, 2001. The effect of sour milk on blood pressure in untreated hypertensive and normotensive subjects. *Journal of Japanese Society of Clinical Nutrition*, 23, 26-31.
- 10 Kajimoto O, Aihara K, Hirata H, Takahashi R, Nakamura Y, 2001. Hypotensive effects of the tablets containing "lactotripeptides (VPP, IPP)". *Journal of Nutritional Food*, 4, 51-61.
- 11 Kajimoto O, Nakamura Y, Yada H, Moriguchi S, Hirata H, Takahashi T, 2001. Hypotensive effects of sour milk in subjects with mild or moderate hypertension. *Japan Society of Nutrition and Food Science*, 54, 347-354.
- 12 Kajimoto O, Kurosaki T, Mizutani J, Ikeda N, Kaneko K, Yabune M, Nakamura Y, 2002. Antihypertensive effects of the liquid yogurt containing "lactotripeptides (VPP, IPP)" in mild hypertensive subjects. *Journal of Nutritional Food*, 5, 55-66.
- 13 Mizuno S, Matsuura K, Gotou T, Nishimura S, Kajimoto O, Yabune M, Kajimoto Y, Yamamoto N, 2005. Antihypertensive effect of casein hydrolysate in a placebo-controlled study in subjects with high-normal blood pressure and mild hypertension. *British Journal of Nutrition*, 94, 84-91.
- 14 Mizushima S, Ohshige K, Watanabe J, Kimura M, Kadokawa T, Nakamura Y, Tochikubo O, Ueshima H, 2004. Randomized controlled trial of sour milk on blood pressure in borderline hypertensive men. *American Journal of Hypertension*, 17, 701-706.
- 15 Nakamura Y, Kajimoto O, Kaneko K, Aihara K, Mizutani J, Ikeda N, Kajimoto Y, 2004. Effects of the liquid yogurts containing "lactotripeptide (VPP, IPP)" on high-normal blood pressure. *Journal of Nutritional Food*, 7, 123-137.
- 16 Nakamura T, Mizutani J, Ohki K, Yamada K, Yamamoto N, Takeshi M, Takazawa K, 2011. Casein hydrolysate containing Val-Pro-Pro and Ile-Pro-Pro improves central blood pressure and arterial stiffness in hypertensive subjects: a randomized, double-blind, placebo-controlled trial. *Atherosclerosis*, 219, 298-303.
- 17 Sano J, Ohki K, Higuchi T, Aihara K, Mizuno S, Kajimoto O, Nakagawa S, Kajimoto Y, Nakamura Y, 2005. Effect of casein hydrolysate, prepared with protease derived from *Aspergillus oryzae*, on subjects with high-normal blood pressure or mild hypertension. *Journal of Medicinal Food*, 8, 423-430.
- 18 Seppo L, Kerojoki O, Suomalainen T, Korpela R, 2002. The effect of a *Lactobacillus helveticus* LBK-16 H fermented milk on hypertension- a pilot study on humans. *Milchwissenschaft*, 57, 124-127.

- 19 Seppo L, Jauhainen T, Poussa T, Korpela R, 2003. A fermented milk high in bioactive peptides has a blood pressure-lowering effect in hypertensive subjects. American Journal of Clinical Nutrition, 77, 326-330.
- 20 Tuomilehto J, Lindstrom J, Hyyrynen J, Korpela R, Karhunen ML, Mikkola L, Jauhainen T, Seppo L, Nissinen A, 2004. Effect of ingesting sour milk fermented using *Lactobacillus helveticus* bacteria producing tripeptides on blood pressure in subjects with mild hypertension. Journal of Human Hypertension, 18, 795-802.
- 21 Turpeinen AM, Kumpu M, Rönnback M, Seppo L, Kautiainen H, Jauhainen T, Vapaatalo H, Korpela R, 2009. Antihypertensive and cholesterol-lowering effects of a spread containing bioactive peptides IPP and VPP and plant sterols. Journal of Functional Foods, 1, 260-265.
- 22 Usinger L, Jensen LT, Flambard B, Linneberg A, Ibsen H, 2010. The antihypertensive effect of fermented milk in individuals with prehypertension or borderline hypertension. Journal of Human Hypertension, 24, 678-683.
- 23 Van der Zander K, Bots ML, Bak AA, Koning MM, De Leeuw PW, 2008. Enzymatically hydrolyzed lactotripeptides do not lower blood pressure in mildly hypertensive subjects. American Journal of Clinical Nutrition, 88, 1697-1702.
- 24 Van der Zander K, Jakel M, Bianco V, Koning MM, 2008. Fermented lactotripeptides-containing milk lowers daytime blood pressure in high normal-to-mild hypertensive subjects. Journal of Human Hypertension, 22, 804-806.
- 25 Van Mierlo LA, Koning MM, Van der Zander K, Draijer R, 2009. Lactotripeptides do not lower ambulatory blood pressure in untreated whites: results from 2 controlled multicenter crossover studies. American Journal of Clinical Nutrition, 89, 617-623.
- 26 Xu JY, Qin LQ, Wang PY, Li W, Chang C, 2008. Effect of milk tripeptides on blood pressure: a meta-analysis of randomized controlled trials. Nutrition, 24, 933-940.
- 27 Yoshizawa M, Maeda S, Miyaki A, Misono M, Choi Y, Shimojo N, Ajisaka R, Tanaka H, 2010. Additive beneficial effects of lactotripeptides intake with regular exercise on endothelium-dependent dilatation in postmenopausal women. American Journal of Hypertension, 23, 368-372.

Lutein and maintenance of normal vision (ID 1603)

- 1 Berson EL, Rosner B, Sandberg MA, Weigel-DiFranco C, Brockhurst RJ, Hayes KC, Johnson EJ, Anderson EJ, Johnson CA, Gaudio AR, Willett WC, Schaefer EJ, 2010. Clinical trial of lutein in patients with retinitis pigmentosa receiving vitamin A. Archives of Ophthalmology, 128, 403-411.
- 2 Duncan JL, Aleman TS, Gardner LM, De Castro E, Marks DA, Emmons JM, Bieber ML, Steinberg JD, Bennett J, Stone EM, MacDonald IM, Cideciyan AV, Maguire MG, Jacobson SG, 2002. Macular pigment and lutein supplementation in choroideremia. Experimental Eye Research, 74, 371-381.
- 3 Koh HH, Murray JJ, Nolan D, Carden D, Feather J, Beatty S, 2004. Plasma and macular responses to lutein supplement in subjects with and without age-related maculopathy: a pilot study. Experimental Eye Research, 79, 21-27.
- 4 Kvansakul J, Rodriguez-Carmona M, Edgar DF, Barker FM, Kopcke W, Schalch W, Barbur JL, 2006. Supplementation with the carotenoids lutein or zeaxanthin improves human visual performance. Ophthalmic and Physiological Optics, 26, 362-371.
- 5 Ma L, Lin XM, Zou ZY, Xu XR, Li Y, Xu R, 2009. A 12-week lutein supplementation improves visual function in Chinese people with long-term computer display light exposure. British Journal of Nutrition, 102, 186-190.

- 6 Olmedilla B, Granado F, Blanco I, Vaquero M, Cajigal C, 2001. Lutein in patients with cataracts and age-related macular degeneration: a long-term supplementation study. *Journal of the Science of Food and Agriculture*, 81, 904-909.
- 7 Olmedilla B, Granado F, Blanco I, Vaquero M, 2003. Lutein, but not alpha-tocopherol, supplementation improves visual function in patients with age-related cataracts: a 2-y double-blind, placebo-controlled pilot study. *Nutrition*, 19, 21-24.
- 8 Richer S, Stiles W, Statkute L, Pulido J, Frankowski J, Rudy D, Pei K, Tsipursky M, Nyland J, 2004. Double-masked, placebo-controlled, randomized trial of lutein and antioxidant supplementation in the intervention of atrophic age-related macular degeneration: the Veterans LAST study (Lutein Antioxidant Supplementation Trial). *Optometry*, 75, 216-230.
- 9 Rodriguez-Carmona M, Kvansakul J, Harlow JA, Kopcke W, Schalch W, Barbur JL, 2006. The effects of supplementation with lutein and/or zeaxanthin on human macular pigment density and colour vision. *Ophthalmic and Physiological Optics*, 26, 137-147.
- 10 Rosenthal JM, Kim J, de Monasterio F, Thompson DJ, Bone RA, Landrum JT, de Moura FF, Khachik F, Chen H, Schleicher RL, Ferris FL, 3rd, Chew EY, 2006. Dose-ranging study of lutein supplementation in persons aged 60 years or older. *Investigative Ophthalmology and Visual Science*, 47, 5227-5233.

Lutein and maintenance of normal vision (ID 1604)

- 1 Amarie S, Arefe K, Starcke JH, Dreuw A, Wachtveitl J, 2008. Identification of an additional low-lying excited state of carotenoid radical cations. *The Journal of Physical Chemistry B*, 112, 14011-14017.
- 2 Barker FM, 2nd, Snodderly DM, Johnson EJ, Schalch W, Koepcke W, Gerss J, Neuringer M, 2011. Nutritional manipulation of primate retinas, V: effects of lutein, zeaxanthin, and n-3 fatty acids on retinal sensitivity to blue-light-induced damage. *Investigative Ophthalmology and Visual Science*, 52, 3934-3942.
- 3 Bohm F, Edge R, Land EJ, Macgarvey DJ, Truscott TG, 1997. Carotenoids enhance vitamin E antioxidant efficiency. *Journal of the American Chemical Society*, 119, 621-622.
- 4 Burke M, Edge R, Land EJ, Truscott TG, 2001. Characterisation of carotenoid radical cations in liposomal environments: interaction with vitamin C. *Journal of Photochemistry and Photobiology. B, Biology*, 60, 1-6.
- 5 Cantrell A, McGarvey DJ, Truscott TG, Rancan F, Bohm F, 2003. Singlet oxygen quenching by dietary carotenoids in a model membrane environment. *Archives of Biochemistry and Biophysics*, 412, 47-54.
- 6 Choi JS, Kim D, Hong YM, Mizuno S, Joo CK, 2006. Inhibition of nNOS and COX-2 expression by lutein in acute retinal ischemia. *Nutrition*, 22, 668-671.
- 7 Chopra M, Willson RL, Thurnham DI, 1993. Free radical scavenging of lutein in vitro. *Annals of the New York Academy of Sciences*, 691, 246-249.
- 8 Chucair AJ, Rotstein NP, Sangiovanni JP, During A, Chew EY, Politi LE, 2007. Lutein and zeaxanthin protect photoreceptors from apoptosis induced by oxidative stress: relation with docosahexaenoic acid. *Investigative Ophthalmology and Visual Science*, 48, 5168-5177.
- 9 Conn PF, Schalch W, Truscott TG, 1991. The singlet oxygen and carotenoid interaction. *Journal of Photochemistry and Photobiology. B, Biology*, 11, 41-47.
- 10 Di Mascio P, Kaiser S, Sies H, 1989. Lycopene as the most efficient biological carotenoid singlet oxygen quencher. *Archives of Biochemistry and Biophysics*, 274, 532-538.

- 11 Di Mascio P, Devasagayam TPA, Kaiser S, Sies H, 1990. Carotenoids, tocopherols and thiols as biological singlet molecular oxygen quenchers. *Biochemical Society Transactions*, 18, 1054-1056.
- 12 Edge R and Truscott TG, 1997. Prooxidant and antioxidant reaction mechanisms of carotene and radical interactions with vitamins E and C. *Nutrition*, 13, 992-994.
- 13 Edge R, Land EJ, McGarvey DJ, Mulroy L, Truscott TG, 1998. Relative one-electron reduction potentials of carotenoid radical cations and the interactions of carotenoids with the vitamin E radical cation. *Journal of the American Chemical Society*, 120, 4087-4090.
- 14 El-Agamy A, Cantrell A, Land EJ, McGarvey DJ, Truscott TG, 2004. Are dietary carotenoids beneficial? Reactions of carotenoids with oxy-radicals and singlet oxygen. *Photochemical and Photobiological Sciences*, 3, 802-811.
- 15 Feeney-Burns L, Neuringer M, Gao CL, 1989. Macular pathology in monkeys fed semipurified diets. *Progress in Clinical and Biological Research*, 314, 601-622.
- 16 Galano A, 2007. Relative antioxidant efficiency of a large series of carotenoids in terms of one electron transfer reactions. *The Journal of Physical Chemistry B*, 111, 12898-12908.
- 17 Hill TJ, Land EJ, McGarvey DJ, Schalch W, Tinkler JH, Truscott TG, 1995. Interactions between carotenoids and the CCl₃O₂ radical. *Journal of the American Chemical Society*, 117, 8322-8326.
- 18 Hupp SL, 1987. Delayed, incomplete recovery of macular function after photic retinal damage associated with extracapsular cataract extraction and posterior lens insertion. Case report. *Archives of Ophthalmology*, 105, 1022-1023.
- 19 Iannone A, Rota C, Bergamini S, Tomasi A, Canfield LM, 1998. Antioxidant activity of carotenoids: an electron-spin resonance study on beta-carotene and lutein interaction with free radicals generated in a chemical system. *Journal of Biochemical and Molecular Toxicology*, 12, 299-304.
- 20 Jaffe GJ and Wood IS, 1988. Retinal phototoxicity from the operating microscope: a protective effect by the fovea. *Archives of Ophthalmology*, 106, 445-446.
- 21 Jeffrey BG, Renner LM, Neuringer M, 2011. Selective loss of central retinal function in rhesus monkeys deficient in xanthophylls and n-3 fatty acids. *ARVO Abstract*, 5567.
- 22 Junghans A, Sies H, Stahl W, 2001. Macular pigments lutein and zeaxanthin as blue light filters studied in liposomes. *Archives of Biochemistry and Biophysics*, 391, 160-164.
- 23 Khachik F, Bernstein PS, Garland DL, 1997. Identification of lutein and zeaxanthin oxidation products in human and monkey retinas. *Investigative Ophthalmology and Visual Science*, 38, 1802-1811.
- 24 Kim SR, Nakanishi K, Itagaki Y, Sparrow JR, 2006. Photooxidation of A2-PE, a photoreceptor outer segment fluorophore, and protection by lutein and zeaxanthin. *Experimental Eye Research*, 82, 828-839.
- 25 Landrum JT, Bone RA, Kilburn MD, 1997. The macular pigment: a possible role in protection from age-related macular degeneration. *Advances in Pharmacology*, 38, 537-556.
- 26 Li B, Ahmed F, Bernstein PS, 2010. Studies on the singlet oxygen scavenging mechanism of human macular pigment. *Archives of Biochemistry and Biophysics*, 504, 56-60.
- 27 Li SY and Lo AC, 2010. Lutein Protects RGC-5 Cells Against Hypoxia and Oxidative Stress. *International Journal of Molecular Sciences*, 11, 2109-2117.
- 28 Li B, Vachali P, Frederick JM, Bernstein PS, 2011. Identification of StARD3 as a lutein-binding protein in the macula of the primate retina. *Biochemistry*, 50, 2541-2549.

- 29 Montenegro MA, Nazareno MA, Durantini EN, Borsarelli CD, 2002. Singlet molecular oxygen quenching ability of carotenoids in a reverse-micelle membrane mimetic system. *Photochemistry and Photobiology*, 75, 353-361.
- 30 Müller L, Fröhlich K, Böhm V, 2011. Comparative antioxidant activities of carotenoids measured by ferric reducing antioxidant power (FRAP), ABTS bleaching assay (α TEAC), DPPH assay and peroxy radical scavenging assay. *Food Chemistry*, 129, 139-148.
- 31 Nakanishi-Ueda T, Kamegawa M, Ishigaki S, Tsukahara M, Yano S, Wada K, Yasuhara H, 2006. Inhibitory effect of lutein and pycnogenol on lipid peroxidation in porcine retinal homogenate. *Journal of Clinical Biochemistry and Nutrition*, 38, 204-210.
- 32 Ouchi A, Aizawa K, Iwasaki Y, Inakuma T, Terao J, Nagaoka S, Mukai K, 2010. Kinetic study of the quenching reaction of singlet oxygen by carotenoids and food extracts in solution. Development of a singlet oxygen absorption capacity (SOAC) assay method. *Journal of Agricultural and Food Chemistry*, 58, 9967-9978.
- 33 Pintea A, Rugina DO, Pop R, Bunea A, Socaciuc C, 2011. Xanthophylls protect against induced oxidation in cultured human retinal pigment epithelial cells. *Journal of Food Composition and Analysis*, 24, 830-836.
- 34 Sasaki M, Ozawa Y, Kurihara T, Noda K, Imamura Y, Kobayashi S, Ishida S, Tsubota K, 2009. Neuroprotective effect of an antioxidant, lutein, during retinal inflammation. *Investigative Ophthalmology and Visual Science*, 50, 1433-1439.
- 35 Sasaki M, Yuki K, Kurihara T, Miyake S, Noda K, Kobayashi S, Ishida S, Tsubota K, Ozawa Y, 2011. Biological role of lutein in the light-induced retinal degeneration. *Journal of Nutritional Biochemistry*, 23, 423-429.
- 36 Serpeloni JM, Grotto D, Mercadante AZ, de Lourdes Pires Bianchi M, Antunes LM, 2010. Lutein improves antioxidant defense in vivo and protects against DNA damage and chromosome instability induced by cisplatin. *Archives of Toxicology*, 84, 811-822.
- 37 Sindhu ER, Preethi KC, Kuttan R, 2010. Antioxidant activity of carotenoid lutein in vitro and in vivo. *Indian Journal of Experimental Biology*, 48, 843-848.
- 38 Soffers AE, Van Haandel MJ, Boersma MG, Tyrakowska B, Laane C, Rietjens IM, 1999. Antioxidant activities of carotenoids: quantitative relationships between theoretical calculations and experimental literature data. *Free Radical Research*, 30, 233-240.
- 39 Stahl W, Junghans A, de Boer B, Driomina ES, Briviba K, Sies H, 1998. Carotenoid mixtures protect multilamellar liposomes against oxidative damage: synergistic effects of lycopene and lutein. *FEBS Letters*, 427, 305-308.
- 40 Subczynski WK, Markowska E, Sielewiesiuk J, 1991. Effect of polar carotenoids on the oxygen diffusion-concentration product in lipid bilayers. An EPR spin label study. *Biochimica et Biophysica Acta*, 1068, 68-72.
- 41 Sujak A, Gabrielska J, Grudzinski W, Borc R, Mazurek P, Gruszecki WI, 1999. Lutein and zeaxanthin as protectors of lipid membranes against oxidative damage: the structural aspects. *Archives of Biochemistry and Biophysics*, 371, 301-307.
- 42 Sundelin SP and Nilsson SE, 2001. Lipofuscin-formation in retinal pigment epithelial cells is reduced by antioxidants. *Free Radical Biology and Medicine*, 31, 217-225.
- 43 Thammanna GSS, Dinesha R, Harsha R, Srinivas L, 2010. Free radical scavenging activity of lutein - isolated from methi leaves (*Trigonella foenum graecum*). *International Journal of Pharmacy and Pharmaceutical Sciences*, 2, 113-117.
- 44 Trevithick-Sutton CC, Foote CS, Collins M, Trevithick JR, 2006. The retinal carotenoids zeaxanthin and lutein scavenge superoxide and hydroxyl radicals: a chemiluminescence and ESR study. *Molecular Vision*, 12, 1127-1135.

- 45 Viljanen K, Sundberg S, Ohshima T, Heinonen M, 2002. Carotenoids as antioxidants to prevent photooxidation. European Journal of Lipid Science and Technology, 104, 353-359.
- 46 Wang M, Tsao R, Zhang S, Dong Z, Yang R, Gong J, Pei Y, 2006. Antioxidant activity, mutagenicity/anti-mutagenicity, and clastogenicity/anti-clastogenicity of lutein from marigold flowers. Food and Chemical Toxicology, 44, 1522-1529.
- 47 Weiter JJ, Delori F, Dorey CK, 1988. Central sparing in annular macular degeneration. American Journal of Ophthalmology, 106, 286-292.

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

- 1 Attaluri A, Donahoe R, Valestin J, Brown K, Rao SS, 2011. Randomised clinical trial: dried plums (prunes) vs. psyllium for constipation. Alimentary Pharmacology and Therapeutics, 33, 822-828.
- 2 Howarth L, Petisko Y, Furchner-Evanson A, Nemoseck T, Kern M, 2010. Snack selection influences nutrient intake, triglycerides, and bowel habits of adult women: a pilot study. Journal of the American Dietetic Association, 110, 1322-1327.
- 3 Lucas EA, Hammond LJ, Mocanu V, Arquitt AB, Trolinger A, Khalil DA, Smith BJ, Soung DY, Daggy BP, Arjmandi BH, 2004. Daily consumption of dried plum by postmenopausal women does not cause undesirable changes in bowel function. The Journal of Applied Research, 4, 37-43.
- 4 Sairanen U, Piirainen L, Nevala R, Korpela R, 2007. Yoghurt containing galacto-oligosaccharides, prunes and linseed reduces the severity of mild constipation in elderly subjects. European Journal of Clinical Nutrition, 61, 1423-1428.
- 5 Tinker LF, Schneeman BO, Davis PA, Gallaher DD, Waggoner CR, 1991. Consumption of prunes as a source of dietary fiber in men with mild hypercholesterolemia. American Journal of Clinical Nutrition, 53, 1259-1265.

Polyphenols in olive and maintenance of normal blood HDL-cholesterol concentrations (ID 1639)

- 1 Covas MI, Nyssonnen K, Poulsen HE, Kaikkonen J, Zunft HJ, Kiesewetter H, Gaddi A, de la Torre R, Mursu J, Baumler H, Nascetti S, Salonen JT, Fito M, Virtanen J, Marrugat J, 2006. The effect of polyphenols in olive oil on heart disease risk factors: a randomized trial. Annals of Internal Medicine, 145, 333-341.
- 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.
- 3 Estevez-Gonzalez MD, Saavedra-Santana P, Lopez-Rios L, Chirino R, Cebrero-Garcia E, Pena-Quintana L, Betancor-Leon P, 2010. HDL cholesterol levels in children with mild hypercholesterolemia: effect of consuming skim milk enriched with olive oil and modulation by the TAQ 1B polymorphism in the CETP gene. Annals of Nutrition and Metabolism, 56, 288-293.
- 4 Fki I, Sahnoun Z, Sayadi S, 2007. Hypocholesterolemic effects of phenolic extracts and purified hydroxytyrosol recovered from olive mill wastewater in rats fed a cholesterol-rich diet. Journal of Agricultural and Food Chemistry, 55, 624-631.

- 5 Gonzalez-Santiago M, Martin-Bautista E, Carrero JJ, Fonolla J, Baro L, Bartolome MV, Gil-Loyzaga P, Lopez-Huertas E, 2006. One-month administration of hydroxytyrosol, a phenolic antioxidant present in olive oil, to hyperlipemic rabbits improves blood lipid profile, antioxidant status and reduces atherosclerosis development. *Atherosclerosis*, 188, 35-42.
- 6 Haban P, Klvanova J, Zidekova E, Nagyova A, 2004. Dietary supplementation with olive oil leads to improved lipoprotein spectrum and lower n-6 PUFAs in elderly subjects. *Medical Science Monitor*, 10, PI49-54.
- 7 Jemai H, Fki I, Bouaziz M, Bouallagui Z, El Feki A, Isoda H, Sayadi S, 2008. Lipid-lowering and antioxidant effects of hydroxytyrosol and its triacetylated derivative recovered from olive tree leaves in cholesterol-fed rats. *Journal of Agricultural and Food Chemistry*, 56, 2630-2636.
- 8 Mangas-Cruz MA, Fernandez-Moyano A, Albi T, Guinda A, Relimpio F, Lanzon A, Pereira JL, Serrera JL, Montilla C, Astorga R, Garcia-Luna PP, 2001. Effects of minor constituents (non-glyceride compounds) of virgin olive oil on plasma lipid concentrations in male Wistar rats. *Clinical Nutrition*, 20, 211-215.
- 9 Marrugat J, Covas MI, Fito M, Schroder H, Miro-Casas E, Gimeno E, Lopez-Sabater MC, de la Torre R, Farre M, 2004. Effects of differing phenolic content in dietary olive oils on lipids and LDL oxidation--a randomized controlled trial. *European Journal of Nutrition*, 43, 140-147.
- 10 Perona JS, Fito M, Covas MI, Garcia M, Ruiz-Gutierrez V, 2011. Olive oil phenols modulate the triacylglycerol molecular species of human very low-density lipoprotein. A randomized, crossover, controlled trial. *Metabolism: Clinical and Experimental*, 60, 893-899.
- 11 Perrinjaquet-Moccetti T, Busjahn A, Schmidlin C, Schmidt A, Bradl B, Aydogan C, 2008. Food supplementation with an olive (*Olea europaea* L.) leaf extract reduces blood pressure in borderline hypertensive monozygotic twins. *Phytotherapy Research*, 22, 1239-1242.
- 12 Ruano J, Lopez-Miranda J, de la Torre R, Delgado-Lista J, Fernandez J, Caballero J, Covas MI, Jimenez Y, Perez-Martinez P, Marin C, Fuentes F, Perez-Jimenez F, 2007. Intake of phenol-rich virgin olive oil improves the postprandial prothrombotic profile in hypercholesterolemic patients. *American Journal of Clinical Nutrition*, 86, 341-346.
- 13 Singleton VL and Rossi JA, Jr., 1965. Colorimetry of total phenolics with phosphomolybdic-phosphotungstic acid reagents. *American Journal of Enology and Viticulture*, 16, 144-158.
- 14 Susalit E, Agus N, Effendi I, Tjandrawinata RR, Nofiarny D, Perrinjaquet-Moccetti T, Verbruggen M, 2011. Olive (*Olea europaea*) leaf extract effective in patients with stage-1 hypertension: comparison with Captopril. *Phytomedicine*, 18, 251-258.
- 15 Violante B, Gerbaudo L, Borretta G, Tassone F, 2009. Effects of extra virgin olive oil supplementation at two different low doses on lipid profile in mild hypercholesterolemic subjects: a randomised clinical trial. *Journal of Endocrinological Investigation*, 32, 794-796.
- 16 Vissers MN, Zock PL, Wiseman SA, Meyboom S, Katan MB, 2001. Effect of phenol-rich extra virgin olive oil on markers of oxidation in healthy volunteers. *European Journal of Clinical Nutrition*, 55, 334-341.
- 17 Weinbrenner T, Fito M, de la Torre R, Saez GT, Rijken P, Tormos C, Coolen S, Albaladejo MF, Abanades S, Schroder H, Marrugat J, Covas MI, 2004. Olive oils high in phenolic compounds modulate oxidative/antioxidative status in men. *Journal of Nutrition*, 134, 2314-2321.

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

- 1 Albertazzi P, Steel SA, Bottazzi M, 2005. Effect of pure genistein on bone markers and hot flushes. *Climacteric*, 8, 371-379.
- 2 Alekel DL, Germain AS, Peterson CT, Hanson KB, Stewart JW, Toda T, 2000. Isoflavone-rich soy protein isolate attenuates bone loss in the lumbar spine of perimenopausal women. *American Journal of Clinical Nutrition*, 72, 844-852.
- 3 Alekel DL, Van Loan MD, Koehler KJ, Hanson LN, Stewart JW, Hanson KB, Kurzer MS, Peterson CT, 2010. The soy isoflavones for reducing bone loss (SIRBL) study: a 3-y randomized controlled trial in postmenopausal women. *American Journal of Clinical Nutrition*, 91, 218-230.
- 4 Anderson JW, Smith BM, Washnock CS, 1999. Cardiovascular and renal benefits of dry bean and soybean intake. *American Journal of Clinical Nutrition*, 70, 464S-474S.
- 5 Anderson JJ, Chen X, Boass A, Symons M, Kohlmeier M, Renner JB, Garner SC, 2002. Soy isoflavones: no effects on bone mineral content and bone mineral density in healthy, menstruating young adult women after one year. *Journal of the American College of Nutrition*, 21, 388-393.
- 6 Arai Y, Watanabe S, Kimira M, Shimoi K, Mochizuki R, Kinae N, 2000. Dietary intakes of flavonols, flavones and isoflavones by Japanese women and the inverse correlation between quercetin intake and plasma LDL cholesterol concentration. *Journal of Nutrition*, 130, 2243-2250.
- 7 Arjmandi BH, Khalil DA, Smith BJ, Lucas EA, Juma S, Payton ME, Wild RA, 2003. Soy protein has a greater effect on bone in postmenopausal women not on hormone replacement therapy, as evidenced by reducing bone resorption and urinary calcium excretion. *Journal of Clinical Endocrinology and Metabolism*, 88, 1048-1054.
- 8 Arjmandi BH, Lucas EA, Khalil DA, Devareddy L, Smith BJ, McDonald J, Arquitt AB, Payton ME, Mason C, 2005. One year soy protein supplementation has positive effects on bone formation markers but not bone density in postmenopausal women. *Nutrition Journal*, 4, 8.
- 9 Atmaca A, Kleerekoper M, Bayraktar M, Kucuk O, 2008. Soy isoflavones in the management of postmenopausal osteoporosis. *Menopause*, 15, 748-757.
- 10 Atteritano M, Mazzaferro S, Frisina A, Cannata ML, Bitto A, D'Anna R, Squadrito F, Macri I, Frisina N, Buemi M, 2009. Genistein effects on quantitative ultrasound parameters and bone mineral density in osteopenic postmenopausal women. *Osteoporosis International*, 20, 1947-1954.
- 11 Barnes S, 2003. Phyto-oestrogens and osteoporosis: what is a safe dose? *British Journal of Nutrition*, 89 Suppl 1, S101-108.
- 12 Bawa S, 2010. The significance of soy protein and soy bioactive compounds in the prophylaxis and treatment of osteoporosis. *Journal of Osteoporosis*, 2010, 891058.
- 13 Bitto A, Polito F, Squadrito F, Marini H, D'Anna R, Irrera N, Minutoli L, Granece R, Altavilla D, 2010. Genistein aglycone: a dual mode of action anti-osteoporotic soy isoflavone rebalancing bone turnover towards bone formation. *Current Medicinal Chemistry*, 17, 3007-3018.
- 14 Blair HC, Jordan SE, Peterson TG, Barnes S, 1996. Variable effects of tyrosine kinase inhibitors on avian osteoclastic activity and reduction of bone loss in ovariectomized rats. *Journal of Cellular Biochemistry*, 61, 629-637.
- 15 Brink E, Coxam V, Robins S, Wahala K, Cassidy A, Branca F, 2008. Long-term consumption of isoflavone-enriched foods does not affect bone mineral density, bone metabolism, or hormonal status in early postmenopausal women: a randomized, double-blind, placebo controlled study. *American Journal of Clinical Nutrition*, 87, 761-770.

- 16 Brooks JD, Ward WE, Lewis JE, Hilditch J, Nickell L, Wong E, Thompson LU, 2004. Supplementation with flaxseed alters estrogen metabolism in postmenopausal women to a greater extent than does supplementation with an equal amount of soy. *American Journal of Clinical Nutrition*, 79, 318-325.
- 17 Cassidy A, Bingham S, Setchell K, 1995. Biological effects of isoflavones in young women: importance of the chemical composition of soyabean products. *British Journal of Nutrition*, 74, 587-601.
- 18 Cassidy A, Albertazzi P, Lise Nielsen I, Hall W, Williamson G, Tetens I, Atkins S, Cross H, Manios Y, Wolk A, Steiner C, Branca F, 2006. Critical review of health effects of soyabean phyto-oestrogens in post-menopausal women. *Proceedings of the Nutrition Society*, 65, 76-92.
- 19 Castelo-Branco C and Cancelo Hidalgo MJ, 2011. Isoflavones: effects on bone health. *Climacteric*, 14, 204-211.
- 20 Chang H, Jin TY, Jin WF, Gu SZ, Zhou YF, 2003. Modulation of isoflavones on bone-nodule formation in rat calvaria osteoblasts in vitro. *Biomedical and Environmental Sciences*, 16, 83-89.
- 21 Chen YM, Ho SC, Lam SS, Ho SS, Woo JL, 2003. Soy isoflavones have a favorable effect on bone loss in Chinese postmenopausal women with lower bone mass: a double-blind, randomized, controlled trial. *Journal of Clinical Endocrinology and Metabolism*, 88, 4740-4747.
- 22 Chen YM, Ho SC, Lam SS, Ho SS, Woo JL, 2004. Beneficial effect of soy isoflavones on bone mineral content was modified by years since menopause, body weight, and calcium intake: a double-blind, randomized, controlled trial. *Menopause*, 11, 246-254.
- 23 Coward L, Barnes NC, Setchell KDR, Barnes S, 1993. Genistein, daidzein, and their beta-glycoside conjugates - Antitumor isoflavones in soybean foods from American and Asian diets. *Journal of Agricultural and Food Chemistry*, 41, 1961-1967.
- 24 Dalais FS, Ebeling PR, Kotsopoulos D, McGrath BP, Teede HJ, 2003. The effects of soy protein containing isoflavones on lipids and indices of bone resorption in postmenopausal women. *Clinical Endocrinology*, 58, 704-709.
- 25 Dong J, Huang ZW, Piao JH, Li F, Zeng J, Gong J, Yang XG, 2008. [Relationship between estrogen receptor gene Px haplotype and the effect of calcium and soy isoflavone supplementation on bone mineral density of Chinese postmenopausal women]. *Zhonghua Yu Fang Yi Xue Za Zhi (Chinese Journal of Preventive Medicine)*, 42, 329-334.
- 26 Evans EM, Racette SB, Van Pelt RE, Peterson LR, Villareal DT, 2007. Effects of soy protein isolate and moderate exercise on bone turnover and bone mineral density in postmenopausal women. *Menopause*, 14, 481-488.
- 27 Gallagher JC, Satpathy R, Rafferty K, Haynatzka V, 2004. The effect of soy protein isolate on bone metabolism. *Menopause*, 11, 290-298.
- 28 Gao YP, Li RH, Guo SZ, 2006. The effect of soy isoflavone on bone metabolism in postmenopausal women. *Journal of Shanxi Medical University*, 37, 633-635.
- 29 Gertz ER, Silverman NE, Wise KS, Hanson KB, Alekel DL, Stewart JW, Perry CD, Bhupathiraju SN, Kohut ML, Van Loan MD, 2010. Contribution of serum inflammatory markers to changes in bone mineral content and density in postmenopausal women: a 1-year investigation. *Journal of Clinical Densitometry*, 13, 277-282.
- 30 Harkness LS, Fiedler K, Sehgal AR, Oravec D, Lerner E, 2004. Decreased bone resorption with soy isoflavone supplementation in postmenopausal women. *Journal of Women's Health*, 13, 1000-1007.
- 31 Huang HY, Yang HP, Yang HT, Yang TC, Shieh MJ, Huang SY, 2006. One-year soy isoflavone supplementation prevents early postmenopausal bone loss but without a dose-dependent effect. *The Journal of Nutritional Biochemistry*, 17, 509-517.

- 32 Jia TL, Wang HZ, Xie LP, Wang XY, Zhang RQ, 2003. Daidzein enhances osteoblast growth that may be mediated by increased bone morphogenetic protein (BMP) production. *Biochemical Pharmacology*, 65, 709-715.
- 33 Kenny AM, Mangano KM, Abourizk RH, Bruno RS, Anamani DE, Kleppinger A, Walsh SJ, Prestwood KM, Kerstetter JE, 2009. Soy proteins and isoflavones affect bone mineral density in older women: a randomized controlled trial. *American Journal of Clinical Nutrition*, 90, 234-242.
- 34 Knight DC, Howes JB, Eden JA, Howes LG, 2001. Effects on menopausal symptoms and acceptability of isoflavone-containing soy powder dietary supplementation. *Climacteric*, 4, 13-18.
- 35 Kreijkamp-Kaspers S, Kok L, Grobbee DE, de Haan EH, Aleman A, Lampe JW, van der Schouw YT, 2004. Effect of soy protein containing isoflavones on cognitive function, bone mineral density, and plasma lipids in postmenopausal women: a randomized controlled trial. *JAMA*, 292, 65-74.
- 36 Levis S, Strickman-Stein N, Ganjei-Azar P, Xu P, Doerge DR, Krischer J, 2011. Soy isoflavones in the prevention of menopausal bone loss and menopausal symptoms: a randomized, double-blind trial. *Archives of Internal Medicine*, 171, 1363-1369.
- 37 Liu J, Ho SC, Su YX, Chen WQ, Zhang CX, Chen YM, 2009. Effect of long-term intervention of soy isoflavones on bone mineral density in women: a meta-analysis of randomized controlled trials. *Bone*, 44, 948-953.
- 38 Lydeking-Olsen E, Beck-Jensen JE, Setchell KD, Holm-Jensen T, 2004. Soymilk or progesterone for prevention of bone loss--a 2 year randomized, placebo-controlled trial. *European Journal of Nutrition*, 43, 246-257.
- 39 Ma DF, Qin LQ, Wang PY, Katoh R, 2008. Soy isoflavone intake inhibits bone resorption and stimulates bone formation in menopausal women: meta-analysis of randomized controlled trials. *European Journal of Clinical Nutrition*, 62, 155-161.
- 40 Ma DF, Qin LQ, Wang PY, Katoh R, 2008. Soy isoflavone intake increases bone mineral density in the spine of menopausal women: meta-analysis of randomized controlled trials. *Clinical Nutrition*, 27, 57-64.
- 41 Marini H, Minutoli L, Polito F, Bitto A, Altavilla D, Atteritano M, Gaudio A, Mazzaferro S, Frisina A, Frisina N, Lubrano C, Bonaiuto M, D'Anna R, Cannata ML, Corrado F, Adamo EB, Wilson S, Squadrato F, 2007. Effects of the phytoestrogen genistein on bone metabolism in osteopenic postmenopausal women: a randomized trial. *Annals of Internal Medicine*, 146, 839-847.
- 42 Marini H, Minutoli L, Polito F, Bitto A, Altavilla D, Atteritano M, Gaudio A, Mazzaferro S, Frisina A, Frisina N, Lubrano C, Bonaiuto M, D'Anna R, Cannata ML, Corrado F, Cancellieri F, Faraci M, Marini R, Adamo EB, Wilson S, Squadrato F, 2008. OPG and sRANKL serum concentrations in osteopenic, postmenopausal women after 2-year genistein administration. *Journal of Bone and Mineral Research*, 23, 715-720.
- 43 Morabito N, Crisafulli A, Vergara C, Gaudio A, Lasco A, Frisina N, D'Anna R, Corrado F, Pizzoleo MA, Cincotta M, Altavilla D, Ientile R, Squadrato F, 2002. Effects of genistein and hormone-replacement therapy on bone loss in early postmenopausal women: a randomized double-blind placebo-controlled study. *Journal of Bone and Mineral Research*, 17, 1904-1912.
- 44 Mori M, Sagara M, Ikeda K, Miki T, Yamori Y, 2004. Soy isoflavones improve bone metabolism in postmenopausal Japanese women. *Clinical and Experimental Pharmacology and Physiology*, 31 Suppl 2, S44-46.
- 45 Newton KM, LaCroix AZ, Levy L, Li SS, Qu P, Potter JD, Lampe JW, 2006. Soy protein and bone mineral density in older men and women: a randomized trial. *Maturitas*, 55, 270-277.

- 46 Nikander E, Metsa-Heikkila M, Ylikorkala O, Tiiainen A, 2004. Effects of phytoestrogens on bone turnover in postmenopausal women with a history of breast cancer. *Journal of Clinical Endocrinology and Metabolism*, 89, 1207-1212.
- 47 Potter SM, Baum JA, Teng H, Stillman RJ, Shay NF, Erdman JW, Jr., 1998. Soy protein and isoflavones: their effects on blood lipids and bone density in postmenopausal women. *American Journal of Clinical Nutrition*, 68, 1375S-1379S.
- 48 Prentice A, Bonjour JP, Branca F, Cooper C, Flynn A, Garabedian M, Muller D, Pannemans D, Weber P, 2003. PASSCLAIM - Bone health and osteoporosis. *European Journal of Nutrition*, 42 Suppl 1, I28-49.
- 49 Ricci E, Cipriani S, Chiaffarino F, Malvezzi M, Parazzini F, 2010. Soy isoflavones and bone mineral density in perimenopausal and postmenopausal Western women: a systematic review and meta-analysis of randomized controlled trials. *Journal of Women's Health*, 19, 1609-1617.
- 50 Scheiber MD, Liu JH, Subbiah MT, Rebar RW, Setchell KD, 2001. Dietary inclusion of whole soy foods results in significant reductions in clinical risk factors for osteoporosis and cardiovascular disease in normal postmenopausal women. *Menopause*, 8, 384-392.
- 51 Shedd-Wise KM, Alekel DL, Hofmann H, Hanson KB, Schiferl DJ, Hanson LN, Van Loan MD, 2011. The soy isoflavones for reducing bone loss study: 3-yr effects on pQCT bone mineral density and strength measures in postmenopausal women. *Journal of Clinical Densitometry*, 14, 47-57.
- 52 Taku K, Melby MK, Kurzer MS, Mizuno S, Watanabe S, Ishimi Y, 2010. Effects of soy isoflavone supplements on bone turnover markers in menopausal women: systematic review and meta-analysis of randomized controlled trials. *Bone*, 47, 413-423.
- 53 Taku K, Melby MK, Takebayashi J, Mizuno S, Ishimi Y, Omori T, Watanabe S, 2010. Effect of soy isoflavone extract supplements on bone mineral density in menopausal women: meta-analysis of randomized controlled trials. *Asia Pacific Journal of Clinical Nutrition*, 19, 33-42.
- 54 Tousen Y, Ezaki J, Fujii Y, Ueno T, Nishimuta M, Ishimi Y, 2011. Natural S-equol decreases bone resorption in postmenopausal, non-equol-producing Japanese women: a pilot randomized, placebo-controlled trial. *Menopause*, 18, 563-574.
- 55 Turhan Ö, Boklan F, Duvan CI, 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.
- 56 Uesugi T, Fukui Y, Yamori Y, 2002. Beneficial effects of soybean isoflavone supplementation on bone metabolism and serum lipids in postmenopausal Japanese women: a four-week study. *Journal of the American College of Nutrition*, 21, 97-102.
- 57 Uesugi T, Toda T, Okuhira T, Chen JT, 2003. Evidence of estrogenic effect by the three-month-intervention of isoflavone on vaginal maturation and bone metabolism in early postmenopausal women. *Endocrine Journal*, 50, 613-619.
- 58 Vatanparast H and Chilibeck PD, 2007. Does the effect of soy phytoestrogens on bone in postmenopausal women depend on the equol-producing phenotype? *Nutrition Reviews*, 65, 294-299.
- 59 Vupadhyayula PM, Gallagher JC, Templin T, Logsdon SM, Smith LM, 2009. Effects of soy protein isolate on bone mineral density and physical performance indices in postmenopausal women--a 2-year randomized, double-blind, placebo-controlled trial. *Menopause*, 16, 320-328.
- 60 Weaver CM, Martin BR, Jackson GS, McCabe GP, Nolan JR, McCabe LD, Barnes S, Reinwald S, Boris ME, Peacock M, 2009. Antiresorptive Effects of Phytoestrogen Supplements Compared with Estradiol or Risedronate in Postmenopausal Women Using 41Ca Methodology. *Journal of Clinical Endocrinology & Metabolism*, 94, 3798-3805.

- 61 Wong WW, Lewis RD, Steinberg FM, Murray MJ, Cramer MA, Amato P, Young RL, Barnes S, Ellis KJ, Shypailo RJ, Fraley JK, Konzelmann KL, Fischer JG, Smith EO, 2009. Soy isoflavone supplementation and bone mineral density in menopausal women: a 2-y multicenter clinical trial. *American Journal of Clinical Nutrition*, 90, 1433-1439.
- 62 Wu J, Oka J, Higuchi M, Tabata I, Toda T, Fujioka M, Fuku N, Teramoto T, Okuhira T, Ueno T, Uchiyama S, Urata K, Yamada K, Ishimi Y, 2006. Cooperative effects of isoflavones and exercise on bone and lipid metabolism in postmenopausal Japanese women: a randomized placebo-controlled trial. *Metabolism: Clinical and Experimental*, 55, 423-433.
- 63 Wu J, Oka J, Tabata I, Higuchi M, Toda T, Fuku N, Ezaki J, Sugiyama F, Uchiyama S, Yamada K, Ishimi Y, 2006. Effects of isoflavone and exercise on BMD and fat mass in postmenopausal Japanese women: a 1-year randomized placebo-controlled trial. *Journal of Bone and Mineral Research*, 21, 780-789.
- 64 Xin Y and Yang HY, 2006. Influence of daidzein tablets on climacteri syndrome and bone mineral density of women. *Chinese Journal of Osteoporosis*, 12, 149-151.
- 65 Xu F, Jin BQ, Wu WP, Lv L, Tang D, 2007. Effects of phyto-estrogens on the bone mineral density and biochemical markers of bone metabolism in postmenopausal women (in Chinese). *Matern Child Health Care China*, 22, 1517-1519.
- 66 Yamori Y, Moriguchi EH, Teramoto T, Miura A, Fukui Y, Honda KI, Fukui M, Nara Y, Taira K, Moriguchi Y, 2002. Soybean isoflavones reduce postmenopausal bone resorption in female Japanese immigrants in Brazil: a ten-week study. *Journal of the American College of Nutrition*, 21, 560-563.
- 67 Ye YB, Tang XY, Verbruggen MA, Su YX, 2006. Soy isoflavones attenuate bone loss in early postmenopausal Chinese women: a single-blind randomized, placebo-controlled trial. *European Journal of Nutrition*, 45, 327-334.
- 68 Yi YB and Shu YX, 2004. Soy isoflavone intake attenuated bone loss in postmenopausal women (in Chinese). *Acta Nutrimenta Sinica*, 26, 49-53.

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

- 1 Basaria S, Wisniewski A, Dupree K, Bruno T, Song MY, Yao F, Ojumu A, John M, Dobs AS, 2009. Effect of high-dose isoflavones on cognition, quality of life, androgens, and lipoprotein in post-menopausal women. *Journal of Endocrinological Investigation*, 32, 150-155.
- 2 Battaglia C, Cianciosi A, Mancini F, Fabbri R, Busacchi P, Nappi RE, Venturoli S, 2009. Genistein supplements might not induce clitoral modifications in postmenopausal women: a prospective, pilot study. *Journal of Sexual Medicine*, 6, 3132-3138.
- 3 Bolaños R, Del Castillo A, Francia J, 2010. Soy isoflavones versus placebo in the treatment of climacteric vasomotor symptoms: systematic review and meta-analysis. *Menopause*, 17, 660-666.
- 4 Bolaños-Diaz R, Zavala-Gonzales JC, Mezones-Holguin E, Francia-Romero J, 2011. Soy extracts versus hormone therapy for reduction of menopausal hot flushes: indirect comparison. *Menopause*, 18, 825-829.
- 5 Cancelo Hidalgo MJ and Castelo Branco C, 2011. Optimizing soy isoflavones effect in postmenopausal women: the impact of timing on climacteric symptoms. *Gynecological Endocrinology*, 27, 696-700.
- 6 Carmignani LO, Pedro AO, Costa-Paiva LH, Pinto-Neto AM, 2010. The effect of dietary soy supplementation compared to estrogen and placebo on menopausal symptoms: a randomized controlled trial. *Maturitas*, 67, 262-269.

- 7 Chedraui P, San Miguel G, Schwager G, 2011. The effect of soy-derived isoflavones over hot flushes, menopausal symptoms and mood in climacteric women with increased body mass index. *Gynecological Endocrinology*, 27, 307-313.
- 8 D'Anna R, Cannata ML, Marini H, Atteritano M, Cancellieri F, Corrado F, Triolo O, Rizzo P, Russo S, Gaudio A, Frisina N, Bitto A, Polito F, Minutoli L, Altavilla D, Adamo EB, Squadrato F, 2009. Effects of the phytoestrogen genistein on hot flushes, endometrium, and vaginal epithelium in postmenopausal women: a 2-year randomized, double-blind, placebo-controlled study. *Menopause*, 16, 301-306.
- 9 Evans M, Elliott JG, Sharma P, Berman R, Guthrie N, 2011. The effect of synthetic genistein on menopause symptom management in healthy postmenopausal women: a multi-center, randomized, placebo-controlled study. *Maturitas*, 68, 189-196.
- 10 Ferrari A, 2009. Soy extract phytoestrogens with high dose of isoflavones for menopausal symptoms. *Journal of Obstetrics and Gynaecology Research*, 35, 1083-1090.
- 11 Hachul H, Brandao LC, D'Almeida V, Bittencourt LR, Baracat EC, Tufik S, 2011. Isoflavones decrease insomnia in postmenopause. *Menopause*, 18, 178-184.
- 12 Kurzer MS, 2008. Soy consumption for reduction of menopausal symptoms. *Inflammopharmacology*, 16, 227-229.
- 13 Kurzer MS, Taku K, Messina M, Kronenberg F, Melby MK, 2009. Soy isoflavones reduce postmenopausal hot flush frequency and severity: results of a systematic review and meta-analysis of randomized controlled trials. *Symposium on Evaluating the Efficacy and Safety of Isoflavones for Postmenopausal Women*, 13-14 May 2009, Milano, Italy.
- 14 Lethaby AE, Marjoribanks J, Kronenberg F, Roberts H, Eden J, Brown J, 2007. Phytoestrogens for vasomotor menopausal symptoms. *Cochrane Database of Systematic Reviews*, CD001395.
- 15 Levis S, Strickman-Stein N, Ganjei-Azar P, Xu P, Doerge DR, Krischer J, 2011. Soy isoflavones in the prevention of menopausal bone loss and menopausal symptoms: a randomized, double-blind trial. *Archives of Internal Medicine*, 171, 1363-1369.
- 16 Lopes de Sousa R, Gouveia Filizola R, de Fátima Formiga Melo Diniz M, Soares Sousa ES, Ribeiro de Moraes JL, 2006. Ensaio clínico placebo-controlado com isoflavonas da soja para sintomas depressivos em mulheres no climatério. *Revista Brasileira de Ginecologia e Obstetrícia*, 28, 91-100.
- 17 Messina M and Hughes C, 2003. Efficacy of soyfoods and soybean isoflavone supplements for alleviating menopausal symptoms is positively related to initial hot flush frequency. *Journal of Medicinal Food*, 6, 1-11.
- 18 Pop EA, Fischer LM, Coan AD, Gitzinger M, Nakamura J, Zeisel SH, 2008. Effects of a high daily dose of soy isoflavones on DNA damage, apoptosis, and estrogenic outcomes in healthy postmenopausal women: a phase I clinical trial. *Menopause*, 15, 684-692.
- 19 Taku K, K MM, Messina M, Kronenberg F, Kurzer MS, 2010. Soy isoflavones reduce postmenopausal hot flush frequency and severity: results of a systematic review and meta-analysis of randomized controlled trials. *9th International Symposium on the Role of Soy in Health Promotion and Chronic Disease Prevention and Treatment*, Washington DC, USA, 16-19 October 2010.
- 20 The North American Menopause Society, 2011. The role of soy isoflavones in menopausal health: report of The North American Menopause Society/Wulf H. Utian Translational Science Symposium in Chicago, IL (October 2010). *Menopause*, 18, 732-753.

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

- 1 Beulens JW, Bots ML, Atsma F, Bartelink ML, Prokop M, Geleijnse JM, Witteman JC, Grobbee DE, van der Schouw YT, 2009. High dietary menaquinone intake is associated with reduced coronary calcification. *Atherosclerosis*, 203, 489-493.
- 2 Braam L and Vermeer C, 2011, unpublished. The effects of a Vitamin K-enriched dairy product on vascular health.
- 3 Gast GC, de Roos NM, Sluijs I, Bots ML, Beulens JW, Geleijnse JM, Witteman JC, Grobbee DE, Peeters PH, van der Schouw YT, 2009. A high menaquinone intake reduces the incidence of coronary heart disease. *Nutrition, Metabolism and Cardiovascular Diseases*, 19, 504-510.
- 4 Geleijnse JM, Vermeer C, Grobbee DE, Schurgers LJ, Knapen MH, van der Meer IM, Hofman A, Witteman JC, 2004. Dietary intake of menaquinone is associated with a reduced risk of coronary heart disease: the Rotterdam Study. *Journal of Nutrition*, 134, 3100-3105.
- 5 Maas AH, van der Schouw YT, Beijerinck D, Deurenberg JJ, Mali WP, Grobbee DE, van der Graaf Y, 2007. Vitamin K intake and calcifications in breast arteries. *Maturitas*, 56, 273-279.
- 6 Moschonis G, Kanellakis S, Papaioannou N, Schaafsma A, Manios Y, 2011. Possible site-specific effect of an intervention combining nutrition and lifestyle counselling with consumption of fortified dairy products on bone mass: the Postmenopausal Health Study II. *Journal of Bone and Mineral Metabolism*, 29, 501-506.
- 7 Vermeer C, 2008, unpublished. Long term administration of Menaquinone-7 (MK-7 as MenaQ7TM) in children.

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.
- 2 Adam J, Barret C, Barret-Bellet A, Benedetti E, Calendini Aea, 1977. Controlled double-blind clinical trials of Ultra-Levure: multi centre study by 25 physicians in 388 cases. *Gazette Medicale de France*, 84, 2072-2078.
- 3 Buts JP, De Keyser N, De Raedemaeker L, 1994. *Saccharomyces boulardii* enhances rat intestinal enzyme expression by endoluminal release of polyamines. *Pediatric Research*, 36, 522-527.
- 4 Can M, Besirbellioglu BA, Avci IY, Beker CM, Pahsa A, 2006. Prophylactic *Saccharomyces boulardii* in the prevention of antibiotic-associated diarrhea: a prospective study. *Medical Science Monitor*, 12, PI19-22.
- 5 Castagliuolo I, LaMont JT, Nikulasson ST, Pothoulakis C, 1996. *Saccharomyces boulardii* protease inhibits *Clostridium difficile* toxin A effects in the rat ileum. *Infection and Immunity*, 64, 5225-5232.
- 6 Castagliuolo I, Riegler MF, Valenick L, LaMont JT, Pothoulakis C, 1999. *Saccharomyces boulardii* protease inhibits the effects of *Clostridium difficile* toxins A and B in human colonic mucosa. *Infection and Immunity*, 67, 302-307.
- 7 Chen X, Kokkotou EG, Mustafa N, Bhaskar KR, Sougioultsis S, O'Brien M, Pothoulakis C, Kelly CP, 2006. *Saccharomyces boulardii* inhibits ERK1/2 mitogen-activated protein kinase activation both in vitro and in vivo and protects against *Clostridium difficile* toxin A-induced enteritis. *Journal of Biological Chemistry*, 281, 24449-24454.

- 8 Cindoruk M, Erkan G, Karakan T, Dursun A, Unal S, 2007. Efficacy and safety of *Saccharomyces boulardii* in the 14-day triple anti-*Helicobacter pylori* therapy: a prospective randomized placebo-controlled double-blind study. *Helicobacter*, 12, 309-316.
- 9 Cremonini F, Di Caro S, Covino M, Armuzzi A, Gabrielli M, Santarelli L, Nista EC, Cammarota G, Gasbarrini G, Gasbarrini A, 2002. Effect of different probiotic preparations on anti-*helicobacter pylori* therapy-related side effects: a parallel group, triple blind, placebo-controlled study. *American Journal of Gastroenterology*, 97, 2744-2749.
- 10 Czerucka D and Rampal P, 1999. Effect of *Saccharomyces boulardii* on cAMP- and Ca²⁺-dependent Cl⁻ secretion in T84 cells. *Digestive Diseases and Sciences*, 44, 2359-2368.
- 11 Czerucka D, Dahan S, Mograbi B, Rossi B, Rampal P, 2000. *Saccharomyces boulardii* preserves the barrier function and modulates the signal transduction pathway induced in enteropathogenic *Escherichia coli*-infected T84 cells. *Infection and Immunity*, 68, 5998-6004.
- 12 Dahan S, Dalmasso G, Imbert V, Peyron JF, Rampal P, Czerucka D, 2003. *Saccharomyces boulardii* Interferes with Enterohemorrhagic *Escherichia coli*-Induced Signaling Pathways in T84 Cells Editor: SHE Kaufmann. *Infection and Immunity*, 71, 766-773.
- 13 D'Souza AL, Rajkumar C, Cooke J, Bulpitt CJ, 2002. Probiotics in prevention of antibiotic associated diarrhoea: meta-analysis. *British Medical Journal*, 324, 1361.
- 14 Duman DG, Bor S, Ozutemiz O, Sahin T, Oguz D, Istan F, Vural T, Sandkci M, Isksal F, Simsek I, Soyturk M, Arslan S, Sivri B, Soykan I, Temizkan A, Bessk F, Kaymakoglu S, Kalayc C, 2005. Efficacy and safety of *Saccharomyces boulardii* in prevention of antibiotic-associated diarrhoea due to *Helicobacter pylori* eradication. *European Journal of Gastroenterology and Hepatology*, 17, 1357-1361.
- 15 Gedek BR, 1999. Adherence of *Escherichia coli* serogroup O 157 and the *Salmonella* Typhimurium mutant DT 104 to the surface of *Saccharomyces boulardii*. *Mycoses*, 42, 261-264.
- 16 Girard P, Pansart Y, Lorette I, Gillardin JM, 2003. Dose-response relationship and mechanism of action of *Saccharomyces boulardii* in castor oil-induced diarrhea in rats. *Digestive Diseases and Sciences*, 48, 770-774.
- 17 Hennequin C, Thierry A, Richard GF, Lecointre G, Nguyen HV, Gaillardin C, Dujon B, 2001. Microsatellite typing as a new tool for identification of *Saccharomyces cerevisiae* strains. *Journal of Clinical Microbiology*, 39, 551-559.
- 18 Hochter W, Chase D, Hagenhoff G, 1990. *Saccharomyces boulardii* in acute adult diarrhea: efficacy and tolerability of treatment. *Munchener Medizinische Wochenschrift*, 132, 188-192.
- 19 Kirchhelle A, Fruhwein N, Toburen D, 1996. [Treatment of persistent diarrhea with *S. boulardii* in returning travelers. Results of a prospective study]. *Fortschritte der Medizin*, 114, 136-140.
- 20 Kollaritsch H, Kremsner P, Wiedermann G, Scheiner O, 1989. Prevention of traveller's diarrhea: Comparison of different nonantibiotic preparations. *Travel Medicine International*, 7, 9-18.
- 21 Kollaritsch H, Holst H, Grobara P, Wiedermann G, 1993. [Prevention of traveler's diarrhea with *Saccharomyces boulardii*. Results of a placebo controlled double-blind study]. *Fortschritte der Medizin*, 111, 152-156.
- 22 Lewis SJ, Potts LF, Barry RE, 1998. The lack of therapeutic effect of *Saccharomyces boulardii* in the prevention of antibiotic-related diarrhoea in elderly patients. *Journal of Infection*, 36, 171-174.
- 23 Mallié M, Nguyen VP, Bertout S, Vaillant C, Bastide J, 2001. Genotypic study of *Saccharomyces boulardii* compared to *Saccharomyces cerevisiae* sensu stricto complex species. *Journal de Mycologie Médicale*, 11, 19-25.
- 24 Mansour-Ghanaei F, Dehbashi N, Yazdanparast K, Shafaghi A, 2003. Efficacy of *saccharomyces boulardii* with antibiotics in acute amoebiasis. *World Journal of Gastroenterology*, 9, 1832-1833.

- 25 McFarland LV, Surawicz CM, Greenberg RN, Elmer GW, Moyer KA, Melcher SA, Bowen KE, Cox JL, 1995. Prevention of beta-lactam-associated diarrhea by *Saccharomyces boulardii* compared with placebo. *American Journal of Gastroenterology*, 90, 439-448.
- 26 McFarland LV, 2006. Meta-analysis of probiotics for the prevention of antibiotic associated diarrhea and the treatment of *Clostridium difficile* disease. *American Journal of Gastroenterology*, 101, 812-822.
- 27 McFarland LV, 2010. Systematic review and meta-analysis of *Saccharomyces boulardii* in adult patients. *World Journal of Gastroenterology*, 16, 2202-2222.
- 28 Qamar A, Aboudola S, Warny M, Michetti P, Pothoulakis C, LaMont JT, Kelly CP, 2001. *Saccharomyces boulardii* stimulates intestinal immunoglobulin A immune response to *Clostridium difficile* toxin A in mice. *Infection and Immunity*, 69, 2762-2765.
- 29 Sezer A, Usta U, Cicin I, 2009. The effect of *Saccharomyces boulardii* on reducing irinotecan-induced intestinal mucositis and diarrhea. *Medical Oncology*, 26, 350-357.
- 30 Sougioultzis S, Simeonidis S, Bhaskar KR, Chen X, Anton PM, Keates S, Pothoulakis C, Kelly CP, 2006. *Saccharomyces boulardii* produces a soluble anti-inflammatory factor that inhibits NF-kappaB-mediated IL-8 gene expression. *Biochemical and Biophysical Research Communications*, 343, 69-76.
- 31 Surawicz CM, Elmer GW, Speelman P, McFarland LV, Chinn J, van Belle G, 1989. Prevention of antibiotic-associated diarrhea by *Saccharomyces boulardii*: a prospective study. *Gastroenterology*, 96, 981-988.
- 32 Surawicz CM, McFarland LV, Greenberg RN, Rubin M, Fekety R, Mulligan ME, Garcia RJ, Brandmarker S, Bowen K, Borjal D, Elmer GW, 2000. The search for a better treatment for recurrent *Clostridium difficile* disease: use of high-dose vancomycin combined with *Saccharomyces boulardii*. *Clinical Infectious Diseases*, 31, 1012-1017.
- 33 Szajewska H and Mrukowicz J, 2005. Meta-analysis: non-pathogenic yeast *Saccharomyces boulardii* in the prevention of antibiotic-associated diarrhoea. *Alimentary Pharmacology and Therapeutics*, 22, 365-372.
- 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.
- 35 Zanello G, Meurens F, Berri M, Salmon H, 2009. *Saccharomyces boulardii* effects on gastrointestinal diseases. *Current Issues in Molecular Biology*, 11, 47-58.

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.
- 2 BCCM/LMG, 2001. AFLP DNA fingerprinting of *Bifidobacterium longum*.
- 3 BCCM/LMG, 2001. SDS-PAGE identification analysis of *Bifidobacterium bifidum* G9-1, *Bifidobacterium longum* MM-2.
- 4 Beutler B, 2003. Science review: key inflammatory and stress pathways in critical illness - the central role of the Toll-like receptors. *Critical Care*, 7, 39-46.
- 5 Bohle B, Jahn-Schmid B, Maurer D, Kraft D, Ebner C, 1999. Oligodeoxynucleotides containing CpG motifs induce IL-12, IL-18 and IFN-gamma production in cells from allergic individuals and inhibit IgE synthesis in vitro. *European Journal of Immunology*, 29, 2344-2353.

- 6 Borruel N, Casellas F, Antolin M, Llopis M, Carol M, Espiin E, Naval J, Guarner F, Malagelada JR, 2003. Effects of nonpathogenic bacteria on cytokine secretion by human intestinal mucosa. *American Journal of Gastroenterology*, 98, 865-870.
- 7 Calder PC, 2007. Immunological parameters: what do they mean? *Journal of Nutrition*, 137, 773S-780S.
- 8 Cario E and Podolsky DK, 2000. Differential alteration in intestinal epithelial cell expression of toll-like receptor 3 (TLR3) and TLR4 in inflammatory bowel disease. *Infection and Immunity*, 68, 7010-7017.
- 9 Christensen HR, Frokiaer H, Pestka JJ, 2002. Lactobacilli differentially modulate expression of cytokines and maturation surface markers in murine dendritic cells. *Journal of Immunology*, 168, 171-178.
- 10 Conti B, Tabarean I, Andrei C, Bartfai T, 2004. Cytokines and fever. *Frontiers in Bioscience*, 9, 1433-1449.
- 11 de Vrese M, Winkler P, Rautenberg P, Harder T, Noah C, Laue C, Ott S, Hampe J, Schreiber S, Heller K, Schrezenmeir J, 2005. Effect of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium longum* SP 07/3, *B. bifidum* MF 20/5 on common cold episodes: a double blind, randomized, controlled trial. *Clinical Nutrition*, 24, 481-491.
- 12 Eccles R, 2000. Pathophysiology of nasal symptoms. *American Journal of Rhinology*, 14, 335-338.
- 13 Eccles R, 2005. Understanding the symptoms of the common cold and influenza. *Lancet Infectious Diseases*, 5, 718-725.
- 14 Exton MS, 1997. Infection-induced anorexia: active host defence strategy. *Appetite*, 29, 369-383.
- 15 Gevers D, Huys G, Swings J, 2001. Applicability of rep-PCR fingerprinting for identification of *Lactobacillus* species. *FEMS Microbiology Letters*, 205, 31-36.
- 16 Ghadimi D, Folster-Holst R, de Vrese M, Winkler P, Heller KJ, Schrezenmeir J, 2008. Effects of probiotic bacteria and their genomic DNA on TH1/TH2-cytokine production by peripheral blood mononuclear cells (PBMCs) of healthy and allergic subjects. *Immunobiology*, 213, 677-692.
- 17 Ghadimi D, de Vrese M, Heller 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.
- 18 Ghadimi D, Vrese M, Heller KJ, Schrezenmeir J, 2010b. Effect of natural commensal-origin DNA on toll-like receptor 9 (TLR9) signaling cascade, chemokine IL-8 expression, and barrier integrity of polarized intestinal epithelial cells. *Inflammatory Bowel Diseases*, 16, 410-427.
- 19 Gill H and Prasad J, 2008. Probiotics, immunomodulation, and health benefits. *Advances in Experimental Medicine and Biology*, 606, 423-454.
- 20 Gleeson M, Bishop NC, Oliveira M, Tauler P, 2011. Daily probiotic's (*Lactobacillus casei* Shirota) reduction of infection incidence in athletes. *International Journal of Sport Nutrition and Exercise Metabolism*, 21, 55-64.
- 21 Guillemard E, Tondu F, Lacoin F, Schrezenmeir J, 2010. Consumption of a fermented dairy product containing the probiotic *Lactobacillus casei* DN-114001 reduces the duration of respiratory infections in the elderly in a randomised controlled trial. *British Journal of Nutrition*, 103, 58-68.
- 22 Hatakka K, Savilahti E, Ponka A, Meurman JH, Poussa T, Nase L, Saxelin M, Korpela R, 2001. Effect of long term consumption of probiotic milk on infections in children attending day care centres: double blind, randomised trial. *BMJ (Clinical Research Ed.)*, 322, 1327.

- 23 Heikkinen T and Jarvinen A, 2003. The common cold. *Lancet*, 361, 51-59.
- 24 Helwig U, Lammers KM, Rizzello F, Brigidi P, Rohleder V, Caramelli E, Gionchetti P, Schrezenmeir J, Foelsch UR, Schreiber S, Campieri M, 2006. Lactobacilli, bifidobacteria and *E. coli* nissle induce pro- and anti-inflammatory cytokines in peripheral blood mononuclear cells. *World Journal of Gastroenterology*, 12, 5978-5986.
- 25 Hessel EM, Chu M, Lizcano JO, Chang B, Herman N, Kell SA, Wills-Karp M, Coffman RL, 2005. Immunostimulatory oligonucleotides block allergic airway inflammation by inhibiting Th2 cell activation and IgE-mediated cytokine induction. *Journal of Experimental Medicine*, 202, 1563-1573.
- 26 Hessle C, Hanson LA, Wold AE, 1999. Lactobacilli from human gastrointestinal mucosa are strong stimulators of IL-12 production. *Clinical and Experimental Immunology*, 116, 276-282.
- 27 Iliev ID, Kitazawa H, Shimosato T, Katoh S, Morita H, He F, Hosoda M, Saito T, 2005. Strong immunostimulation in murine immune cells by *Lactobacillus rhamnosus* GG DNA containing novel oligodeoxynucleotide pattern. *Cellular Microbiology*, 7, 403-414.
- 28 Jackson GG, Dowling HF, Spiesman IG, Board AV, 1958. Transmission of the common cold to volunteers under controlled conditions. I. The common cold as a clinical entity. *AMA Archives of Internal Medicine*, 101, 267-278.
- 29 Johnston S and Holgate S, 1996. Epidemiology of viral respiratory tract infections. In: *Viral and other infections of the human respiratory tract*. Myint S and Taylor-Robinson D (eds.). Chapman & Hall, London.
- 30 Klein G, Pack A, Bonaparte C, Reuter G, 1998. Taxonomy and physiology of probiotic lactic acid bacteria. *International Journal of Food Microbiology*, 41, 103-125.
- 31 Kline JN, Waldschmidt TJ, Businga TR, Lemish JE, Weinstock JV, Thorne PS, Krieg AM, 1998. Modulation of airway inflammation by CpG oligodeoxynucleotides in a murine model of asthma. *Journal of Immunology*, 160, 2555-2559.
- 32 Klinman DM, Yi AK, Beaucage SL, Conover J, Krieg AM, 1996. CpG motifs present in bacteria DNA rapidly induce lymphocytes to secrete interleukin 6, interleukin 12, and interferon gamma. *Proceedings of the National Academy of Sciences of the United States of America*, 93, 2879-2883.
- 33 Kopp MV, Härtel C, Ankermann T, 2011. Clinical potential for the use of probiotics in the management of respiratory conditions and cold- and influenza-like symptoms. *Nutrition and Dietary Supplements*, 3.
- 34 Labor L+S AG, 2010. Statement API Test - *Lactobacillus gasseri* NITE BP-819.
- 35 Labor L+S AG, 2010. Statement API Test - *Bifidobacterium bifidum* NITE BP-817.
- 36 Labor L+S AG, 2010. Statement API Test - *Bifidobacterium longum* NITE BP-818.
- 37 Lammers KM, Brigidi P, Vitali B, Gionchetti P, Rizzello F, Caramelli E, Matteuzzi D, Campieri M, 2003. Immunomodulatory effects of probiotic bacteria DNA: IL-1 and IL-10 response in human peripheral blood mononuclear cells. *FEMS Immunology and Medical Microbiology*, 38, 165-172.
- 38 Mack DR, Ahrne S, Hyde L, Wei S, Hollingsworth MA, 2003. Extracellular MUC3 mucin secretion follows adherence of *Lactobacillus* strains to intestinal epithelial cells in vitro. *Gut*, 52, 827-833.
- 39 Matsuguchi T, Takagi A, Matsuzaki T, Nagaoka M, Ishikawa K, Yokokura T, Yoshikai Y, 2003. Lipoteichoic acids from *Lactobacillus* strains elicit strong tumor necrosis factor alpha-inducing activities in macrophages through Toll-like receptor 2. *Clinical and Diagnostic Laboratory Immunology*, 10, 259-266.

- 40 Mattarelli P, Bonaparte C, Pot B, Biavati B, 2008. Proposal to reclassify the three biotypes of Bifidobacterium longum as three subspecies: Bifidobacterium longum subsp. longum subsp. nov., Bifidobacterium longum subsp. infantis comb. nov. and Bifidobacterium longum subsp. suis comb. nov. International Journal of Systematic and Evolutionary Microbiology, 58, 767-772.
- 41 Meier R and Steuerwald M, 2005. Place of probiotics. Current Opinion in Critical Care, 11, 318-325.
- 42 Merck, 2010. 16S rRNA Sequence analysis - Lactobacillus gasseri NITE BP-819
- 43 Merck, 2010. 16S rRNA Sequence analysis - Bifidobacterium longum NITE BP-818.
- 44 Merck, 2010. 16S rRNA Sequence analysis - Bifidobacterium bifidum NITE BP-817.
- 45 Minocha A, 2009. Probiotics for preventive health. Nutrition in Clinical Practice, 24, 227-241.
- 46 Monto AS, 2002. Epidemiology of viral respiratory infections. American Journal of Medicine, 112 Suppl 6A, 4S-12S.
- 47 Mossad SB, Macknin ML, Medendorp SV, Mason P, 1996. Zinc gluconate lozenges for treating the common cold. A randomized, double-blind, placebo-controlled study. Annals of Internal Medicine, 125, 81-88.
- 48 Muzio M, Bosisio D, Polentarutti N, D'Amico G, Stoppacciaro A, Mancinelli R, van't Veer C, Penton-Rol G, Ruco LP, Allavena P, Mantovani A, 2000. Differential expression and regulation of toll-like receptors (TLR) in human leukocytes: selective expression of TLR3 in dendritic cells. Journal of Immunology, 164, 5998-6004.
- 49 NPMRD, 2009. Certificate of International Culture Collection - Bifidobacterium longum NITE BP-818.
- 50 NPMRD, 2009. Certificate of International Culture Collection - Bifidobacterium bifidum NITE BP-817.
- 51 NPMRD, 2009. Certificate of International Culture Collection - Lactobacillus gasseri NITE BP-819.
- 52 Ohno H, Tsunemine S, Isa Y, Shimakawa M, Yamamura H, 2005. Oral administration of Bifidobacterium bifidum G9-1 suppresses total and antigen specific immunoglobulin E production in mice. Biological and Pharmaceutical Bulletin, 28, 1462-1466.
- 53 Pena JA and Versalovic J, 2003. Lactobacillus rhamnosus GG decreases TNF-alpha production in lipopolysaccharide-activated murine macrophages by a contact-independent mechanism. Cellular Microbiology, 5, 277-285.
- 54 Perdigon G, Medina M, Vintini E, Valdez JC, 2000. Intestinal pathway of internalisation of lactic acid bacteria and gut mucosal immunostimulation. International Journal of Immunopathology and Pharmacology, 13, 141-150.
- 55 Pregliasco F, Anselmi G, Fonte L, Giussani F, Schieppati S, Soletti L, 2008. A new chance of preventing winter diseases by the administration of synbiotic formulations. Journal of Clinical Gastroenterology, 42 Suppl 3 Pt 2, S224-233.
- 56 Proud D, Reynolds CJ, Lacapra S, Kagey-Sobotka A, Lichtenstein LM, Naclerio RM, 1988. Nasal provocation with bradykinin induces symptoms of rhinitis and a sore throat. American Review of Respiratory Disease, 137, 613-616.
- 57 Rosenfeldt V, Benfeldt E, Valerius NH, Paerregaard A, Michaelsen KF, 2004. Effect of probiotics on gastrointestinal symptoms and small intestinal permeability in children with atopic dermatitis. Journal of Pediatrics, 145, 612-616.
- 58 Shibayama Y, Skoner D, Suehiro S, Konishi JE, Fireman P, Kaplan AP, 1996. Bradykinin levels during experimental nasal infection with rhinovirus and attenuated influenza virus. Immunopharmacology, 33, 311-313.

- 59 Stansfield SK, Pierre-Louis M, Lerebours G, Augustin A, 1993. Vitamin A supplementation and increased prevalence of childhood diarrhoea and acute respiratory infections. Lancet, 342, 578-582.
- 60 Stoutenbeek CP, van Saene HK, Miranda DR, Zandstra DF, 1984. The effect of selective decontamination of the digestive tract on colonisation and infection rate in multiple trauma patients. Intensive Care Medicine, 10, 185-192.
- 61 Treanor JJ, Hayden FG, Vrooman PS, Barbarash R, Bettis R, Riff D, Singh S, Kinnersley N, Ward P, Mills RG, 2000. Efficacy and safety of the oral neuraminidase inhibitor oseltamivir in treating acute influenza: a randomized controlled trial. US Oral Neuraminidase Study Group. JAMA, 283, 1016-1024.
- 62 Tyrrell DA, Cohen S, Schlarb JE, 1993. Signs and symptoms in common colds. Epidemiology and Infection, 111, 143-156.
- 63 Vouloumanou EK, Makris GC, Karageorgopoulos DE, Falagas ME, 2009. Probiotics for the prevention of respiratory tract infections: a systematic review. International Journal of Antimicrobial Agents, 34, 197 e191-110.
- 64 Walker WA, 2008. Mechanisms of action of probiotics. Clinical Infectious Diseases, 46 Suppl 2, S87-91; discussion S144-151.
- 65 Winkler P, de Vrese M, Laue C, Schrezenmeir J, 2005. Effect of a dietary supplement containing probiotic bacteria plus vitamins and minerals on common cold infections and cellular immune parameters. International Journal of Clinical Pharmacology and Therapeutics, 43, 318-326.
- 66 Winkler P, Ghadimi D, Schrezenmeir J, Kraehenbuhl JP, 2007. Molecular and cellular basis of microflora-host interactions. Journal of Nutrition, 137, 756S-772S.
- 67 Zambon MC, Stockton JD, Clewley JP, Fleming DM, 2001. Contribution of influenza and respiratory syncytial virus to community cases of influenza-like illness: an observational study. Lancet, 358, 1410-1416.

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.
- 2 Aslim B and Kilic E, 2006. Some probiotic properties of vaginal lactobacilli isolated from healthy women. Japanese Journal of Infectious Diseases, 59, 249-253.
- 3 Basta A and Kolawa W, 1998. Mechanisms Controlling Vaginal Biocenosis and Clinical Aspects of Vaginal Biocenosis Disorders. Mikrobiologia Medycyna, 4, 3-7.
- 4 Biochemistry and Biophysics Institute, Sequential data of Lactobacillus bacteria marked as 57A, 57B, 57C. Appendix 1 to Heczko, P.B., 2004.
- 5 Boskey ER, Telsch KM, Whaley KJ, Moench TR, Cone RA, 1999. Acid production by vaginal flora in vitro is consistent with the rate and extent of vaginal acidification. Infection and Immunity, 67, 5170-5175.
- 6 Bręborowicz GH, 2005. Obstetrics and gynecology. Wydawnictwo Lekarskie PZWL.
- 7 Caillouette JC, Sharp CFJ, Zimmerman GJ, Roy S, 1997. Vaginal pH as a marker for bacterial pathogens and menopausal status. American Journal of Obstetrics and Gynecology, 176, 1270-1277.
- 8 Donders GG, 2007. Definition and classification of abnormal vaginal flora. Best Practice & Research Clinical Obstetrics & Gynaecology, 21, 355-373.

- 9 Genomed Co. Ltd., 2010, unpublished. Identification method of the 57B *Lactobacillus plantarum* strain with the use of allelic typing (multilocus sequence typing, MLST) of genes amplified from bacterial lyophilizate.
- 10 Genomed Co. Ltd., 2010, unpublished. Comparison of results of identification of *Lactobacillus* and *Bifidobacterium* geni bacteria using the method of sequencing of the 16S rRNA coding gene.
- 11 Heczko PB, 2004, unpublished. Laboratory test report on probiotic properties of *Lactobacillus* strains.
- 12 Heczko PB, 2005. Identification of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C bacterial strains using pulsed-field gel electrophoresis. Appendix 2 to Heczko, P.B., 2004.
- 13 Heczko PB, 2005. Erratum to Identification of *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C bacterial strains using pulsed-field gel electrophoresis. Appendix 3 to Heczko, P.B., 2004.
- 14 Heczko PB, 2006, unpublished. Report on the laboratory research on the probiotic properties of the strains of the bacteria from the *Lactobacillus* genus in the prOVag preparation of the IBSS BIOMED S.A. company in Cracow.
- 15 Heczko PB, 2008, unpublished. Report on research on development of molecular methods for identification of *Lactobacillus* strains of vaginal origin.
- 16 IBSS BIOMED S.A., 2005, unpublished. Report of toxicological assessment.
- 17 IBSS BIOMED S.A., 2008. Protocols of stability data for active substance and finished product.
- 18 Main Pharmaceutical Inspectorate, 2009. Certificate of GMP compliance of a manufacturer.
- 19 Motyl I, 2010. Study on L(+) and D(-) lactic acid production by *Lactobacillus* probiotic bacteria in the presence of: glucose, lactose, maltodextrin as the only source of carbon.
- 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.
- 21 Ocaña VS, de Ruiz Holgado AA, Nader-Macias ME, 1999. Growth inhibition of *Staphylococcus aureus* by H₂O₂-producing *Lactobacillus paracasei* subsp. *paracasei* isolated from the human vagina. FEMS Immunology and Medical Microbiology, 23, 87-92.
- 22 Osset J, Bartolome RM, Garcia E, Andreu A, 2001. Assessment of the capacity of *Lactobacillus* to inhibit the growth of uropathogens and block their adhesion to vaginal epithelial cells. Journal of Infectious Diseases, 183, 485-491.
- 23 Priestley CJ, Jones BM, Dhar J, Goodwin L, 1997. What is normal vaginal flora? Genitourinary Medicine, 73, 23-28.
- 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.
- 26 PROLAB, 2010, unpublished. Study report on antimicrobial resistance of probiotic bacteria.
- 27 PROLAB, 2010, unpublished. Report on studies on ability of probiotic strains *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B, *Lactobacillus gasseri* 57C, and their mixture to inhibit adhesion of pathogens to surface of vaginal epithelium.
- 28 Reid G, 2001. Probiotic agents to protect the urogenital tract against infection. American Journal of Clinical Nutrition, 73, 437S-443S.

- 29 Saarela M, Mogensen G, Fonden R, Matto J, Mattila-Sandholm T, 2000. Probiotic bacteria: safety, functional and technological properties. *Journal of Biotechnology*, 84, 197-215.
- 30 Samet A, Artukowicz E, Nowicki R, Baranska-Rybak W, Emerich J, 2003. Influence of antibiotics prescribed in respiratory tract infections on bacterial and fungal flora of genital tract. *Zakazenia*, 4, 52-55.
- 31 Strus M, Brzychczy-Wtoch M, Kohan P, Heczko PB, 2004. [Hydrogen peroxide produced by Lactobacillus species as a regulatory molecule for vaginal microflora]. *Medycyna Doswiadcza i Mikrobiologia*, 56, 67-77.
- 32 Strus M, 2005. [Scientific background for usage of vaginal probiotics in urogenital infections]. *Probiotyki zakazenia*, 4, 40-43.
- 33 Strus M, Kochan P, Chełmicki Z, Chełmicki A, Stefanski G, Dechnik K, Jabłonska E, Heczko PB, 2008. The influence of oral administration of three probiotic Lactobacillus strains on the enhancement of the pH and composition of the vaginal microflora in women of reproductive age [Translated from Polish]. *Ginekologia po dyplomie*, 53-59.
- 34 Strus M, Chmielarczyk A, Kochan P, Adamski P, Chełmicki Z, Chełmicki A, Heczko P, 2011, unpublished. Studies on the effect of probiotic Lactobacillus mixture given orally on vaginal and rectal colonization and on parameters of vaginal health in women with intermediate vaginal flora. *BMC Infectious Diseases*.
- 35 TÜV Rheinland Cert GMBH, 2007. HACCP Certificate-IBSS biomed S.A.
- 36 Vasquez A, Jakobsson T, Ahrne S, Forsum U, Molin G, 2002. Vaginal lactobacillus flora of healthy Swedish women. *Journal of Clinical Microbiology*, 40, 2746-2749.
- 37 WHO/FAO (World Health Organization and Food and Agriculture Organization), 2001. Health and nutritional properties of probiotics in food including powder milk with live lactic acid bacteria. Report of a joint FAO/WHO expert consultation on evaluation of health and nutritional properties of probiotics in food including powder milk with live lactic acid bacteria.

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.
- 2 Arseneault-Breard J, Rondeau I, Gilbert K, Girard SA, Tompkins TA, Godbout R, Rousseau G, 2011. Combination of *Lactobacillus helveticus* R0052 and *Bifidobacterium longum* R0175 reduces post-myocardial infarction depression symptoms and restores intestinal permeability in a rat model. *British Journal of Nutrition*, 1-7.
- 3 Diop L, Guillou S, Durand H, 2008. Probiotic food supplement reduces stress-induced gastrointestinal symptoms in volunteers: a double-blind, placebo-controlled, randomized trial. *Nutrition Research*, 28, 1-5.
- 4 Easo JG, Measham JD, Munroe J, Green-Johnson JM, 2002. Immunostimulatory Actions of Lactobacilli: Mitogenic Induction of Antibody Production and Spleen Cell Proliferation by *Lactobacillus delbrueckii* subsp. *bulgaricus* and *Lactobacillus acidophilus*. *Food and Agricultural Immunology*, 14, 73-83.
- 5 Estrada A, Drew MD, Van Kessel A, 2001. Effect of the dietary supplementation of fructooligosaccharides and *Bifidobacterium longum* to early-weaned pigs on Performance and fecal bacterial populations. *Canadian Journal of Animal Science*, 81, 141-148.
- 6 Firmesse O, Mogenet A, Bresson JL, Corthier G, Furet JP, 2008. *Lactobacillus rhamnosus* R11 consumed in a food supplement survived human digestive transit without modifying microbiota

- equilibrium as assessed by real-time polymerase chain reaction. *Journal of Molecular Microbiology and Biotechnology*, 14, 90-99.
- 7 Girard SA, Bah TM, Kaloustian S, Lada-Moldovan L, Rondeau I, Tompkins TA, Godbout R, Rousseau G, 2009. *Lactobacillus helveticus* and *Bifidobacterium longum* taken in combination reduce the apoptosis propensity in the limbic system after myocardial infarction in a rat model. *British Journal of Nutrition*, 102, 1420-1425.
- 8 Haskey N and Dahl WJ, 2006. Synbiotic therapy: a promising new adjunctive therapy for ulcerative colitis. *Nutrition Reviews*, 64, 132-138.
- 9 Johnson-Henry KC, Hagen KE, Gordonpour M, Tompkins TA, Sherman PM, 2007. Surface-layer protein extracts from *Lactobacillus helveticus* inhibit enterohaemorrhagic *Escherichia coli* O157:H7 adhesion to epithelial cells. *Cellular Microbiology*, 9, 356-367.
- 10 Kheadr E, 2006. Impact of acid and oxgall on antibiotic susceptibility of Probiotic Lactobacilli. *African Journal of Agricultural Research*, 1, 172-181.
- 11 Kheadr E, Dabour N, Le Lay C, Lacroix C, Fliss I, 2007. Antibiotic susceptibility profile of bifidobacteria as affected by oxgall, acid, and hydrogen peroxide stress. *Antimicrobial Agents and Chemotherapy*, 51, 169-174.
- 12 Mattarelli P, Bonaparte C, Pot B, Biavati B, 2008. Proposal to reclassify the three biotypes of *Bifidobacterium longum* as three subspecies: *Bifidobacterium longum* subsp. *longum* subsp. nov., *Bifidobacterium longum* subsp. *infantis* comb. nov. and *Bifidobacterium longum* subsp. *suis* comb. nov. *International Journal of Systematic and Evolutionary Microbiology*, 58, 767-772.
- 13 Messaoudi M, Lalonde R, Violle N, Javelot H, Desor D, Nejdi A, Bisson JF, Rougeot C, Pichelin M, Cazaubiel M, Cazaubiel JM, 2010. Assessment of psychotropic-like properties of a probiotic formulation (*Lactobacillus helveticus* R0052 and *Bifidobacterium longum* R0175) in rats and human subjects. *British Journal of Nutrition*, 105, 755-764.
- 14 Messaoudi M, Violle N, Bisson JF, Desor D, Javelot H, Rougeot C, 2011. Beneficial psychological effects of a probiotic formulation (*Lactobacillus helveticus* R0052 and *Bifidobacterium longum* R0175) in healthy human volunteers. *Gut Microbes*, 2, 256-261.
- 15 Naser SM, Hagen KE, Vancanneyt M, Cleenwerck I, Swings J, Tompkins TA, 2006. *Lactobacillus suntoryeus* Cachat and Priest 2005 is a later synonym of *Lactobacillus helveticus* (Orla-Jensen 1919) Bergey et al. 1925 (Approved Lists 1980). *International Journal of Systematic and Evolutionary Microbiology*, 56, 355-360.
- 16 Possemiers S, Marzorati M, Verstraete W, Van de Wiele T, 2010. Bacteria and chocolate: a successful combination for probiotic delivery. *International Journal of Food Microbiology*, 141, 97-103.
- 17 Wallace TD, Bradley S, Buckley ND, Green-Johnson JM, 2003. Interactions of lactic acid bacteria with human intestinal epithelial cells: effects on cytokine production. *Journal of Food Protection*, 66, 466-472.
- 18 Wine E, Gareau MG, Johnson-Henry K, Sherman PM, 2009. Strain-specific probiotic (*Lactobacillus helveticus*) inhibition of *Campylobacter jejuni* invasion of human intestinal epithelial cells. *FEMS Microbiology Letters*, 300, 146-152.

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.
- 2 Alekna A, Clyne M, Shanahan F, Tompkins T, Corcionevochi N, Bourke B, 2010. Probiotic colonization of the adherent mucus layer of HT29MTXE12 cells attenuates *Campylobacter jejuni* virulence properties. *Infection and Immunity*, 78, 2812-2822.
- 3 Aryayev M and Kononenko N, 2009. [Prevention of antibiotic-associated diarrhoea in patients with Cystic Fibrosis]. *Odessa Medical Journal*, 4, 58-62, (Translation from Ukrainian).
- 4 Brzozowski T, Konturek PC, Mierzwa M, Drozdowicz D, Bielanski W, Kwiecien S, Konturek SJ, Stachura J, Pawlik WW, Hahn EG, 2006. Effect of probiotics and triple eradication therapy on the cyclooxygenase (COX)-2 expression, apoptosis, and functional gastric mucosal impairment in *Helicobacter pylori*-infected Mongolian gerbils. *Helicobacter*, 11, 10-20.
- 5 Dykstra NS, Hyde L, Adawi D, Kulik D, Ahrne S, Molin G, Jeppsson B, Mackenzie A, Mack DR, 2011. Pulse probiotic administration induces repeated small intestinal Muc3 expression in rats. *Pediatric Research*, 69, 206-211.
- 6 Gareau MG, Jury J, MacQueen G, Sherman PM, Perdue MH, 2007. Probiotic treatment of rat pups normalises corticosterone release and ameliorates colonic dysfunction induced by maternal separation. *Gut*, 56, 1522-1528.
- 7 Gareau MG, Wine E, Reardon C, Sherman PM, 2010. Probiotics prevent death caused by *Citrobacter rodentium* infection in neonatal mice. *Journal of Infectious Diseases*, 201, 81-91.
- 8 Gnaytenko O, Lychkovska O, Kulachkovska Y, Semen V, 2009. [Antibiotics-associated diarrhoea as a complication of antihelicobacter therapy in children]. *Practical medicine*, 5, 76-83, (Translation from Ukrainian).
- 9 Jandu N, Zeng ZJ, Johnson-Henry KC, Sherman PM, 2009. Probiotics prevent enterohaemorrhagic *Escherichia coli* O157:H7-mediated inhibition of interferon-gamma-induced tyrosine phosphorylation of STAT-1. *Microbiology*, 155, 531-540.
- 10 Johnson-Henry KC, Mitchell DJ, Avitzur Y, Galindo-Mata E, Jones NL, Sherman PM, 2004. Probiotics reduce bacterial colonization and gastric inflammation in *H. pylori*-infected mice. *Digestive Diseases and Sciences*, 49, 1095-1102.
- 11 Johnson-Henry KC, Nadjafi M, Avitzur Y, Mitchell DJ, Ngan BY, Galindo-Mata E, Jones NL, Sherman PM, 2005. Amelioration of the effects of *Citrobacter rodentium* infection in mice by pretreatment with probiotics. *Journal of Infectious Diseases*, 191, 2106-2117.
- 12 Johnson-Henry KC, Hagen KE, Gordonpour M, Tompkins TA, Sherman PM, 2007. Surface-layer protein extracts from *Lactobacillus helveticus* inhibit enterohaemorrhagic *Escherichia coli* O157:H7 adhesion to epithelial cells. *Cellular Microbiology*, 9, 356-367.
- 13 Marushko Y and Shef G, 2007. [Current status of antibiotics-associated bowel disorders issue in children]. *Perinatology and Pediatrics*, 4, 65-68, (Translation from Ukrainian).
- 14 Maydannik V, Khaytovich N, Boyarskaya O, Gnatyeyko O, et al, 2010. [Efficiency and safety of Lacidofil in children with Antibiotic-Associated Diarrhoea caused by *Clostridium difficile*]. *Pediatrics, Obstetrics and Gynecology* 3, 53-57, (Translation from Ukrainian).
- 15 Naser SM, Hagen KE, Vancanneyt M, Cleenwerck I, Swings J, Tompkins TA, 2006. *Lactobacillus suntoryeius* Cachat and Priest 2005 is a later synonym of *Lactobacillus helveticus* (Orla-Jensen 1919) Bergey et al. 1925 (Approved Lists 1980). *International Journal of Systematic and Evolutionary Microbiology*, 56, 355-360.
- 16 Provencher C, LaPointe G, Sirois S, Van Calsteren MR, Roy D, 2003. Consensus-degenerate hybrid oligonucleotide primers for amplification of priming glycosyltransferase genes of the

- exopolysaccharide locus in strains of the *Lactobacillus casei* group. *Applied and Environmental Microbiology*, 69, 3299-3307.
- 17 Roy D and Ward P, 2004. Comparison of fructose-1,6-bisphosphatase gene (*fbp*) sequences for the identification of *Lactobacillus rhamnosus*. *Current Microbiology*, 49, 313-320.
- 18 Sherman PM, Johnson-Henry KC, Yeung HP, Ngo PS, Goulet J, Tompkins TA, 2005. Probiotics reduce enterohemorrhagic *Escherichia coli* O157:H7- and enteropathogenic *E. coli* O127:H6-induced changes in polarized T84 epithelial cell monolayers by reducing bacterial adhesion and cytoskeletal rearrangements. *Infection and Immunity*, 73, 5183-5188.
- 19 Song HJ, Kim JY, Jung SA, Kim SE, Park HS, Jeong Y, Hong SP, Cheon JH, Kim WH, Kim HJ, Ye BD, Yang SK, Kim SW, Shin SJ, Kim HS, Sung JK, Kim EY, 2010. Effect of probiotic *Lactobacillus* (Lacidofil(R) cap) for the prevention of antibiotic-associated diarrhea: a prospective, randomized, double-blind, multicenter study. *Journal of Korean Medical Science*, 25, 1784-1791.
- 20 Tlaskal P, Michkova E, Klayarova H, Jerabkova L, et al., 1995. [Lactobacillus Acidophilus in the treatment of children with gastrointestinal tract illnesses]. *Cesko-Slovenská Pediatrie*, 51, 615-619, (Translation from Czech).
- 21 Tlaskal P, Schramlova J, Kokesova A, Adamus J, et al., 2005. Probiotics in the treatment of diarrheal disease of viral etiology in children. *NAFAS* 3, 25-28.
- 22 Vdovychenkon V, Demidovn A, Bidyuk O, 2008. [Effectiveness of quadra therapy probiotics in patients with duodenal ulcers]. *Current Gastroenterology*, 5, 90-92, (Translated from Ukrainian).
- 23 Verdu EF, Bercik P, Huang XX, Lu J, Al-Mutawaly N, Sakai H, Tompkins TA, Croitoru K, Tsuchida E, Perdue M, Collins SM, 2008. The role of luminal factors in the recovery of gastric function and behavioral changes after chronic *Helicobacter pylori* infection. *American Journal of Physiology Gastrointestinal and Liver Physiology*, 295, G664-670.
- 24 Wallace TD, Bradley S, Buckley ND, Green-Johnson JM, 2003. Interactions of lactic acid bacteria with human intestinal epithelial cells: effects on cytokine production. *Journal of Food Protection*, 66, 466-472.
- 25 Wine E, Gareau MG, Johnson-Henry K, Sherman PM, 2009. Strain-specific probiotic (*Lactobacillus helveticus*) inhibition of *Campylobacter jejuni* invasion of human intestinal epithelial cells. *FEMS Microbiology Letters*, 300, 146-152.
- 26 Yeung PS, Sanders ME, Kitts CL, Cano R, Tong PS, 2002. Species-specific identification of commercial probiotic strains. *Journal of Dairy Science*, 85, 1039-1051.
- 27 Zareie M, Johnson-Henry K, Jury J, Yang PC, Ngan BY, McKay DM, Soderholm JD, Perdue MH, Sherman PM, 2006. Probiotics prevent bacterial translocation and improve intestinal barrier function in rats following chronic psychological stress. *Gut*, 55, 1553-1560.
- 28 Ziemniak W, 2006. Efficacy of *Helicobacter pylori* eradication taking into account its resistance to antibiotics. *Journal of Physiology and Pharmacology*, 57 Suppl 3, 123-141.

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.
- 2 Bouglé D, Roland N, Lebeurrier F, Arhan P, 1999. Effect of propionibacteria supplementation on fecal bifidobacteria and segmental colonic transit time in healthy human subjects. *Scandinavian Journal of Gastroenterology*, 34, 144-148.
- 3 Hervé C, Fondrevez M, Cheron A, Barloy-Hubler F, Jan G, 2007. Transcarboxylase mRNA: a marker which evidences *P. freudenreichii* survival and metabolic activity during its transit in the human gut. *International Journal of Food Microbiology*, 113, 303-314.

- 4 Huang Y and Adams MC, 2004. In vitro assessment of the upper gastrointestinal tolerance of potential probiotic dairy propionibacteria. International Journal of Food Microbiology, 91, 253-260.
- 5 Jan G, Leverrier P, Proud I, Roland N, 2002. Survival and beneficial effects of propionibacteria in the human gut: in vivo and in vitro investigations. Lait, 82, 131-144.
- 6 Lan A, Bruneau A, Philippe C, Rochet V, Herve C, Roland N, Rabot S, Jan G, 2007. Survival and metabolic activity of selected strains of *Propionibacterium freudenreichii* in the gastrointestinal tract of human microbiota-associated rats. British Journal of Nutrition, 97, 714-724.

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

- 1 Dossier submitted by the competent authority of Belgium on *Bifidobacterium animalis* ssp *lactis* THT 010801 and digestive health/intestinal flora, ID 960. 2011.
- 2 Alander M, Matto J, Kneifel W, Johansson M, Kogler B, Crittenden R, Mattila-Sandholm T, Saarela M, 2001. Effect of galacto-oligosaccharide supplementation on human faecal microflora and on survival and persistence of *Bifidobacterium lactis* Bb-12 in the gastrointestinal tract. International Dairy Journal, 11, 817-825.
- 3 Amor KB, Breeuwer P, Verbaarschot P, Rombouts FM, Akkermans AD, De Vos WM, Abbe T, 2002. Multiparametric flow cytometry and cell sorting for the assessment of viable, injured, and dead *bifidobacterium* cells during bile salt stress. Applied and Environmental Microbiology, 68, 5209-5216.
- 4 Crittenden RG, Morris LF, Harvey ML, Tran LT, Mitchell HL, Playne MJ, 2001. Selection of a *Bifidobacterium* strain to complement resistant starch in a synbiotic yoghurt. Journal of Applied Microbiology, 90, 268-278.
- 5 Masco L, Ventura M, Zink R, Huys G, Swings J, 2004. Polyphasic taxonomic analysis of *Bifidobacterium animalis* and *Bifidobacterium lactis* reveals relatedness at the subspecies level: reclassification of *Bifidobacterium animalis* as *Bifidobacterium animalis* subsp. *animalis* subsp. nov. and *Bifidobacterium lactis* as *Bifidobacterium animalis* subsp. *lactis* subsp. nov. International Journal of Systematic and Evolutionary Microbiology, 54, 1137-1143.
- 6 Matsumoto M, Tadenuma T, Nakamura K, Kume H, Imai T, Kihara R, Watanabe M, Benno Y, 2000. Effect of *Bifidobacterium lactis* LKM 512 Yogurt on Fecal Microflora in Middle to Old Aged Persons. Microbial Ecology in Health and Disease, 12, 77-80.
- 7 Matsumoto M, Ohishi H, Benno Y, 2004. H⁺-ATPase activity in *Bifidobacterium* with special reference to acid tolerance. International Journal of Food Microbiology, 93, 109-113.
- 8 Mattö J, Malinen E, Suihko ML, Alander M, Palva A, Saarela M, 2004. Genetic heterogeneity and functional properties of intestinal bifidobacteria. Journal of Applied Microbiology, 97, 459-470.
- 9 McMaster LD, Kokott SA, Reid SJ, Abratt VR, 2005. Use of traditional African fermented beverages as delivery vehicles for *Bifidobacterium lactis* DSM 10140. International Journal of Food Microbiology, 102, 231-237.
- 10 Roy D and Sirois S, 2000. Molecular differentiation of *Bifidobacterium* species with amplified ribosomal DNA restriction analysis and alignment of short regions of the *ldh* gene. FEMS Microbiology Letters, 191, 17-24.
- 11 Ventura M and Zink R, 2002. Rapid identification, differentiation, and proposed new taxonomic classification of *Bifidobacterium lactis*. Applied and Environmental Microbiology, 68, 6429-6434.

- 12 Ventura M, Canchaya C, Del Casale A, Dellaglio F, Neviani E, Fitzgerald GF, van Sinderen D, 2006. Analysis of bifidobacterial evolution using a multilocus approach. International Journal of Systematic and Evolutionary Microbiology, 56, 2783-2792.

ID 961: *Bifidobacterium animalis* ssp. *lactis* THT 010801

- 1 Dossier submitted by the competent authority of Belgium on *Bifidobacterium animalis* ssp *lactis* THT 010801 and intestinal transit, ID 961. 2011.
- 2 Amor KB, Breeuwer P, Verbaarschot P, Rombouts FM, Akkermans AD, De Vos WM, Abeel T, 2002. Multiparametric flow cytometry and cell sorting for the assessment of viable, injured, and dead *bifidobacterium* cells during bile salt stress. Applied and Environmental Microbiology, 68, 5209-5216.
- 3 Berrada N, Lemeland JF, Laroche G, Thouvenot P, Piaia M, 1991. *Bifidobacterium* from fermented milks: survival during gastric transit. Journal of Dairy Science, 74, 409-413.
- 4 Crittenden RG, Morris LF, Harvey ML, Tran LT, Mitchell HL, Playne MJ, 2001. Selection of a *Bifidobacterium* strain to complement resistant starch in a synbiotic yoghurt. Journal of Applied Microbiology, 90, 268-278.
- 5 Duez H, Pelletier C, Cools S, Aissi E, Cayuela C, Gavini F, Bouquelet S, Neut C, Mengaud J, 2000. A colony immunoblotting method for quantitative detection of a *Bifidobacterium animalis* probiotic strain in human faeces. Journal of Applied Microbiology, 88, 1019-1027.
- 6 Masco L, Ventura M, Zink R, Huys G, Swings J, 2004. Polyphasic taxonomic analysis of *Bifidobacterium animalis* and *Bifidobacterium lactis* reveals relatedness at the subspecies level: reclassification of *Bifidobacterium animalis* as *Bifidobacterium animalis* subsp. *animalis* subsp. nov. and *Bifidobacterium lactis* as *Bifidobacterium animalis* subsp. *lactis* subsp. nov. International Journal of Systematic and Evolutionary Microbiology, 54, 1137-1143.
- 7 Matsumoto M, Ohishi H, Benno Y, 2004. H⁺-ATPase activity in *Bifidobacterium* with special reference to acid tolerance. International Journal of Food Microbiology, 93, 109-113.
- 8 Matto J, Malinen E, Suihko ML, Alander M, Palva A, Saarela M, 2004. Genetic heterogeneity and functional properties of intestinal bifidobacteria. Journal of Applied Microbiology, 97, 459-470.
- 9 McMaster LD, Kokott SA, Reid SJ, Abratt VR, 2005. Use of traditional African fermented beverages as delivery vehicles for *Bifidobacterium lactis* DSM 10140. International Journal of Food Microbiology, 102, 231-237.
- 10 Roy D and Sirois S, 2000. Molecular differentiation of *Bifidobacterium* species with amplified ribosomal DNA restriction analysis and alignment of short regions of the *ldh* gene. FEMS Microbiology Letters, 191, 17-24.
- 11 Ventura M and Zink R, 2002. Rapid identification, differentiation, and proposed new taxonomic classification of *Bifidobacterium lactis*. Applied and Environmental Microbiology, 68, 6429-6434.
- 12 Ventura M, Canchaya C, Del Casale A, Dellaglio F, Neviani E, Fitzgerald GF, van Sinderen D, 2006. Analysis of bifidobacterial evolution using a multilocus approach. International Journal of Systematic and Evolutionary Microbiology, 56, 2783-2792.

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.
- 2 Gill HS, Rutherford KJ, Cross ML, Gopal PK, 2001. Enhancement of immunity in the elderly by dietary supplementation with the probiotic *Bifidobacterium lactis* HN019. American Journal of Clinical Nutrition, 74, 833-839.
- 3 Gopal PK, Prasad J, Smart J, Gill HS, 2001. In vitro adherence properties of *Lactobacillus rhamnosus* DR20 and *Bifidobacterium lactis* DR10 strains and their antagonistic activity against an enterotoxigenic *Escherichia coli*. International Journal of Food Microbiology, 67, 207-216.
- 4 Masco L, Ventura M, Zink R, Huys G, Swings J, 2004. Polyphasic taxonomic analysis of *Bifidobacterium animalis* and *Bifidobacterium lactis* reveals relatedness at the subspecies level: reclassification of *Bifidobacterium animalis* as *Bifidobacterium animalis* subsp. *animalis* subsp. nov. and *Bifidobacterium lactis* as *Bifidobacterium animalis* subsp. *lactis* subsp. nov. International Journal of Systematic and Evolutionary Microbiology, 54, 1137-1143.
- 5 Miettinen M, Vuopio-Varkila J, Varkila K, 1996. Production of human tumor necrosis factor alpha, interleukin-6, and interleukin-10 is induced by lactic acid bacteria. Infection and Immunity, 64, 5403-5405.
- 6 Ouwehand AC, Isolauri E, Kirjavainen PV, Salminen SJ, 1999. Adhesion of four *Bifidobacterium* strains to human intestinal mucus from subjects in different age groups. FEMS Microbiology Letters, 172, 61-64.
- 7 Ouwehand AC, Isolauri E, Kirjavainen PV, Tolkkoo S, Salminen SJ, 2000. The mucus binding of *Bifidobacterium lactis* Bb12 is enhanced in the presence of *Lactobacillus GG* and *Lact. delbrueckii* subsp. *bulgaricus*. Letters in Applied Microbiology, 30, 10-13.
- 8 Roy D and Sirois S, 2000. Molecular differentiation of *Bifidobacterium* species with amplified ribosomal DNA restriction analysis and alignment of short regions of the *ldh* gene. FEMS Microbiology Letters, 191, 17-24.
- 9 Schiffrin EJ, Rochat F, Link-Amster H, Aeschlimann JM, Donnet-Hughes A, 1995. Immunomodulation of human blood cells following the ingestion of lactic acid bacteria. Journal of Dairy Science, 78, 491-497.
- 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.
- 11 Ventura M and Zink R, 2002. Rapid identification, differentiation, and proposed new taxonomic classification of *Bifidobacterium lactis*. Applied and Environmental Microbiology, 68, 6429-6434.
- 12 Ventura M, Canchaya C, Del Casale A, Dellaglio F, Neviani E, Fitzgerald GF, van Sinderen D, 2006. Analysis of bifidobacterial evolution using a multilocus approach. International Journal of Systematic and Evolutionary Microbiology, 56, 2783-2792.

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.
- 2 BCCM/LMG, 2011. Report on DNA fingerprinting (AFLPTM) of 6 bacterial cultures using two primer combinations.
- 3 Charteris WP, Kelly PM, Morelli L, Collins JK, 1998. Development and application of an in vitro methodology to determine the transit tolerance of potentially probiotic *Lactobacillus* and

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

- 4 Gagnon M, Kheadr EE, Le Blay G, Fliss I, 2004. In vitro inhibition of Escherichia coli O157:H7 by bifidobacterial strains of human origin. International Journal of Food Microbiology, 92, 69-78.
- 5 Kim JW, Lee SJ, Park KH, 2002. Antimicrobial effect of Bifidobacterium breve and Bifidobacterium infantis against Salmonella typhimurium KCTC 1925 and E. coli O157:H7 ATCC 43895. Food Science Biotechnology, 11, 89-92.

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.
- 2 BCCM/LMG, 2011. Report on DNA fingerprinting (AFLPTM) of 6 bacterial cultures using two primer combinations.
- 3 Gagnon M, Kheadr EE, Le Blay G, Fliss I, 2004. In vitro inhibition of Escherichia coli O157:H7 by bifidobacterial strains of human origin. International Journal of Food Microbiology, 92, 69-78.
- 4 Kim JW, Lee SJ, Park KH, 2002. Antimicrobial effect of Bifidobacterium breve and Bifidobacterium infantis against Salmonella typhimurium KCTC 1925 and E. coli O157:H7 ATCC 43895. Food Science and Biotechnology, 11, 89-92.
- 5 Mullie C, Yazourh A, Thibault H, Odou MF, Singer E, Kalach N, Kremp O, Romond MB, 2004. Increased poliovirus-specific intestinal antibody response coincides with promotion of Bifidobacterium longum-infantis and Bifidobacterium breve in infants: a randomized, double-blind, placebo-controlled trial. Pediatric Research, 56, 791-795.
- 6 Park SY, Ji GE, Ko YT, Jung HK, Ustunol Z, Pestka JJ, 1999. Potentiation of hydrogen peroxide, nitric oxide, and cytokine production in RAW 264.7 macrophage cells exposed to human and commercial isolates of Bifidobacterium. International Journal of Food Microbiology, 46, 231-241.

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.
- 2 BCCM/LMG, 2011. Report on DNA fingerprinting (AFLPTM) of 6 bacterial cultures using two primer combinations.
- 3 Colecchia A, Vestito A, La Rocca A, Pasqui F, Nikiforaki A, Festi D, 2006. Effect of a symbiotic preparation on the clinical manifestations of irritable bowel syndrome, constipation-variant. Results of an open, uncontrolled multicenter study. Minerva Gastroenterologica e Dietologica, 52, 349-358.
- 4 Puccio G, Cajozzo C, Meli F, Rochat F, Grathwohl D, Steenhout P, 2007. Clinical evaluation of a new starter formula for infants containing live Bifidobacterium longum BL999 and prebiotics. Nutrition, 23, 1-8.

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.
- 2 BCCM/LMG, 2011. Report on DNA fingerprinting (AFLPTM) of 6 bacterial cultures using two primer combinations.

- 3 Matsumoto M, Tani H, Ono H, Ohishi H, Benno Y, 2002. Adhesive property of *Bifidobacterium lactis* LKM512 and predominant bacteria of intestinal microflora to human intestinal mucin. *Current Microbiology*, 44, 212-215.
- 4 Riedel CU, Foata F, Goldstein DR, Blum S, Eikmanns BJ, 2006. Interaction of bifidobacteria with Caco-2 cells-adhesion and impact on expression profiles. *International Journal of Food Microbiology*, 110, 62-68.
- 5 Riedel CU, Foata F, Philippe D, Adolfsson O, Eikmanns BJ, Blum S, 2006. Anti-inflammatory effects of bifidobacteria by inhibition of LPS-induced NF-kappaB activation. *World Journal of Gastroenterology*, 12, 3729-3735.
- 6 Young SL, Simon MA, Baird MA, Tannock GW, Bibiloni R, Spencely K, Lane JM, Fitzharris P, Crane J, Town I, Addo-Yobo E, Murray CS, Woodcock A, 2004. Bifidobacterial species differentially affect expression of cell surface markers and cytokines of dendritic cells harvested from cord blood. *Clinical and Diagnostic Laboratory Immunology*, 11, 686-690.

ID 971: *Bifidobacterium psuedolongum* ssp *psuedolongum* THT 010501

- 1 Dossier submitted by the competent Authority of Belgium on *Bifidobacterium psuedolongum* subsp *pseudolongum* THT 010501 and digestive health/intestinal flora, ID 971. 2011.
- 2 BCCM/LMG, 2011. Report on the identification/characterisation by DNA fingerprinting (AFLP™) of 6 bacterial cultures using two primer combinations.
- 3 Bezkorovainy A, 2001. Probiotics: determinants of survival and growth in the gut. *American Journal of Clinical Nutrition*, 73, 399S-405S.
- 4 Crociani J, Grill JP, Huppert M, Ballongue J, 1995. Adhesion of different bifidobacteria strains to human enterocyte-like Caco-2 cells and comparison with in vivo study. *Letters in Applied Microbiology*, 21, 146-148.
- 5 Gagnon M, Kheadr EE, Le Blay G, Fliss I, 2004. In vitro inhibition of *Escherichia coli* O157:H7 by bifidobacterial strains of human origin. *International Journal of Food Microbiology*, 92, 69-78.
- 6 Jian W, Zhu L, Dong X, 2001. New approach to phylogenetic analysis of the genus *Bifidobacterium* based on partial HSP60 gene sequences. *International Journal of Systematic and Evolutionary Microbiology*, 51, 1633-1638.
- 7 Leblond-Bourget N, Philippe H, Mangin I, Decaris B, 1996. 16S rRNA and 16S to 23S internal transcribed spacer sequence analyses reveal inter- and intraspecific *Bifidobacterium* phylogeny. *International Journal of Systematic Bacteriology*, 46, 102-111.
- 8 Masco L, Huys G, Gevers D, Verbrugghen L, Swings J, 2003. Identification of *Bifidobacterium* species using rep-PCR fingerprinting. *Systematic and Applied Microbiology*, 26, 557-563.
- 9 Ventura M, Canchaya C, Del Casale A, Dellaglio F, Neviani E, Fitzgerald GF, van Sinderen D, 2006. Analysis of bifidobacterial evolution using a multilocus approach. *International Journal of Systematic and Evolutionary Microbiology*, 56, 2783-2792.

ID 972: *Bifidobacterium psuedolongum* ssp *psuedolongum* THT 010501

- 1 Dossier submitted by the competent Authority of Belgium on *Bifidobacterium pseudolongum* subsp *pseudolongum* THT 010501 and natural defences/immune system, ID 972. 2011.
- 2 Bezkorovainy A, 2001. Probiotics: determinants of survival and growth in the gut. *American Journal of Clinical Nutrition*, 73, 399S-405S.
- 3 Crociani J, Grill JP, Huppert M, Ballongue J, 1995. Adhesion of different bifidobacteria strains to human enterocyte-like Caco-2 cells and comparison with in vivo study. *Letters in Applied Microbiology*, 21, 146-148.

- 4 Gagnon M, Kheadr EE, Le Blay G, Fliss I, 2004. In vitro inhibition of Escherichia coli O157:H7 by bifidobacterial strains of human origin. International Journal of Food Microbiology, 92, 69-78.
- 5 Jian W, Zhu L, Dong X, 2001. New approach to phylogenetic analysis of the genus *Bifidobacterium* based on partial HSP60 gene sequences. International Journal of Systematic and Evolutionary Microbiology, 51, 1633-1638.
- 6 Leblond-Bourget N, Philippe H, Mangin I, Decaris B, 1996. 16S rRNA and 16S to 23S internal transcribed spacer sequence analyses reveal inter- and intraspecific *Bifidobacterium* phylogeny. International Journal of Systematic Bacteriology, 46, 102-111.
- 7 Masco L, Huys G, Gevers D, Verbrugghen L, Swings J, 2003. Identification of *Bifidobacterium* species using rep-PCR fingerprinting. Systematic Applied Microbiology, 26, 557-563.
- 8 Ventura M, Canchaya C, Del Casale A, Dellaglio F, Neviani E, Fitzgerald GF, van Sinderen D, 2006. Analysis of bifidobacterial evolution using a multilocus approach. International Journal of Systematic and Evolutionary Microbiology, 56, 2783-2792.

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.
- 2 Araujo Aires K., Cianciarullo AM, Carneiro SM, Villa LL, Boccardo E, Perez-Martinez G, Perez-Arellano I, Oliveira ML, Ho PL, 2006. Production of human papillomavirus type 16 L1 virus-like particles by recombinant *Lactobacillus casei* cells. Applied and Environmental Microbiology, 72, 745-752.
- 3 Chavagnat F, Haueter M, Jimeno J, Casey MG, 2002. Comparison of partial tuf gene sequences for the identification of lactobacilli. FEMS Microbiology Letters, 217, 177-183.
- 4 Dicks LM, Du Plessis EM, Dellaglio F, Lauer E, 1996. Reclassification of *Lactobacillus casei* subsp. *casei* ATCC 393 and *Lactobacillus rhamnosus* ATCC 15820 as *Lactobacillus zeae* nom. rev., designation of ATCC 334 as the neotype of *L. casei* subsp. *casei*, and rejection of the name *Lactobacillus paracasei*. International Journal of Systematic Bacteriology, 46, 337-340.
- 5 Felis GE, Dellaglio F, Mizzi L, Torriani S, 2001. Comparative sequence analysis of a recA gene fragment brings new evidence for a change in the taxonomy of the *Lactobacillus casei* group. International Journal of Systematic and Evolutionary Microbiology, 51, 2113-2117.
- 6 Hazebrouck S, Oozeer R, Adel-Patient K, Langella P, Rabot S, Wal JM, Corthier G, 2006. Constitutive delivery of bovine beta-lactoglobulin to the digestive tracts of gnotobiotic mice by engineered *Lactobacillus casei*. Applied and Environmental Microbiology, 72, 7460-7467.
- 7 Mercenier A, Wiedermann U, Breiteneder H, 2001. Edible genetically modified microorganisms and plants for improved health. Current Opinion in Biotechnology, 12, 510-515.
- 8 Oliveira ML, Areas AP, Campos IB, Monedero V, Perez-Martinez G, Miyaji EN, Leite LC, Aires KA, Lee Ho P, 2006. Induction of systemic and mucosal immune response and decrease in *Streptococcus pneumoniae* colonization by nasal inoculation of mice with recombinant lactic acid bacteria expressing pneumococcal surface antigen A. Microbes and Infection, 8, 1016-1024.
- 9 Pant N, Hultberg A, Zhao Y, Svensson L, Pan-Hammarstrom Q, Johansen K, Pouwels PH, Ruggeri FM, Hermans P, Frenken L, Boren T, Marcotte H, Hammarstrom L, 2006. Lactobacilli expressing variable domain of llama heavy-chain antibody fragments (lactobodies) confer protection against rotavirus-induced diarrhea. Journal of Infectious Diseases, 194, 1580-1588.
- 10 Sato K, 1984. Enhancement of host resistance against *Listeria* infection by *Lactobacillus casei*: role of macrophages. Infection and Immunity, 44, 445-451.
- 11 Song Y, Kato N, Liu C, Matsumiya Y, Kato H, Watanabe K, 2000. Rapid identification of 11 human intestinal *Lactobacillus* species by multiplex PCR assays using group- and species-

specific primers derived from the 16S-23S rRNA intergenic spacer region and its flanking 23S rRNA. FEMS Microbiology Letters, 187, 167-173.

- 12 Wayne LG, 1994. Actions of the Judicial Commission of the International Committee on Systematic Bacteriology on Requests for Opinions Published Between January 1985 and July 1993. International Journal on Systematic and Evolutionary Microbiology, 44, 177-178.

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.
- 2 Chavagnat F, Haueter M, Jimeno J, Casey MG, 2002. Comparison of partial tuf gene sequences for the identification of lactobacilli. FEMS Microbiology Letters, 217, 177-183.
- 3 Dicks LM, Du Plessis EM, Dellaglio F, Lauer E, 1996. Reclassification of *Lactobacillus casei* subsp. *casei* ATCC 393 and *Lactobacillus rhamnosus* ATCC 15820 as *Lactobacillus zeae* nom. rev., designation of ATCC 334 as the neotype of *L. casei* subsp. *casei*, and rejection of the name *Lactobacillus paracasei*. International Journal of Systematic Bacteriology, 46, 337-340.
- 4 Edelman S, Westerlund-Wikstrom B, Leskela S, Kettunen H, Rautonen N, Apajalahti J, Korhonen TK, 2002. In vitro adhesion specificity of indigenous Lactobacilli within the avian intestinal tract. Applied Environmental Microbiology, 68, 5155-5159.
- 5 Felis GE, Dellaglio F, Mizzi L, Torriani S, 2001. Comparative sequence analysis of a recA gene fragment brings new evidence for a change in the taxonomy of the *Lactobacillus casei* group. International Journal of Systematic and Evolutionary Microbiology, 51, 2113-2117.
- 6 Hazebrouck S, Oozeer R, Adel-Patient K, Langella P, Rabot S, Wal JM, Corthier G, 2006. Constitutive delivery of bovine beta-lactoglobulin to the digestive tracts of gnotobiotic mice by engineered *Lactobacillus casei*. Applied and Environmental Microbiology, 72, 7460-7467.
- 7 Kajikawa A, Satoh E, Leer RJ, Yamamoto S, Igimi S, 2007. Intragastric immunization with recombinant *Lactobacillus casei* expressing flagellar antigen confers antibody-independent protective immunity against *Salmonella enterica* serovar Enteritidis. Vaccine, 25, 3599-3605.
- 8 Oliveira ML, Areas AP, Campos IB, Monedero V, Perez-Martinez G, Miyaji EN, Leite LC, Aires KA, Lee Ho P, 2006. Induction of systemic and mucosal immune response and decrease in *Streptococcus pneumoniae* colonization by nasal inoculation of mice with recombinant lactic acid bacteria expressing pneumococcal surface antigen A. Microbes and Infection, 8, 1016-1024.
- 9 Plant LJ and Conway PL, 2002. Adjuvant properties and colonization potential of adhering and non-adhering *Lactobacillus* spp following oral administration to mice. FEMS Immunology and Medical Microbiology, 34, 105-111.
- 10 Ratajczak C, Duez C, Granette C, Pochard P, Tonnel AB, Pestel J, 2007. Impact of lactic Acid bacteria on dendritic cells from allergic patients in an experimental model of intestinal epithelium. Journal of Biomedical Biotechnology, 2007, 71921.
- 11 Song Y, Kato N, Liu C, Matsumiya Y, Kato H, Watanabe K, 2000. Rapid identification of 11 human intestinal *Lactobacillus* species by multiplex PCR assays using group- and species-specific primers derived from the 16S-23S rRNA intergenic spacer region and its flanking 23S rRNA. FEMS Microbiology Letters, 187, 167-173.
- 12 Wayne LG, 1994. Actions of the Judicial Commission of the International Committee on Systematic Bacteriology on Requests for Opinions Published Between January 1985 and July 1993. International Journal on Systematic and Evolutionary Microbiology, 44, 177-178.

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.
- 2 BCCM/LMG, 2011. Report on DNA fingerprinting (AFLPTM) of 1 bacterial culture using two primer combination.
- 3 Conway PL, Gorbach SL, Goldin BR, 1987. Survival of Lactic-Acid Bacteria in the Human Stomach and Adhesion to Intestinal-Cells. *Journal of Dairy Science*, 70, 1-12.
- 4 Fernandez MF, Boris S, Barbes C, 2003. Probiotic properties of human lactobacilli strains to be used in the gastrointestinal tract. *Journal of Applied Microbiology*, 94, 449-455.
- 5 Greene JD and Klaenhammer TR, 1994. Factors Involved in Adherence of Lactobacilli to Human Caco-2 Cells. *Applied and Environmental Microbiology*, 60, 4487-4494.
- 6 Olivares M, Diaz-Ropero MP, Gomez N, Lara-Villoslada F, Sierra S, Maldonado JA, Martin R, Lopez-Huertas E, Rodriguez JM, Xaus J, 2006. Oral administration of two probiotic strains, Lactobacillus gasseri CECT5714 and Lactobacillus coryniformis CECT5711, enhances the intestinal function of healthy adults. *International Journal of Food Microbiology*, 107, 104-111.
- 7 Ushiyama A, Tanaka K, Aiba Y, Shiba T, Takagi A, Mine T, Koga Y, 2003. Lactobacillus gasseri OLL2716 as a probiotic in clarithromycin-resistant Helicobacter pylori infection. *Journal of Gastroenterology and Hepatology*, 18, 986-991.
- 8 Usman and Hosono A, 1999. Bile tolerance, taurocholate deconjugation, and binding of cholesterol by Lactobacillus gasseri strains. *Journal of Dairy Science*, 82, 243-248.

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.
- 2 BCCM/LMG, 2011. Report on DNA fingerprinting (AFLPTM) of 1 bacterial culture using two primer combination.
- 3 Conway PL, Gorbach SL, Goldin BR, 1987. Survival of Lactic-Acid Bacteria in the Human Stomach and Adhesion to Intestinal-Cells. *Journal of Dairy Science*, 70, 1-12.
- 4 de Vrese M, Winkler P, Rautenberg P, Harder T, Noah C, Laue C, Ott S, Hampe J, Schreiber S, Heller K, Schrezenmeir J, 2005. Effect of Lactobacillus gasseri PA 16/8, Bifidobacterium longum SP 07/3, B. bifidum MF 20/5 on common cold episodes: a double blind, randomized, controlled trial. *Clinical Nutrition*, 24, 481-491.
- 5 Fernandez MF, Boris S, Barbes C, 2003. Probiotic properties of human lactobacilli strains to be used in the gastrointestinal tract. *Journal of Applied Microbiology*, 94, 449-455.
- 6 Greene JD and Klaenhammer TR, 1994. Factors Involved in Adherence of Lactobacilli to Human Caco-2 Cells. *Applied and Environmental Microbiology*, 60, 4487-4494.
- 7 Olivares M, Diaz-Ropero MP, Gomez N, Lara-Villoslada F, Sierra S, Maldonado JA, Martin R, Lopez-Huertas E, Rodriguez JM, Xaus J, 2006. Oral administration of two probiotic strains, Lactobacillus gasseri CECT5714 and Lactobacillus coryniformis CECT5711, enhances the intestinal function of healthy adults. *International Journal of Food Microbiology*, 107, 104-111.
- 8 Olivares M, Diaz-Ropero MP, Gomez N, Lara-Villoslada F, Sierra S, Maldonado JA, Martin R, Rodriguez JM, Xaus J, 2006. The consumption of two new probiotic strains, Lactobacillus gasseri CECT 5714 and Lactobacillus coryniformis CECT 5711, boosts the immune system of healthy humans. *International Microbiology*, 9, 47-52.

- 9 Sakamoto I, Igarashi M, Kimura K, Takagi A, Miwa T, Koga Y, 2001. Suppressive effect of Lactobacillus gasseri OLL 2716 (LG21) on Helicobacter pylori infection in humans. *Journal of Antimicrobial Chemotherapy*, 47, 709-710.
- 10 Ushiyama A, Tanaka K, Aiba Y, Shiba T, Takagi A, Mine T, Koga Y, 2003. Lactobacillus gasseri OLL2716 as a probiotic in clarithromycin-resistant Helicobacter pylori infection. *Journal of Gastroenterology and Hepatology*, 18, 986-991.
- 11 Usman and Hosono A, 1999. Bile tolerance, taurocholate deconjugation, and binding of cholesterol by Lactobacillus gasseri strains. *Journal of Dairy Science*, 82, 243-248.

ID 985: *Lactobacillus helveticus* THT 031102

- 1 Dossier submitted by the competent Authority of Belgium on *Lactobacillus helveticus* THT 031102 and digestive health/intestinal flora, ID 985. 2011.
- 2 BCCM/LMG, 2011. Report on DNA fingerprinting (AFLPTM) of 6 bacterial cultures using two primer combinations.
- 3 Çadirci BH and Citak S, 2005. A comparison of two methods used for measuring antagonistic activity of lactic acid bacteria. *Pakistan Journal of Nutrition*, 4, 237-241.
- 4 Johnson-Henry KC, Hagen KE, Gordonpour M, Tompkins TA, Sherman PM, 2007. Surface-layer protein extracts from *Lactobacillus helveticus* inhibit enterohaemorrhagic *Escherichia coli* O157:H7 adhesion to epithelial cells. *Cellular Microbiology*, 9, 356-367.
- 5 Majhenic AC and Matijašic BB, 2001. Antibiotics influence on lactic acid bacteria inhabiting gastrointestinal tract. *Mljekarstvo/Dairy*, 51, 119-134.
- 6 Shinoda T, Kusuda D, Ishida Y, Ikeda N, Kaneko K, Masuda O, Yamamoto N, 2001. Survival of *Lactobacillus helveticus* strain CP53 in the human gastrointestinal tract. *Letters of Applied Microbiology*, 32, 108-113.

ID 986: *Lactobacillus helveticus* THT 031102

- 1 Dossier submitted by the competent Authority of Belgium on *Lactobacillus helveticus* THT 031102 and natural defences/immune system, ID 986. 2011.
- 2 BCCM/LMG, 2011. Report on DNA fingerprinting (AFLPTM) of 6 bacterial cultures using two primer combinations.
- 3 Çadirci BH and Citak S, 2005. A comparison of two methods used for measuring antagonistic activity of lactic acid bacteria. *Pakistan Journal of Nutrition*, 4, 237-241.
- 4 de Moreno de LeBlanc A, Matar C, LeBlanc N, Perdigón G, 2005. Effects of milk fermented by *Lactobacillus helveticus* R389 on a murine breast cancer model. *Breast Cancer Research*, 7, R477-486.
- 5 Johnson-Henry KC, Hagen KE, Gordonpour M, Tompkins TA, Sherman PM, 2007. Surface-layer protein extracts from *Lactobacillus helveticus* inhibit enterohaemorrhagic *Escherichia coli* O157:H7 adhesion to epithelial cells. *Cellular Microbiology*, 9, 356-367.
- 6 Leblanc J, Fliss I, Matar C, 2004. Induction of a humoral immune response following an *Escherichia coli* O157:H7 infection with an immunomodulatory peptidic fraction derived from *Lactobacillus helveticus*-fermented milk. *Clinical and Diagnostic Laboratory Immunology*, 11, 1171-1181.
- 7 Matar C, Valdez JC, Medina M, Rachid M, Perdigón G, 2001. Immunomodulating effects of milks fermented by *Lactobacillus helveticus* and its non-proteolytic variant. *Journal of Dairy Research*, 68, 601-609.

- 8 Shinoda T, Kusuda D, Ishida Y, Ikeda N, Kaneko K, Masuda O, Yamamoto N, 2001. Survival of Lactobacillus helveticus strain CP53 in the human gastrointestinal tract. Letters of Applied Microbiology, 32, 108-113.

ID 994: Lactobacillus plantarum THT 030701

- 1 Dossier submitted by the competent Authority of Belgium on Lactobacillus plantarum THT 030701 and digestive health/intestinal flora, ID 994. 2011.
- 2 BCCM/LMG, 2011. Report on the identification/characterisation by DNA fingerprinting (AFLPTM) of 6 bacterial cultures using two primer combinations.
- 3 Nollet L and Verstraete W, 1996. Gastro-enteric methane versus sulphate and volatile fatty acid production. Environmental Monitoring and Assessment, 42, 113-131.
- 4 Vesa T, Pochart P, Marteau P, 2000. Pharmacokinetics of Lactobacillus plantarum NCIMB 8826, Lactobacillus fermentum KLD, and Lactococcus lactis MG 1363 in the human gastrointestinal tract. Alimentary Pharmacology & Therapeutics, 14, 823-828.

ID 995: Lactobacillus plantarum THT 030701

- 1 Dossier submitted by the competent Authority of Belgium on Lactobacillus plantarum THT 030701 and natural defences/immune system, ID 995. 2011.
- 2 BCCM/LMG, 2011. Report on the identification/characterisation by DNA fingerprinting (AFLPTM) of 6 bacterial cultures using two primer combinations.
- 3 Daniel C, Poiret S, Goudercourt D, Dennin V, Leyer G, Pot B, 2006. Selecting lactic acid bacteria for their safety and functionality by use of a mouse colitis model. Applied Environmental Microbiology, 72, 5799-5805.
- 4 Foligne B, Nutten S, Steidler L, Dennin V, Goudercourt D, Mercenier A, Pot B, 2006. Recommendations for improved use of the murine TNBS-induced colitis model in evaluating anti-inflammatory properties of lactic acid bacteria: technical and microbiological aspects. Digestive Diseases and Sciences, 51, 390-400.
- 5 Müller-Alouf H, Granette C, Goudercourt D, Reveneau N, Mercenier A, 1999. Comparative cytokine inducing pattern of lactic acid bacteria used for mucosal vaccine development. Immunology Letters, 69, 33.
- 6 Pavan S, Desreumaux P, Mercenier A, 2003. Use of mouse models to evaluate the persistence, safety, and immune modulation capacities of lactic acid bacteria. Clinical and Diagnostic Laboratory Immunology, 10, 696-701.
- 7 Pochard P, Hammad H, Ratajczak C, Charbonnier-Hatzfeld AS, Just N, Tonnel AB, Pestel J, 2005. Direct regulatory immune activity of lactic acid bacteria on Der p 1-pulsed dendritic cells from allergic patients. Journal of Allergy Clinical Immunology, 116, 198-204.
- 8 Vesa T, Pochart P, Marteau P, 2000. Pharmacokinetics of Lactobacillus plantarum NCIMB 8826, Lactobacillus fermentum KLD, and Lactococcus lactis MG 1363 in the human gastrointestinal tract. Alimentary Pharmacology and Therapeutics, 14, 823-828.

ID 996: Lactobacillus plantarum THT 030707

- 1 Dossier submitted by the competent Authority of Belgium on Lactobacillus plantarum THT 030707 and digestive health/intestinal flora, ID 996. 2011.
- 2 BCCM/LMG, 2011. Report on the identification/characterisation by DNA fingerprinting (AFLPTM) of 6 bacterial cultures using two primer combinations.

- 3 Nollet L and Verstraete W, 1996. Gastro-enteric methane versus sulphate and volatile fatty acid production. Environmental Monitoring and Assessment, 42, 113-131.
- 4 Vesa T, Pochart P, Marteau P, 2000. Pharmacokinetics of *Lactobacillus plantarum* NCIMB 8826, *Lactobacillus fermentum* KLD, and *Lactococcus lactis* MG 1363 in the human gastrointestinal tract. Alimentary Pharmacology and Therapeutics, 14, 823-828.

ID 997: *Lactobacillus plantarum* THT 030707

- 1 Dossier submitted by the competent Authority of Belgium on *Lactobacillus plantarum* THT 030707 and natural defences/immune system, ID 997. 2011.
- 2 BCCM/LMG, 2011. Report on the identification/characterisation by DNA fingerprinting (AFLPTM) of 6 bacterial cultures using two primer combinations.
- 3 Daniel C, Poiret S, Goudercourt D, Dennin V, Leyen G, Pot B, 2006. Selecting lactic acid bacteria for their safety and functionality by use of a mouse colitis model. Applied Environmental Microbiology, 72, 5799-5805.
- 4 Foligne B, Nutten S, Steidler L, Dennin V, Goudercourt D, Mercenier A, Pot B, 2006. Recommendations for improved use of the murine TNBS-induced colitis model in evaluating anti-inflammatory properties of lactic acid bacteria: technical and microbiological aspects. Digestive Diseases and Sciences, 51, 390-400.
- 5 Müller-Alouf H, Grangette C, Goudercourt D, Reveneau N, Mercenier A, 1999. Comparative cytokine inducing pattern of lactic acid bacteria used for mucosal vaccine development. Immunology Letters, 69, 33.
- 6 Pavan S, Desreumaux P, Mercenier A, 2003. Use of mouse models to evaluate the persistence, safety, and immune modulation capacities of lactic acid bacteria. Clinical and Diagnostic Laboratory Immunology, 10, 696-701.
- 7 Pochard P, Hammad H, Ratajczak C, Charbonnier-Hatzfeld AS, Just N, Tonnel AB, Pestel J, 2005. Direct regulatory immune activity of lactic acid bacteria on Der p 1-pulsed dendritic cells from allergic patients. Journal of Allergy and Clinical Immunology, 116, 198-204.
- 8 Vesa T, Pochart P, Marteau P, 2000. Pharmacokinetics of *Lactobacillus plantarum* NCIMB 8826, *Lactobacillus fermentum* KLD, and *Lactococcus lactis* MG 1363 in the human gastrointestinal tract. Alimentary Pharmacology and Therapeutics, 14, 823-828.

ID 998: *Lactobacillus reuteri* THT 030802

- 1 Dossier submitted by the competent Authority of Belgium on *Lactobacillus reuteri* THT 030802 and digestive health/intestinal flora, ID 998, 2011.
- 2 Asahara T, Nomoto K, Watanuki M, Yokokura T, 2001. Antimicrobial activity of intraurethrally administered probiotic *Lactobacillus casei* in a murine model of *Escherichia coli* urinary tract infection. Antimicrobial Agents and Chemotherapy, 45, 1751-1760.
- 3 Chavagnat F, Haueter M, Jimeno J, Casey MG, 2002. Comparison of partial tuf gene sequences for the identification of lactobacilli. FEMS Microbiology Letters, 217, 177-183.
- 4 Edelman S, Westerlund-Wikstrom B, Leskela S, Kettunen H, Rautonen N, Apajalahti J, Korhonen TK, 2002. In vitro adhesion specificity of indigenous lactobacilli within the avian intestinal tract. Applied and Environmental Microbiology, 68, 5155-5159.
- 5 Jacobsen CN, Nielsen VR, Hayford AE, Moller PL, Michaelsen KF, Paerregaard A, Sandstrom B, Tvede M, Jakobsen M, 1999. Screening of probiotic activities of forty-seven strains of *Lactobacillus* spp. by in vitro techniques and evaluation of the colonization ability of five selected strains in humans. Applied and Environmental Microbiology, 65, 4949-4956.

- 6 Johansson ML, Quednau M, Ahrné S, Molin G, 1995. Classification of *Lactobacillus plantarum* by Restriction Endonuclease Analysis of Total Chromosomal DNA Using Conventional Agarose Gel Electrophoresis. *International Journal of Systematic Bacteriology*, 45, 670-675.
- 7 Jonsson H, Strom E, Roos S, 2001. Addition of mucin to the growth medium triggers mucus-binding activity in different strains of *Lactobacillus reuteri* in vitro. *FEMS Microbiology Letters*, 204, 19-22.
- 8 Kostinek M, Specht I, Edward VA, Schillinger U, Hertel C, Holzapfel WH, Franz CMAP, 2005. Diversity and technological properties of predominant lactic acid bacteria from fermented cassava used for the preparation of Gari, a traditional African food. *Systematic and Applied Microbiology*, 28, 527-540.
- 9 Kwon H-S, Yang E-H, Yeon S-W, Kang B-H, Kim T-Y, 2004. Rapid identification of probiotic *Lactobacillus* species by multiplex PCR using species-specific primers based on the region extending from 16S rRNA through 23S rRNA. *FEMS Microbiology Letters*, 239, 267-275.
- 10 Matsuguchi T, Takagi A, Matsuzaki T, Nagaoka M, Ishikawa K, Yokokura T, Yoshikai Y, 2003. Lipoteichoic acids from *Lactobacillus* strains elicit strong tumor necrosis factor alpha-inducing activities in macrophages through toll-like receptor 2. *Clinical and Diagnostic Laboratory Immunology*, 10, 259-266.
- 11 Miyoshi Y, Okada S, Uchimura T, Satoh E, 2006. A mucus adhesion promoting protein, MapA, mediates the adhesion of *Lactobacillus reuteri* to Caco-2 human intestinal epithelial cells. *Bioscience Biotechnology and Biochemistry*, 70, 1622-1628.
- 12 Nikawa H, Makihira S, Fukushima H, Nishimura H, Ozaki Y, Ishida K, Darmawan S, Hamada T, Hara K, Matsumoto A, Takemoto T, Aimi R, 2004. *Lactobacillus reuteri* in bovine milk fermented decreases the oral carriage of mutans streptococci. *International Journal of Food Microbiology*, 95, 219-223.
- 13 Niv E, Naftali T, Hallak R, Vaismann N, 2005. The efficacy of *Lactobacillus reuteri* ATCC 55730 in the treatment of patients with irritable bowel syndrome - a double blind, placebo-controlled, randomized study. *Clinical Nutrition*, 24, 925-931.
- 14 Song Y-L, Kato N, Liu C-X, Matsumiya Y, Kato H, Watanabe K, 2000. Rapid identification of 11 human intestinal *Lactobacillus* species by multiplex PCR assays using group- and species-specific primers derived from the 16S–23S rRNA intergenic spacer region and its flanking 23S rRNA. *FEMS Microbiology Letters*, 187, 167-173.
- 15 Todoriki K, Mukai T, Sato S, Toba T, 2001. Inhibition of adhesion of food-borne pathogens to Caco-2 cells by *Lactobacillus* strains. *Journal of Applied Microbiology*, 91, 154-159.
- 16 Tubelius P, Stan V, Zachrisson A, 2005. Increasing work-place healthiness with the probiotic *Lactobacillus reuteri*: a randomised, double-blind placebo-controlled study. *Environmental Health: A Global Access Science Source*, 4, 25.
- 17 Valeur N, Engel P, Carbajal N, Connolly E, Ladefoged K, 2004. Colonization and immunomodulation by *Lactobacillus reuteri* ATCC 55730 in the human gastrointestinal tract. *Applied and Environmental Microbiology*, 70, 1176-1181.
- 18 Weizman Z, Asli G, Alsheikh A, 2005. Effect of a probiotic infant formula on infections in child care centers: Comparison of two probiotic agents. *Pediatrics*, 115, 5-9.
- 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.
- 20 Yeung PSM, Sanders ME, Kitts CL, Cano R, Tong PS, 2002. Species-Specific Identification of Commercial Probiotic Strains. *Journal of Dairy Science*, 85, 1039-1051.

ID 999: *Lactobacillus reuteri* THT 030802

- 1 Dossier submitted by the competent Authority of Belgium on *Lactobacillus reuteri* THT 030802 and natural defences/immune system, ID 999, 2011.
- 2 Chavagnat F, Haueter M, Jimeno J, Casey MG, 2002. Comparison of partial tuf gene sequences for the identification of lactobacilli. *FEMS Microbiology Letters*, 217, 177-183.
- 3 Jacobsen CN, Nielsen VR, Hayford AE, Moller PL, Michaelsen KF, Paerregaard A, Sandstrom B, Tvede M, Jakobsen M, 1999. Screening of probiotic activities of forty-seven strains of *Lactobacillus* spp. by in vitro techniques and evaluation of the colonization ability of five selected strains in humans. *Applied and Environmental Microbiology*, 65, 4949-4956.
- 4 Johansson ML, Quednau M, Ahrne S, Molin G, 1995. Classification of *Lactobacillus plantarum* by Restriction Endonuclease Analysis of Total Chromosomal DNA Using Conventional Agarose Gel Electrophoresis. *International Journal of Systematic Bacteriology*, 45, 670-675.
- 5 Kostinek M, Specht I, Edward VA, Schillinger U, Hertel C, Holzapfel WH, Franz CMAP, 2005. Diversity and technological properties of predominant lactic acid bacteria from fermented cassava used for the preparation of Gari, a traditional African food. *Systematic and Applied Microbiology*, 28, 527-540.
- 6 Kwon H-S, Yang E-H, Yeon S-W, Kang B-H, Kim T-Y, 2004. Rapid identification of probiotic *Lactobacillus* species by multiplex PCR using species-specific primers based on the region extending from 16S rRNA through 23S rRNA. *FEMS Microbiology Letters*, 239, 267-275.
- 7 Matsuguchi T, Takagi A, Matsuzaki T, Nagaoka M, Ishikawa K, Yokokura T, Yoshikai Y, 2003. Lipoteichoic acids from *Lactobacillus* strains elicit strong tumor necrosis factor alpha-inducing activities in macrophages through toll-like receptor 2. *Clinical and Diagnostic Laboratory Immunology*, 10, 259-266.
- 8 Nikawa H, Makihira S, Fukushima H, Nishimura H, Ozaki Y, Ishida K, Darmawan S, Hamada T, Hara K, Matsumoto A, Takemoto T, Aimi R, 2004. *Lactobacillus reuteri* in bovine milk fermented decreases the oral carriage of mutans streptococci. *International Journal of Food Microbiology*, 95, 219-223.
- 9 Niv E, Naftali T, Hallak R, Vaisman N, 2005. The efficacy of *Lactobacillus reuteri* ATCC 55730 in the treatment of patients with irritable bowel syndrome - a double blind, placebo-controlled, randomized study. *Clinical Nutrition*, 24, 925-931.
- 10 Song Y-L, Kato N, Liu C-X, Matsumiya Y, Kato H, Watanabe K, 2000. Rapid identification of 11 human intestinal *Lactobacillus* species by multiplex PCR assays using group- and species-specific primers derived from the 16S-23S rRNA intergenic spacer region and its flanking 23S rRNA. *Fems Microbiology Letters*, 187, 167-173.
- 11 Tubelius P, Stan V, Zachrisson A, 2005. Increasing work-place healthiness with the probiotic *Lactobacillus reuteri*: a randomised, double-blind placebo-controlled study. *Environmental Health: A Global Access Science Source*, 4, 25.
- 12 Valeur N, Engel P, Carbajal N, Connolly E, Ladefoged K, 2004. Colonization and immunomodulation by *Lactobacillus reuteri* ATCC 55730 in the human gastrointestinal tract. *Applied and Environmental Microbiology*, 70, 1176-1181.
- 13 Weizman Z, Asli G, Alsheikh A, 2005. Effect of a probiotic infant formula on infections in child care centers: Comparison of two probiotic agents. *Pediatrics*, 115, 5-9.
- 14 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.
- 15 Yeung PSM, Sanders ME, Kitts CL, Cano R, Tong PS, 2002. Species-Specific Identification of Commercial Probiotic Strains. *Journal of Dairy Science*, 85, 1039-1051.

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.
- 2 Dunne C, O'Mahony L, Murphy L, Thornton G, Morrissey D, O'Halloran S, Feeney M, Flynn S, Fitzgerald G, Daly C, Kiely B, O'Sullivan GC, Shanahan F, Collins JK, 2001. In vitro selection criteria for probiotic bacteria of human origin: correlation with in vivo findings. *Am J Clin Nutr*, 73, 386S-392S.
- 3 Li Y, Raftis E, Canchaya C, Fitzgerald GF, van Sinderen D, O'Toole PW, 2006. Polyphasic analysis indicates that *Lactobacillus salivarius* subsp. *salivarius* and *Lactobacillus salivarius* subsp. *salicinius* do not merit separate subspecies status. *International Journal of Systematic and Evolutionary Microbiology*, 56, 2397-2403.
- 4 McCarthy J, O'Mahony L, O'Callaghan L, Sheil B, Vaughan EE, Fitzsimons N, Fitzgibbon J, O'Sullivan GC, Kiely B, Collins JK, Shanahan F, 2003. Double blind, placebo controlled trial of two probiotic strains in interleukin 10 knockout mice and mechanistic link with cytokine balance. *Gut*, 52, 975-980.
- 5 O'Mahony L, Feeney M, O'Halloran S, Murphy L, Kiely B, Fitzgibbon J, Lee G, O'Sullivan G, Shanahan F, Collins JK, 2001. Probiotic impact on microbial flora, inflammation and tumour development in IL-10 knockout mice. *Alimentary Pharmacology and Therapeutics*, 15, 1219-1225.
- 6 Pavan S, Desreumaux P, Mercenier A, 2003. Use of mouse models to evaluate the persistence, safety, and immune modulation capacities of lactic acid bacteria. *Clinical and Diagnostic Laboratory Immunology*, 10, 696-701.
- 7 Rogosa M, Wiseman RF, Mitchell JA, Disraely MN, Beaman AJ, 1953. Species differentiation of oral lactobacilli from man including descriptions of *Lactobacillus salivarius* nov spec and *Lactobacillus cellobiosus* nov spec. *Journal of Bacteriology*, 65, 681.
- 8 Takizawa S, Kojima S, Tamura S, Fujinaga S, Benno Y, Nakase T, 1994. *Lactobacillus kefirgranum* sp. nov. and *Lactobacillus parakefir* sp. nov., two new species from kefir grains. *International Journal of Systematic Bacteriology*, 44, 435-439.

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.
- 2 Dunne C, O'Mahony L, Murphy L, Thornton G, Morrissey D, O'Halloran S, Feeney M, Flynn S, Fitzgerald G, Daly C, Kiely B, O'Sullivan GC, Shanahan F, Collins JK, 2001. In vitro selection criteria for probiotic bacteria of human origin: correlation with in vivo findings. *American Journal of Clinical Nutrition*, 73, 386S-392S.
- 3 Li Y, Raftis E, Canchaya C, Fitzgerald GF, van Sinderen D, O'Toole PW, 2006. Polyphasic analysis indicates that *Lactobacillus salivarius* subsp. *salivarius* and *Lactobacillus salivarius* subsp. *salicinius* do not merit separate subspecies status. *International Journal of Systematic and Evolutionary Microbiology*, 56, 2397-2403.
- 4 McCarthy J, O'Mahony L, O'Callaghan L, Sheil B, Vaughan EE, Fitzsimons N, Fitzgibbon J, O'Sullivan GC, Kiely B, Collins JK, Shanahan F, 2003. Double blind, placebo controlled trial of two probiotic strains in interleukin 10 knockout mice and mechanistic link with cytokine balance. *Gut*, 52, 975-980.
- 5 Morotomi M, Yuki N, Kado Y, Kushiro A, Shimazaki T, Watanabe K, Yuyama T, 2002. *Lactobacillus equi* sp. nov., a predominant intestinal *Lactobacillus* species of the horse isolated

- from faeces of healthy horses. International Journal of Systematic and Evolutionary Microbiology, 52, 211-214.
- 6 O'Mahony L, Feeney M, O'Halloran S, Murphy L, Kiely B, Fitzgibbon J, Lee G, O'Sullivan G, Shanahan F, Collins JK, 2001. Probiotic impact on microbial flora, inflammation and tumour development in IL-10 knockout mice. Alimentary Pharmacology and Therapeutics, 15, 1219-1225.
 - 7 O'Mahony L, O'Callaghan L, McCarthy J, Shilling D, Scully P, Sibartie S, Kavanagh E, Kirwan WO, Redmond HP, Collins JK, Shanahan F, 2006. Differential cytokine response from dendritic cells to commensal and pathogenic bacteria in different lymphoid compartments in humans. American journal of Physiology. Gastrointestinal and Liver Physiology, 290, G839-845.
 - 8 Pavan S, Desreumaux P, Mercenier A, 2003. Use of mouse models to evaluate the persistence, safety, and immune modulation capacities of lactic acid bacteria. Clinical and Diagnostic Laboratory Immunology, 10, 696-701.
 - 9 Rogosa M, Wiseman RF, Mitchell JA, Disraely MN, Beaman AJ, 1953. Species differentiation of oral lactobacilli from man including descriptions of *Lactobacillus salivarius* nov spec and *Lactobacillus cellobiosus* nov spec. Journal of Bacteriology, 65, 681.
 - 10 Sheil B, McCarthy J, O'Mahony L, Bennett MW, Ryan P, Fitzgibbon JJ, Kiely B, Collins JK, Shanahan F, 2004. Is the mucosal route of administration essential for probiotic function? Subcutaneous administration is associated with attenuation of murine colitis and arthritis. Gut, 53, 694-700.
 - 11 Takizawa S, Kojima S, Tamura S, Fujinaga S, Benno Y, Nakase T, 1994. *Lactobacillus kefirgranum* sp. nov. and *Lactobacillus parakefir* sp. nov., two new species from kefir grains. International Journal of Systematic Bacteriology, 44, 435-439.
 - 12 Yuki N, Watanabe K, Mike A, Tagami Y, Tanaka R, Ohwaki M, Morotomi M, 1999. Survival of a probiotic, *Lactobacillus casei* strain Shirota, in the gastrointestinal tract: selective isolation from faeces and identification using monoclonal antibodies. International Journal of Food Microbiology, 48, 51-57.

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.
- 2 Belloch C, Querol A, Garcia MD, Barrio E, 2000. Phylogeny of the genus *Kluyveromyces* inferred from the mitochondrial cytochrome-c oxidase II gene. International Journal of Systematic and Evolutionary Microbiology, 50 Pt 1, 405-416.
- 3 Buts JP, Bernasconi P, Vaerman JP, Dive C, 1990. Stimulation of secretory IgA and secretory component of immunoglobulins in small intestine of rats treated with *Saccharomyces boulardii*. Digestive Diseases and Sciences, 35, 251-256.
- 4 Castagliuolo I, Riegler MF, Valenick L, LaMont JT, Pothoulakis C, 1999. *Saccharomyces boulardii* protease inhibits the effects of *Clostridium difficile* toxins A and B in human colonic mucosa. Infection and Immunity, 67, 302-307.
- 5 Centina-Sauri G and Sierra Basto G, 1994. Therapeutic evaluation of *Saccharomyces boulardii* in children with acute diarrhea. Annales de Pediatrie , 41, 397-400.
- 6 Fietto JL, Araujo RS, Valadao FN, Fietto LG, Brandao RL, Neves MJ, Gomes FC, Nicoli JR, Castro IM, 2004. Molecular and physiological comparisons between *Saccharomyces cerevisiae* and *Saccharomyces boulardii*. Canadian Journal of Microbiology, 50, 615-621.

- 7 Gonzalez SS, Barrio E, Gafner J, Querol A, 2006. Natural hybrids from *Saccharomyces cerevisiae*, *Saccharomyces bayanus* and *Saccharomyces kudriavzevii* in wine fermentations. *FEMS Yeast Research*, 6, 1221-1234.
- 8 Guslandi M, Mezzi G, Sorghi M, Testoni PA, 2000. *Saccharomyces boulardii* in maintenance treatment of Crohn's disease. *Digestive Diseases and Sciences*, 45, 1462-1464.
- 9 Guslandi M, Giollo P, Testoni PA, 2003. A pilot trial of *Saccharomyces boulardii* in ulcerative colitis. *European Journal of Gastroenterology and Hepatology*, 15, 697-698.
- 10 Kollaritsch H, Kemsner P, Wiedermann G, Scheiner O, 1989. Prevention of traveler's diarrhoea. Comparison of different non-antibiotic preparations. *Travel Med Int*, 9-17.
- 11 Kotowska M, Albrecht P, Szajewska H, 2005. *Saccharomyces boulardii* in the prevention of antibiotic-associated diarrhoea in children: a randomized double-blind placebo-controlled trial. *Alimentary Pharmacology and Therapeutics*, 21, 583-590.
- 12 Kurtzman CP and Robnett CJ, 1998. Identification and phylogeny of ascomycetous yeasts from analysis of nuclear large subunit (26S) ribosomal DNA partial sequences. *Antonie van Leeuwenhoek*, 73, 331-371.
- 13 Kurtzman CP and Robnett CJ, 2003. Phylogenetic relationships among yeasts of the 'Saccharomyces complex' determined from multigene sequence analyses. *FEMS Yeast Research*, 3, 417-432.
- 14 Kurugol Z and Koturoglu G, 2005. Effects of *Saccharomyces boulardii* in children with acute diarrhoea. *Acta Paediatrica*, 94, 44-47.
- 15 Maupas J, Champemont P, Delforge M, 1983. Treatment of irritable bowel syndrome with *Saccharomyces boulardii*: a double blind, placebo controlled study. *Medicine Chirurgie Digestives*, 12, 77-79.
- 16 McFarland L and Bernasconi P, 1993. *Saccharomyces boulardii*: a review of an innovative biotherapeutic agent. *Microbial Ecology in Health and Disease*, 6, 157-171.
- 17 McFarland LV, Surawicz CM, Greenberg RN, Fekety R, Elmer GW, Moyer KA, Melcher SA, Bowen KE, Cox JL, Noorani Z, et al., 1994. A randomized placebo-controlled trial of *Saccharomyces boulardii* in combination with standard antibiotics for *Clostridium difficile* disease. *JAMA*, 271, 1913-1918.
- 18 McFarland LV, Surawicz CM, Greenberg RN, Elmer GW, Moyer KA, Melcher SA, Bowen KE, Cox JL, 1995. Prevention of beta-lactam-associated diarrhea by *Saccharomyces boulardii* compared with placebo. *American Journal of Gastroenterology*, 90, 439-448.
- 19 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.
- 20 Vandenplas Y, 1999. Bacteria and yeasts in the treatment of acute and chronic infectious diarrhea. Part II: Yeasts. *Clinical Microbiology and Infection*, 5, 389-395.
- 21 Villarruel G, Rubio DM, Lopez F, Cintioni J, Gurevech R, Romero G, Vandenplas Y, 2007. *Saccharomyces boulardii* in acute childhood diarrhoea: a randomized, placebo-controlled study. *Acta Paediatrica*, 96, 538-541.

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.
- 2 Belloch C, Querol A, Garcia MD, Barrio E, 2000. Phylogeny of the genus *Kluyveromyces* inferred from the mitochondrial cytochrome-c oxidase II gene. International Journal of Systematic and Evolutionary Microbiology, 50 Pt 1, 405-416.
- 3 Buts JP, Bernasconi P, Van Craynest MP, Maldague P, De Meyer R, 1986. Response of human and rat small intestinal mucosa to oral administration of *Saccharomyces boulardii*. Pediatric Research, 20, 192-196.
- 4 Buts JP, Bernasconi P, Vaerman JP, Dive C, 1990. Stimulation of secretory IgA and secretory component of immunoglobulins in small intestine of rats treated with *Saccharomyces boulardii*. Digestive Diseases and Sciences, 35, 251-256.
- 5 Caetano JA, Parames MT, Babo MJ, Santos A, Ferreira AB, Freitas AA, Coelho MR, Mateus AM, 1986. Immunopharmacological effects of *Saccharomyces boulardii* in healthy human volunteers. International Journal of Immunopharmacology, 8, 245-259.
- 6 Gonzalez SS, Barrio E, Gafner J, Querol A, 2006. Natural hybrids from *Saccharomyces cerevisiae*, *Saccharomyces bayanus* and *Saccharomyces kudriavzevii* in wine fermentations. FEMS Yeast Research, 6, 1221-1234.
- 7 Kurtzman CP and Robnett CJ, 1998. Identification and phylogeny of ascomycetous yeasts from analysis of nuclear large subunit (26S) ribosomal DNA partial sequences. Antonie van Leeuwenhoek, 73, 331-371.
- 8 Kurtzman CP and Robnett CJ, 2003. Phylogenetic relationships among yeasts of the 'Saccharomyces complex' determined from multigene sequence analyses. FEMS Yeast Research, 3, 417-432.
- 9 McFarland L and Bernasconi P, 1993. *Saccharomyces boulardii*: a review of an innovative biotherapeutic agent. Microbial Ecology in Health and Disease, 6, 157-171.
- 10 Rodrigues AC, Cara DC, Fretez SH, Cunha FQ, Vieira EC, Nicoli JR, Vieira LQ, 2000. *Saccharomyces boulardii* stimulates sIgA production and the phagocytic system of gnotobiotic mice. Journal of Applied Microbiology, 89, 404-414.
- 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.
- 12 Vandenplas Y, 1999. Bacteria and yeasts in the treatment of acute and chronic infectious diarrhea. Part II: Yeasts. Clinical Microbiology and Infection, 5, 389-395.
- 13 Zanello G, Meurens F, Berri M, Salmon H, 2009. *Saccharomyces boulardii* effects on gastrointestinal diseases. Current Issues in Molecular Biology, 11, 47-58.

ID 1014: *Streptococcus thermophilus* THT 070102

- 1 Dossier submitted by the competent Authority of Belgium on *Streptococcus thermophilus* THT 070102 and digestive health/intestinal flora, ID 1014. 2011.
- 2 BCCM/LMG, 2011. Report on DNA fingerprinting (AFLPTM) of 6 bacterial cultures using two primer combinations.
- 3 Conway PL, Gorbach SL, Goldin BR, 1987. Survival of lactic acid bacteria in the human stomach and adhesion to intestinal cells. Journal of Dairy Science, 70, 1-12.

- 4 Dilmi-Bouras A and Sadoun D, 2002. Survie des ferment du yaourt dans le tube digestif du lapin. Lait, 82, 247-253.
- 5 Marteau P, Minekus M, Havenaar R, Huis in't Veld JH, 1997. Survival of lactic acid bacteria in a dynamic model of the stomach and small intestine: validation and the effects of bile. Journal of Dairy Science, 80, 1031-1037.
- 6 Venturi A, Gionchetti P, Rizzello F, Johansson R, Zucconi E, Brigidi P, Matteuzzi D, Campieri M, 1999. Impact on the composition of the faecal flora by a new probiotic preparation: preliminary data on maintenance treatment of patients with ulcerative colitis. Alimentary Pharmacology and Therapeutics, 13, 1103-1108.

ID 1015: *Streptococcus thermophylus* THT 070102

- 1 Dossier submitted by the competent Authority of Belgium on *Streptococcus thermophilus* THT 070102 and natural defences/immune system, ID 1015. 2011.
- 2 BCCM/LMG, 2011. Report on DNA fingerprinting (AFLPTM) of 6 bacterial cultures using two primer combinations.
- 3 Conway PL, Gorbach SL, Goldin BR, 1987. Survival of lactic acid bacteria in the human stomach and adhesion to intestinal cells. Journal of Dairy Science, 70, 1-12.
- 4 Dilmi-Bouras A and Sadoun D, 2002. Survie des ferment du yaourt dans le tube digestif du lapin. Lait, 82, 247-253.
- 5 Marteau P, Minekus M, Havenaar R, Huis in't Veld JH, 1997. Survival of lactic acid bacteria in a dynamic model of the stomach and small intestine: validation and the effects of bile. Journal of Dairy Science, 80, 1031-1037.
- 6 Perdigon G, Nader de Macias ME, Alvarez S, Oliver G, Pesce de Ruiz Holgado AA, 1987. Enhancement of immune response in mice fed with *Streptococcus thermophilus* and *Lactobacillus acidophilus*. Journal of Dairy Science, 70, 919-926.
- 7 Solis-Pereyra B, Aattouri N, Lemonnier D, 1997. Role of food in the stimulation of cytokine production. American Journal of Clinical Nutrition, 66, 521S-525.
- 8 Venturi A, Gionchetti P, Rizzello F, Johansson R, Zucconi E, Brigidi P, Matteuzzi D, Campieri M, 1999. Impact on the composition of the faecal flora by a new probiotic preparation: preliminary data on maintenance treatment of patients with ulcerative colitis. Alimentary Pharmacology and Therapeutics, 13, 1103-1108.

ID 1030: *Lactobacillus crispatus* P 17631

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus crispatus* P17631, ID1030. 2011.
- 2 AAT, 2011. Report on sample key for AFLP study.
- 3 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus crispatus* P17631, using molecular methods.
- 4 BCCM/LMG, 1997. Report on the identification of 3 bacterial isolates.
- 5 Dondi G and Morelli L, 1999. Lactobacilli strains having inhibitory and/or microbicidal activity against pathogenic microorganisms and a method for inducing and keeping said activity in lactobacilli cultures, EP0949330A2, European Patent Office.
- 6 Dondi G and Morelli L, 2002. Lactobacilli strains having inhibitory and/or microbicidal activity against pathogenic microorganisms and a method for inducing and keeping said activity in lactobacilli cultures, US6342366B1, United States Patent and Trademark Office.

- 7 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. *Applied and Environmental Microbiology*, 59, 945.
- 8 Morelli L, 1997. Microbiological analysis of 6 strains of lactobacillus for a patent deposit. Università Cattolica del Sacro Cuore di Piacenza.
- 9 Pietronave S, Bonetti A, Martinotti MG, 2003. Caratterizzazione delle proprietà probiotiche di alcuni ceppi del genere *Lactobacillus* spp. Proceedings of the 5° Congresso Federazione Italiana Scienze della Vita (FISV), 168.
- 10 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. *Systematic and Applied Microbiology*, 23, 504-509.

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.
- 2 Del Piano M, Montino F, Carmagnola S, Anderloni A, Orsello M, Garello E, Sforza F, Ballare M, 2005. The use of probiotics in the treatment of constipation in the elderly. *Cibus*, 1, 23-30.
- 3 Del Piano M, Carmagnola S, Anderloni A, Andorno S, Ballarà M, Balzarini M, Montino F, Orsello M, Pagliarulo M, Sartori M, 2010. The use of probiotics in healthy volunteers with evacuation disorders and hard stools: a double-blind, randomized, placebo-controlled study. *Journal of Clinical Gastroenterology*, 44, S30-34.
- 4 Del Piano M, Carmagnola S, Andorno S, Pagliarulo M, Tari R, Mogna L, Strozzi GP, Sforza F, Capurso L, 2010. Evaluation of the intestinal colonization by microencapsulated probiotic bacteria in comparison with the same uncoated strains. *Journal of Clinical Gastroenterology*, 44 Suppl 1, S42-46.
- 5 Del Piano M, Carmagnola S, Ballarà M, Sartori M, Orsello M, Balzarini M, Pagliarulo M, Tari R, Anderloni A, Strozzi GP, Mogna L, Sforza F, Capurso L, 2011. Is microencapsulation the future of probiotic preparations? The increased efficacy of gastro-protected probiotics. *Gut Microbes*, 2, 120-123.
- 6 Nicola S, Mogna L, Allesina S, Barba M, al. e, 2010. Interaction between probiotics and human immune cells. The prospective anti-inflammatory activity of *Bifidobacterium breve BR03 AgroFOOD*, 21, S44-47.

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.
- 2 Del Piano M, Montino F, Carmagnola S, Anderloni A, Orsello M, Garello E, Sforza F, Ballare M, 2005. The use of probiotics in the treatment of constipation in the elderly. *Cibus*, 1, 23-30.

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 plantarum LP 01 (LMG P-21021)* and Intestinal transit time, ID 2938. 2011.
- 2 Del Piano M, Carmagnola S, Anderloni A, Andorno S, Ballarà M, Balzarini M, Montino F, Orsello M, Pagliarulo M, Sartori M, 2010. The use of probiotics in healthy volunteers with

evacuation disorders and hard stools: a double-blind, randomized, placebo-controlled study. Journal of Clinical Gastroenterology, 44, S30-34.

- 3 Del Piano M, Carmagnola S, Andorno S, Pagliarulo M, Tari R, Mogna L, Strozzi GP, Sforza F, Capurso L, 2010. Evaluation of the intestinal colonization by microencapsulated probiotic bacteria in comparison with the same uncoated strains. Journal of Clinical Gastroenterology, 42, S42-46.
- 4 Del Piano M, Carmagnola S, Ballaré M, Sartori M, Orsello M, Balzarini M, Pagliarulo M, Tari R, Anderloni A, Strozzi GP, Mogna L, Sforza F, Capurso L, 2011. Is microencapsulation the future of probiotic preparations? The increased efficacy of gastro-protected probiotics. Gut Microbes, 2, 120-123.
- 5 Nicola S, Mogna L, Allesina S, Barba M, al. e, 2010. Interaction between probiotics and human immune cells. The prospective anti-inflammatory activity of *Bifidobacterium breve* BR03 AgroFOOD, 21, S44-47.
- 6 Saggioro A, 2004. Probiotics in the treatment of irritable bowel syndrome. Journal of Clinical Gastroenterology, 38, S104.

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.
- 2 Del Piano M, Montino F, Carmagnola S, Anderloni A, Orsello M, Garello E, Sforza F, Ballare M, 2005. The use of probiotics in the treatment of constipation in the elderly. Cibus, 1, 23-30.
- 3 Del Piano M, Carmagnola S, Anderloni A, Andorno S, Ballaré M, Balzarini M, Montino F, Orsello M, Pagliarulo M, Sartori M, 2010. The use of probiotics in healthy volunteers with evacuation disorders and hard stools: a double-blind, randomized, placebo-controlled study. Journal of Clinical Gastroenterology, 44, S30-34.

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.
- 2 Del Piano M, Carmagnola S, Anderloni A, Andorno S, Ballaré M, Balzarini M, Montino F, Orsello M, Pagliarulo M, Sartori M, 2010. The use of probiotics in healthy volunteers with evacuation disorders and hard stools: a double-blind, randomized, placebo-controlled study. Journal of Clinical Gastroenterology, 44, S30-34.
- 3 Pregliasco F, Anselmi G, Fonte L, Giussani F, Schieppati S, Soletti L, 2008. A new chance of preventing winter diseases by the administration of synbiotic formulations. Journal of Clinical Gastroenterology, 42, S224-S233.

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.
- 2 Finamore A, 2011. Immunological changes in elderly subjects after probiotic supplementation. Abstract presented in World Immune Regulation Meeting V, 24.-27. March 2011, Davos.
- 3 Identification from Lallemand Supply's Frame Agreement 956-2011U-07

- 4 Naser SM, Hagen KE, Vancanneyt M, Cleenwerck I, Swings J, Tompkins TA, 2006. *Lactobacillus suntoryeus* Cachat and Priest 2005 is a later synonym of *Lactobacillus helveticus* (Orla-Jensen 1919) Bergey et al. 1925 (Approved Lists 1980). International Journal of Systematic and Evolutionary Microbiology, 56, 355-360.
- 5 Vitali B, Ndagijimana M, Cruciani F, Carnevali P, Candela M, Guerzoni M, Brigidi P, 2010. Impact of a synbiotic food on the gut microbial ecology and metabolic profiles. BMC Microbiology, 10, 4.

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.
- 2 Del Piano M, Carmagnola S, Anderloni A, Andorno S, Ballaré M, Balzarini M, Montino F, Orsello M, Pagliarulo M, Sartori M, 2010. The use of probiotics in healthy volunteers with evacuation disorders and hard stools: a double-blind, randomized, placebo-controlled study. Journal of Clinical Gastroenterology, 44, S30-34.
- 3 Del Piano M, Carmagnola S, Andorno S, Pagliarulo M, Tari R, Mogna L, Strozzi GP, Sforza F, Capurso L, 2010. Evaluation of the intestinal colonization by microencapsulated probiotic bacteria in comparison with the same uncoated strains. Journal of Clinical Gastroenterology, 42, S42-46.
- 4 Del Piano M, Carmagnola S, Ballaré M, Sartori M, Orsello M, Balzarini M, Pagliarulo M, Tari R, Anderloni A, Strozzi GP, Mogna L, Sforza F, Capurso L, 2011. Is microencapsulation the future of probiotic preparations? The increased efficacy of gastro-protected probiotics. Gut Microbes, 2, 120-123.
- 5 Saggioro A, 2004. Probiotics in the treatment of irritable bowel syndrome. Journal of Clinical Gastroenterology, 38, 104-106.

ID 2946: *Lactobacillus acidophilus P 18806*

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus acidophilus P18806*, ID 2946. 2011.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus acidophilus P18806*, using molecular methods.
- 3 BCCM/LMG, 1999. Report on the determination of carbohydrate fermentation pattern SDS-PAGE protein profiling.
- 4 Bernet MF, Brassart D, Neeser JR, Servin AL, 1994. *Lactobacillus acidophilus LA 1* binds to cultured human intestinal cell lines and inhibits cell attachment and cell invasion by enterovirulent bacteria. Gut, 35, 483.
- 5 Dondi G, 2000. Method for the selection of adhesive lactobacilli strains having therapeutical properties and strains obtained by said method, EP1046713A2, European Patent Office.
- 6 Elli M, Callegari ML, Ferrari S, Bessi E, Cattivelli D, Soldi S, Morelli L, Goupil Feuillerat N, Antoine JM, 2006. Survival of yogurt bacteria in the human gut. Applied and Environmental Microbiology, 72, 5113-5117.
- 7 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. Applied and Environmental Microbiology, 59, 945.

- 8 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. *Systematic and Applied Microbiology*, 23, 504-509.

ID 2947: *Lactobacillus acidophilus* P 18806

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus acidophilus* P18806, ID 2947. 2011.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus acidophilus* P18806, using molecular methods.
- 3 BCCM/LMG, 1999. Report on the determination of carbohydrate fermentation pattern SDS-PAGE protein profiling.
- 4 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. *Applied and Environmental Microbiology*, 59, 945.
- 5 Mastrandrea F, Coradduzza G, Serio G, Minardi A, Manelli M, Ardito S, Muratore L, 2004. Probiotics reduce the CD34+ hemopoietic precursor cell increased traffic in allergic subjects. *European Annals of Allergy and Clinical Immunology*, 36, 118-122.6 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. *Systematic and Applied Microbiology*, 23, 504-509.

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.
- 2 D'Incà R, Barollo M, Scarpa M, Grillo A, Brun P, Vettorato M, Castagliuolo I, Sturniolo G, 2011. Rectal Administration of *Lactobacillus casei* DG Modifies Flora Composition and Toll-Like Receptor Expression in Colonic Mucosa of Patients with Mild Ulcerative Colitis. *Digestive Diseases and Sciences*, 56, 1178-1187.
- 3 Drago L, De Vecchi E, Valli M, Nicola L, Lomabardi A, Gismondo MR, 2002. Colonizzazione intestinale di *Lactobacillus casei* subsp.*casei* l-1572 CNCM (*L.casei* DG) in volontari sani e in topi germ-free. *Farmaci e Terapia*, 19, 72-76.
- 4 Tursi A, Brandimarte G, Giorgetti GM, Modeo ME, 2004. Effect of *Lactobacillus casei* supplementation on the effectiveness and tolerability of a new second-line 10-day quadruple therapy after failure of a first attempt to cure *Helicobacter pylori* infection. *Medical Science Monitor: International Medical Journal of Experimental and Clinical Research*, 10, CR662.
- 5 Tursi A, Brandimarte G, Giorgetti GM, Elisei W, 2006. Mesalazine and/or *Lactobacillus casei* in preventing recurrence of symptomatic uncomplicated diverticular disease of the colon: a prospective, randomized, open-label study. *Journal of Clinical Gastroenterology*, 40, 312.
- 6 Tursi A, Brandimarte G, Marco Giorgetti G, Elisei W, 2008. Mesalazine and/or *Lactobacillus casei* in maintaining long-term remission of symptomatic uncomplicated diverticular disease of the colon. *Hepato-gastroenterology*, 55, 916-920.

ID 2950: *Lactobacillus crispatus* P 17631

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus crispatus* P17631, ID 2950. 2011.
- 2 AAT, 2011. Report on sample key for AFLP study.

- 3 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, Lactobacillus crispatus P17631, using molecular methods.
- 4 BCCM/LMG, 1997. Report on the identification of 3 bacterial isolates.
- 5 Dondi G and Morelli L, 1999. Lactobacilli strains having inhibitory and/or microbicidal activity against pathogenic microorganisms and a method for inducing and keeping said activity in lactobacilli cultures, EP0949330A2, European Patent Office.
- 6 Dondi G and Morelli L, 2002. Lactobacilli strains having inhibitory and/or microbicidal activity against pathogenic microorganisms and a method for inducing and keeping said activity in lactobacilli cultures, US6342366B1, United States Patent and Trademark Office.
- 7 Gianella C, 2003. Activity and tolerability study of lactobacillus crispatus P 17631 vaginal capsules administered in repeated dose regimen to 24 females suffering from vaginal infections. Institute for Pharmacokinetic and Analytical Studies, Ligornetto, Switzerland.
- 8 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. Applied and Environmental Microbiology, 59, 945.
- 9 Morelli L, 1997. Microbiological analysis of 6 strains of lactobacillus for a patent deposit. Final report.
- 10 Pietronave S, Bonetti A, Martinotti MG, 2003. Caratterizzazione delle proprietà probiotiche di alcuni ceppi del genere Lactobacillus spp. Atti del 5° Congresso Federazione Italiana Scienze della Vita (FISV), Rimini, 168.
- 11 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of Lactobacillus spp. Isolated from Fecal and Vaginal Samples. Systematic and Applied Microbiology, 23, 504-509.

ID 2951: Lactobacillus delbrueckii P 18805

- 1 Dossier submitted by the competent Authority of Italy on Lactobacillus delbrueckii P18805, ID 2951. 2011.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, Lactobacillus delbrueckii P18805, using molecular methods.
- 3 AAT, 2011. Report on sample key for AFLP study.
- 4 BCCM/LMG, 1999. Report on the determination of carbohydrate fermentation pattern SDS-PAGE protein profiling.
- 5 Dondi G, 2000. Method for the selection of adhesive lactobacilli strains having therapeutical properties and strains obtained by said method, EP1046713A2, European Patent Office.
- 6 Elli M, Callegari ML, Ferrari S, Bessi E, Cattivelli D, Soldi S, Morelli L, Goupil Feuillerat N, Antoine JM, 2006. Survival of yogurt bacteria in the human gut. Appl Environ Microbiol, 72, 5113-5117.
- 7 Giraffa G, De Vecchi P, Rossetti L, 1998. Note: Identification of Lactobacillus delbrueckii subspecies bulgaricus and subspecies lactis dairy isolates by amplified rDNA restriction analysis. Journal of Applied Microbiology, 85, 918-918.
- 8 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. Applied and Environmental Microbiology, 59, 945.
- 9 Miteva V, Boudakov I, Ivanova-Stoyancheva G, Marinova B, Mitev V, Mengaud J, 2001. Differentiation of Lactobacillus delbrueckii subspecies by ribotyping and amplified ribosomal DNA restriction analysis (ARDRA). Journal of Applied Microbiology, 90, 909-918.

- 10 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. *Systematic and Applied Microbiology*, 23, 504-509.

ID 2952: *Lactobacillus delbrueckii* P 18805

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus delbrueckii* P18805, ID 2952. 2011.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus delbrueckii* P18805, using molecular methods.
- 3 AAT, 2011. Report on sample key for AFLP study.
- 4 BCCM/LMG, 1999. Report on the determination of carbohydrate fermentation pattern SDS-PAGE protein profiling.
- 5 Giraffa G, De Vecchi P, Rossetti L, 1998. Note: Identification of *Lactobacillus delbrueckii* subspecies *bulgaricus* and subspecies *lactis* dairy isolates by amplified rDNA restriction analysis. *Journal of Applied Microbiology*, 85, 918-918.
- 6 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. *Applied and Environmental Microbiology*, 59, 945.
- 7 Mastrandrea F, Coradduzza G, Serio G, Minardi A, Manelli M, Ardito S, Muratore L, 2004. Probiotics reduce the CD34+ hemopoietic precursor cell increased traffic in allergic subjects. *European Annals of Allergy and Clinical Immunology*, 36, 118-122.
- 8 Miteva V, Boudakov I, Ivanova-Stoyancheva G, Marinova B, Mitev V, Mengaud J, 2001. Differentiation of *Lactobacillus delbrueckii* subspecies by ribotyping and amplified ribosomal DNA restriction analysis (ARDRA). *Journal of Applied Microbiology*, 90, 909-918.
- 9 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. *Systematic and Applied Microbiology*, 23, 504-509.

ID 2956: *Lactobacillus gasseri* P 17632

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus gasseri* P17632, ID 2956. 2011.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus gasseri* P 17632, using molecular methods.
- 3 BCCM/LMG, 1997. Report on the identification of 3 bacterial isolates.
- 4 Dondi G and Morelli L, 1999. Lactobacilli strains having inhibitory and/or microbicidal activity against pathogenic microorganisms and a method for inducing and keeping said activity in lactobacilli cultures, EP0949330A2, European Patent Office.
- 5 Dondi G and Morelli L, 2002. Lactobacilli strains having inhibitory and/or microbicidal activity against pathogenic microorganisms and a method for inducing and keeping said activity in lactobacilli cultures, US6342366B1, United States Patent and Trademark Office.
- 6 Dondi G, 2004. Use of agent active against *Candida* in the treatment of disorders of the oral and intestinal mucosa, US2004/0043011A1, United States Patent and Trademark Office.
- 7 Dondi G, 2007. Use of agents active against *Candida* in the treatment of disorders of the oral and intestinal mucosa, EP1339419B1, European Patent Office.

- 8 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. *Applied and Environmental Microbiology*, 59, 945.
- 9 Morelli L, 1997. Microbiological analysis of 6 strains of lactobacillus for a patent deposit. Università Cattolica del Sacro Cuore di Piacenza.
- 10 Pietronave S, Bonetti A, Martinotti MG, 2003. Caratterizzazione delle proprietà probiotiche di alcuni ceppi del genere *Lactobacillus* spp. Atti del 5° Congresso Federazione Italiana Scienze della Vita (FISV), Rimini, 168.
- 11 Pietronave S, Malfa P, Martinotti MG, 2004. *Lactobacillus gasseri* P17632: a potential probiotic strain. Atti del 6° Congresso Federazione Italiana Scienze della Vita (FISV), Riva del Garda, 473.
- 12 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. *Systematic and Applied Microbiology*, 23, 504-509.

ID 2957: *Lactobacillus gasseri* BCCM/LMG P 18137

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus gasseri* P18137, ID2957. 2011.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus gasseri* P18137, using molecular methods.
- 3 BCCM/LMG, 1998. Report on the determination of carbohydrate fermentation pattern.
- 4 Dondi G and Morelli L, 1999. Lactobacilli strains having inhibitory and/or microbicidal activity against pathogenic microorganisms and a method for inducing and keeping said activity in lactobacilli cultures, EP0949330A2, European Patent Office.
- 5 Dondi G and Morelli L, 2002. Lactobacilli strains having inhibitory and/or microbicidal activity against pathogenic microorganisms and a method for inducing and keeping said activity in lactobacilli cultures, US6342366B1, United States Patent and Trademark Office.
- 6 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. *Applied and Environmental Microbiology*, 59, 945.
- 7 Pietronave S, Bonetti A, Martinotti MG, 2003. Caratterizzazione delle proprietà probiotiche di alcuni ceppi del genere *Lactobacillus* spp. Atti del 5° Congresso Federazione Italiana Scienze della Vita (FISV), Rimini, 168.
- 8 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. *Systematic and Applied Microbiology*, 23, 504-509.

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

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus gasseri* P18137, ID 2958. 2011.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus gasseri* P18137, using molecular methods.
- 3 BCCM/LMG, 1998. Report on the determination of carbohydrate fermentation pattern.
- 4 Dondi G and Morelli L, 1999. Lactobacilli strains having inhibitory and/or microbicidal activity against pathogenic microorganisms and a method for inducing and keeping said activity in lactobacilli cultures, EP0949330A2, European Patent Office.

- 5 Dondi G and Morelli L, 2002. Lactobacilli strains having inhibitory and/or microbicidal activity against pathogenic microorganisms and a method for inducing and keeping said activity in lactobacilli cultures, US6342366B1, United States Patent and Trademark Office.
- 6 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. Applied and Environmental Microbiology, 59, 945.
- 7 Pietronave S, Bonetti A, Martinotti MG, 2003. Caratterizzazione delle proprietà probiotiche di alcuni ceppi del genere *Lactobacillus* spp. Atti del 5° Congresso Federazione Italiana Scienze della Vita (FISV), Rimini, 168.
- 8 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. Systematic and Applied Microbiology, 23, 504-509.

ID 2960: *Lactobacillus paracasei* CNCM I 1687

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus paracasei* I1687, ID 2960. 2011.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus paracasei* I1687, using molecular methods.
- 3 AAT, 2011. Report on sample key for AFLP study.
- 4 Castellazzi A, 2007. In vitro study on the immunomodulant properties of the bacterial strain *Lactobacillus paracasei* I 1687. University of Pavia, Department of Pediatric Sciences, Immunity and Nutrition Laboratory.
- 5 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. Applied and Environmental Microbiology, 59, 945.
- 6 Morelli L, 1996. Identification of two strains of *lactobacillus* for a patent deposit. Università Cattolica del Sacro Cuore di Piacenza.
- 7 Morelli L, 1997. Microbiological analysis of 6 strains of *lactobacillus* for a patent deposit. Università Cattolica del Sacro Cuore di Piacenza.
- 8 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. Systematic and Applied Microbiology, 23, 504-509.

ID 2961: *Lactobacillus paracasei* CNCM I 1687

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus paracasei* I1687, ID 2961. 2011.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus paracasei* I1687, using molecular methods.
- 3 AAT, 2011. Report on sample key for AFLP study.
- 4 Bonetti A, 2002. Assessment of the persistence in the human intestinal tract of two probiotic lactobacilli *Lactobacillus salivarius* I 1794 and *Lactobacillus paracasei* I 1688. Microbial Ecology in Health and Disease, 14, 229-233.
- 5 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. Applied and Environmental Microbiology, 59, 945.

- 6 Morelli L, 1996. Identification of two strains of lactobacillus for a patent deposit. Università Cattolica del Sacro Cuore di Piacenza.
- 7 Morelli L, 1997. Microbiological analysis of 6 strains of lactobacillus for a patent deposit. Università Cattolica del Sacro Cuore di Piacenza.
- 8 Pedraglio G, 2004. Novel lactobacilli strains useful in the treatment of disorders of the gastrointestinal system, EP0861905B1, European Patent Office.
- 9 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of Lactobacillus spp. Isolated from Fecal and Vaginal Samples. Systematic and Applied Microbiology, 23, 504-509.

ID 2962: Lactobacillus paracasei CNCM I 1688

- 1 Dossier submitted by the competent Authority of Italy on Lactobacillus paracasei I1688, ID 2962. 2011.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, Lactobacillus paracasei I1688, using molecular methods.
- 3 Castellazzi A, Avanzini MA, Oliveri M, Valsecchi C, Malfa P, Marseglia G, 2006. "In vitro" and "in vivo" immunomodulant attivity of PSMIX (Lactobacillus paracasei I 1688 and Lactobacillus salivarius I 1794). Poster at the 6th Annual Meeting of the Federation of Clinical Immunology Societies, San Francisco.
- 4 Castellazzi AM, 2007a, unpublished. Final report on Florilac Trial. University of Pavia.
- 5 Castellazzi AM, Valsecchi C, Montagna L, Malfa P, Ciprandi G, Avanzini MA, Marseglia GL, 2007b. In vitro activation of mononuclear cells by two probiotics: Lactobacillus paracasei I 1688, Lactobacillus salivarius I 1794, and their mixture (PSMIX). Immunological Investigations, 36, 413-421.
- 6 Dondi G and Malfa P, 2007. Use of specific lactic bacteria for the preparation of immunomodulating compositions, WO2007/015132A2, Organization WIP.
- 7 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. Applied and Environmental Microbiology, 59, 945.
- 8 Morelli L, 1996. Identification of two strains of lactobacillus for a patent deposit. Università Cattolica del Sacro Cuore di Piacenza.
- 9 Morelli L, 1997. Microbiological analysis of 6 strains of lactobacillus for a patent deposit. Università Cattolica del Sacro Cuore di Piacenza.
- 10 Valsecchi C, Marseglia A, Licari A, Montagna L, Leone M, Marseglia G, Castellazzi AM, 2008. PSMIX nuova miscela brevettata a base di L. paracasei I-1688 e L. salivarius I-1794: attivita probiotiche e razionale di impiego clinico. Archives of Medical Therapy, 2, 9-14.
- 11 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of Lactobacillus spp. Isolated from Fecal and Vaginal Samples. Systematic and Applied Microbiology, 23, 504-509.

ID 2963: Lactobacillus paracasei CNCM I 1688

- 1 Dossier submitted by the competent Authority of Italy on Lactobacillus paracasei I1688, ID 2963. 2011.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, Lactobacillus paracasei I1688, using molecular methods.

- 3 Bonetti A, Morelli L, Campominosi E, 2002. Assessment of the persistence in the human intestinal tract of two probiotic lactobacilli *Lactobacillus salivarius* I 1794 and *Lactobacillus paracasei* I 1688. *Microbial Ecology in Health and Disease*, 14, 229-233.
- 4 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. *Applied and Environmental Microbiology*, 59, 945.
- 5 Morelli L, 1996. Identification of two strains of *lactobacillus* for a patent deposit. Università Cattolica del Sacro Cuore di Piacenza.
- 6 Morelli L, 1997. Microbiological analysis of 6 strains of *lactobacillus* for a patent deposit. Università Cattolica del Sacro Cuore di Piacenza.
- 7 Pedraglio G, 2004. Novel lactobacilli strains useful in the treatment of disorders of the gastrointestinal system, EP0861905B1, European Patent Office.
- 8 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. *Systematic and Applied Microbiology*, 23, 504-509.

ID 2965: *Lactobacillus plantarum* LP 01

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus plantarum* LP01 (LMG P-21021), ID 2965. 2011.
- 2 Del Piano M, Montino F, Carmagnola S, Anderloni A, Orsello M, Garello E, Sforza F, Ballare M, 2005. The use of probiotics in the treatment of constipation in the elderly. *Cibus*, 1, 23-30.
- 3 Del Piano M, Carmagnola S, Anderloni A, Andorno S, Ballare M, Balzarini M, Montino F, Orsello M, Pagliarulo M, Sartori M, 2010. The use of probiotics in healthy volunteers with evacuation disorders and hard stools: a double-blind, randomized, placebo-controlled study. *Journal of Clinical Gastroenterology*, 44, S30-34.
- 4 Del Piano M, Carmagnola S, Andorno S, Pagliarulo M, Tari R, Mogna L, Strozzi GP, Sforza F, Capurso L, 2010. Evaluation of the intestinal colonization by microencapsulated probiotic bacteria in comparison with the same uncoated strains. *Journal of Clinical Gastroenterology*, 44, S42-46.
- 5 Del Piano M, Carmagnola S, Ballare M, Sartori M, Orsello M, Balzarini M, Pagliarulo M, Tari R, Anderloni A, Strozzi GP, 2011. Is microencapsulation the future of probiotic preparations? *Gut Microbes*, 2, 120-123.

ID 2966: *Lactobacillus plantarum* BCCM/LMG P 17630

- 1 Report on Semiautomatic annotation of one *Lactobacillus plantarum* (LPL2) genome. 2010.
- 2 Dossier submitted by the competent Authority of Italy on *Lactobacillus plantarum* P17630, ID 2966. 2011.
- 3 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus plantarum* P17630, using molecular methods.
- 4 BCCM/LMG, 1997. Report on the identification of 3 bacterial isolates.
- 5 Dho G, Marchese A, Debbia E, 2003. Microbiological characteristics of *Lactobacillus plantarum* P17630 contained in vaginal suppositories. *Giornale Italiano di Microbiologia Medica Odontoiatrica e Clinica*, 7, 102-108.
- 6 Dondi G, 2000. Method for the selection of adhesive lactobacilli strains having therapeutical properties and strains obtained by said method, EP1046713A2, European Patent Office.

- 7 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. *Applied and Environmental Microbiology*, 59, 945.
- 8 Morelli L, 1997. Microbiological analysis of 6 strains of lactobacillus for a patent deposit. Università Cattolica del Sacro Cuore di Piacenza.
- 9 Morelli L, 2000. Microbiological characteristics of *Lactobacillus Plantarum* P17630 contained in vaginal suppositories. Università Cattolica del Sacro Cuore di Piacenza.
- 10 Pietronave S, Bonetti A, Martinotti MG, 2003. Caratterizzazione delle proprietà probiotiche di alcuni ceppi del genere *Lactobacillus* spp. Atti del 5° Congresso Federazione Italiana Scienze della Vita (FISV), Rimini, 168.
- 11 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. *Systematic and Applied Microbiology*, 23, 504-509.

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

- 1 Report on Semiautomatic annotation of one *Lactobacillus plantarum* (LPL2) genome. 2010.
- 2 Dossier submitted by the competent Authority of Italy on *Lactobacillus plantarum* P17630, ID 2967. 2011.
- 3 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus plantarum* P17630, using molecular methods.
- 4 BCCM/LMG, 1997. Report on the identification of 3 bacterial isolates.
- 5 Bonetti A, Morelli L, Campominosi E, Ganora E, Sforza F, 2003. Adherence of *Lactobacillus plantarum* P 17630 in soft-gel capsule formulation versus Doderlein's bacillus in tablet formulation to vaginal epithelial cells. *Minerva Ginecologica*, 55, 279-287.
- 6 Carriero C, Lezzi V, Mancini T, Selvaggi L, 2007. Vaginal capsules of *Lactobacillus plantarum* P17630 for prevention of relapse of candida vulvovaginitis: an Italian multicentre observational study. *International Journal of Probiotics and Prebiotics*, 2, 155-162.
- 7 Culici M, Dal Sasso M, Braga P, 2004. L'adesione del *Lactobacillus plantarum* P 17630 alle cellule vaginali inibisce l'adesività della *Candida albicans*. *Giornale Italiano di Microbiologia Medica Odontoiatrica e Clinica*, 8, 34-41.
- 8 Dondi G, 2000. Method for the selection of adhesive lactobacilli strains having therapeutical properties and strains obtained by said method, EP1046713A2, European Patent Office.
- 9 Escorsell J, 2007. *Lactobacillus plantarum* P 17630: Eficacia y tolerabilidad en el tratamiento y la prevención de la vaginitis recurrente. *Drugs of Today*, 43 (supl. 5), 1-14.
- 10 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. *Applied and Environmental Microbiology*, 59, 945.
- 11 Morelli L, 1997. Microbiological analysis of 6 strains of lactobacillus for a patent deposit. Università Cattolica del Sacro Cuore di Piacenza.
- 12 Morelli L, 2000. Microbiological characteristics of *Lactobacillus Plantarum* P17630 contained in vaginal suppositories. Università Cattolica del Sacro Cuore di Piacenza.
- 13 Nava S, Garone GP, Colombo D, Mongelli L, 2002. Considerazioni sull'impiego del *Lactobacillus plantarum* P17630 nella patologia vaginale su base infettivo-infiammatoria. *Riv. Ostetr. Ginecol. Pratica e Med Perin*, 17, 14-19.

- 14 Pietronave S, Bonetti A, Martinotti MG, 2003. Caratterizzazione delle proprietà probiotiche di alcuni ceppi del genere *Lactobacillus* spp. Atti del 5° Congresso Federazione Italiana Scienze della Vita (FISV), Rimini, 168.
- 15 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. Systematic and Applied Microbiology, 23, 504-509.

ID 2968: *Lactobacillus rhamnosus* LR 04 (DSM 16605)

- 1 Dossier submitted by the competent Authority of Italy on claim ID 2968 *L.rhamnosus*. 2011.
- 2 Arck PC, Handjiski B, Peters EM, Peter AS, Hagen E, Fischer A, Klapp BF, Paus R, 2003. Stress inhibits hair growth in mice by induction of premature catagen development and deleterious perifollicular inflammatory events via neuropeptide substance P-dependent pathways. American Journal of Pathology, 162, 803-814.
- 3 Arck P, Handjiski B, Hagen E, Pincus M, Bruenahl C, Bienenstock J, Paus R, 2010. Is there a 'gut-brain-skin axis'? Experimental Dermatology, 19, 401-405.
- 4 Biavati B, Scardovi V, Moore WEC, 1982. Electrophoretic patterns of proteins in the genus *Bifidobacterium* and proposal of four new species. International Journal of Systematic Bacteriology, 32, 358-373.
- 5 Bowe WP and Logan AC, 2011. Acne vulgaris, probiotics and the gut-brain-skin axis - back to the future? Gut Pathogens, 3, 1.
- 6 Caramia G, Atzei A, Fanos V, 2008. Probiotics and the skin. Clinics in Dermatology, 26, 4-11.
- 7 Charteris WP, Kelly PM, Morelli L, Collins JK, 1998. Development and application of an in vitro methodology to determine the transit tolerance of potentially probiotic *Lactobacillus* and *Bifidobacterium* species in the upper human gastrointestinal tract. Journal of Applied Microbiology, 84, 759-768.
- 8 Charteris WP, Kelly PM, Morelli L, Collins JK, 2001. Gradient diffusion antibiotic susceptibility testing of potentially probiotic lactobacilli. Journal of Food Protection, 64, 2007-2014.
- 9 Danielsen M and Wind A, 2003. Susceptibility of *Lactobacillus* spp. to antimicrobial agents. International Journal of Food Microbiology, 82, 1-11.
- 10 Del Piano M, Morelli L, Strozzi GP, Allesina S, Barba M, Deidda F, Lorenzini P, Ballare M, Montino F, Orsello M, Sartori M, Garello E, Carmagnola S, Pagliarulo M, Capurso L, 2006. Probiotics: from research to consumer. Digestive and Liver Disease, 38 Suppl 2, S248-255.
- 11 Del Piano M, Strozzi P, Barba M, Allesina S, Deidda F, Lorenzini P, Morelli L, Carmagnola S, Pagliarulo M, Balzarini M, Ballare M, Orsello M, Montino F, Sartori M, Garello E, Capurso L, 2008. In vitro sensitivity of probiotics to human pancreatic juice. Journal of Clinical Gastroenterology, 42 Suppl 3 Pt 2, S170-173.
- 12 Della Bella S, Riva A, Tanzi E, Nicola S, Amendola A, Vecchi L, Nebbia G, Longhi R, Zanetti AR, Villa ML, 2005. Hepatitis C virus-specific reactivity of CD4+-lymphocytes in children born from HCV-infected women. Journal of Hepatology, 43, 394-402.
- 13 Dezi A, Carmagnola S, Ballarè M, et al., 2004. Probiotics and chronic diarrhoea in the elderly. Cibus, 8, 58-64.
- 14 Egervarn M, Danielsen M, Roos S, Lindmark H, Lindgren S, 2007. Antibiotic susceptibility profiles of *Lactobacillus reuteri* and *Lactobacillus fermentum*. Journal of Food Protection, 70, 412-418.
- 15 Elewski BE, 2005. Clinical Diagnosis of Common Scalp Disorders. Journal of Investigative Dermatology. Symposium Proceedings, 10, 190-193.

- 16 Fuss IJ, Kanof ME, Smith PD, Zola H, 2009. Isolation of whole mononuclear cells from peripheral blood and cord blood. *Current Opinion in Immunology*, Chapter 7, Unit 7 1.
- 17 Gill HS, 2003. Probiotics to enhance anti-infective defences in the gastrointestinal tract. *Best Practice and Research. Clinical Gastroenterology*, 17, 755-773.
- 18 Gregory B and Ho VC, 1992. Cutaneous manifestations of gastrointestinal disorders. Part II. *Journal of the American Academy of Dermatology*, 26, 371-383.
- 19 Gregory B and Ho VC, 1992. Cutaneous manifestations of gastrointestinal disorders. Part I. *Journal of the American Academy of Dermatology*, 26, 153-166.
- 20 Gueniche A, Benyacoub J, Buetler TM, Smola H, Blum S, 2006. Supplementation with oral probiotic bacteria maintains cutaneous immune homeostasis after UV exposure. *European Journal of Dermatology*, 16, 511-517.
- 21 Gueniche A, Philippe D, Bastien P, Blum S, Buyukpamukcu E, Castiel-Higounenc I, 2009. Probiotics for photoprotection. *Dermatoendocrinology*, 1, 275-279.
- 22 Gupta AK, Batra R, Bluhm R, Boekhout T, Dawson TL, Jr., 2004. Skin diseases associated with Malassezia species. *Journal of the American Academy of Dermatology*, 51, 785-798.
- 23 Holmes K, Lantz LM, Fowlkes BJ, Schmid I, Giorgi JV, 2001. Preparation of cells and reagents for flow cytometry. *Curr Protoc Immunol*, Chapter 5, Unit 5 3.
- 24 Holmes K, Otten G, Yokoyama WM, 2001. Flow cytometry analysis using the Becton Dickinson FACS Calibur. *Current Protocols in Immunology*, 5.4.1-5.4.22.
- 25 Hornbeck P, 1992. Enzyme-Linked Immunosorbent Assays. *Current Protocols in Immunology*, 2.1.1-2.1.22.
- 26 ISAPP (International Scientific Association for Probiotics and Prebiotics), 2008. Report from ISAPP Meeting on Antibiotic Resistance in Probiotic Bacteria Held December 13, 2007 Paris.
- 27 Jancin B, 2009. Oral probiotic reduces severe dandruff in small study. *Skin & allergy news*, 26.
- 28 Kalliomäki M, 2005. Pandemic of atopic diseases--a lack of microbial exposure in early infancy? *Medicinal Chemistry Reviews*, 2, 299-302.
- 29 Manuel F and Ranganathan S, 2011. A new postulate on two stages of dandruff: a clinical perspective. *International Journal of Trichology*, 3, 3-6.
- 30 Marteau P and Shanahan F, 2003. Basic aspects and pharmacology of probiotics: an overview of pharmacokinetics, mechanisms of action and side-effects. *Best Practice and Research. Clinical Gastroenterology*, 17, 725-740.
- 31 McKay DM and Bienenstock J, 1994. The interaction between mast cells and nerves in the gastrointestinal tract. *Immunology Today*, 15, 533-538.
- 32 Mogna G and Strozzi GP, 2006. Probiotic bacteria based composition and use thereof in the prevention and/or treatment of respiratory pathologies and/or infections and in the improvement of the intestinal functionality, WO/2006/054135, World Intellectual Property Organization.
- 33 Mogna G and Strozzi GP, 2007. Method for the preparation of anallergic probiotic bacterial cultures and related use, WO/2007/054989, World Intellectual Property Organization.
- 34 Mogna G, Strozzi GP, Mogna L, 2009. Composition based on probiotic bacteria in association with a prebiotic and use thereof in the prevention and/or treatment of respiratory pathologies and/or infections and in the improvement of intestinal functionality, WO/2009/071578, Organization WIP.
- 35 Nermes M, Kantele JM, Atosuo TJ, Salminen S, Isolauri E, 2011. Interaction of orally administered Lactobacillus rhamnosus GG with skin and gut microbiota and humoral immunity in infants with atopic dermatitis. *Clinical and Experimental Allergy*, 41, 370-377.

- 36 Nutman TB, 1991. Measurement of Polyclonal Immunoglobulin Synthesis Using ELISA. Current protocols in Immunology, Chapter 7.
- 37 Peguet-Navarro J, Dezutter-Dambuyant C, Buetler T, Leclaire J, Smola H, Blum S, Bastien P, Breton L, Gueniche A, 2008. Supplementation with oral probiotic bacteria protects human cutaneous immune homeostasis after UV exposure-double blind, randomized, placebo controlled clinical trial. European Journal of Dermatology, 18, 504-511.
- 38 Rigano L, 2007. Valutazione dell'idratazione, elasticita', efficacia sebonormalizzante e antiforfora dopo uso.
- 39 Rigano L, 2009. Valutazione strumentale, clinica e soggettiva dell'efficacia antiforfora. 313/09/01-02.
- 40 Rinaldi F, Sorbellini E, Bezzola P, Marchioretto DI, 2003. Biogenina based food supplement: hair growth enhancer. Nutrafoods, 1-7.
- 41 Salminen SJ, Gueimonde M, Isolauri E, 2005. Probiotics that modify disease risk. Journal of Nutrition, 135, 1294-1298.
- 42 Strozzi GP and Mogna L, 2008. Tablet comprising microorganisms and a combination of excipients and the manufacture process thereof., WO/2008/107746, Organization WIP.
- 43 Teitelman G, Joh TH, Reis DJ, 1981. Linkage of the brain-skin-gut axis: islet cells originate from dopaminergic precursors. Peptides, 2 Suppl 2, 157-168.
- 44 Tough DF, Sprent J, Stephens GL, 2007. Measurement of T and B cell turnover with bromodeoxyuridine. Current Opinion in Immunology, Chapter 4, Unit 4 7.
- 45 Tynkkynen S, Satokari R, Saarela M, Mattila-Sandholm T, Saxelin M, 1999. Comparison of ribotyping, randomly amplified polymorphic DNA analysis, and pulsed-field gel electrophoresis in typing of *Lactobacillus rhamnosus* and *L. casei* strains. Applied and Environmental Microbiology, 65, 3908-3914.
- 46 Walter J, Tannock GW, Tilsala-Timisjarvi A, Rodtong S, Loach DM, Munro K, Alatossava T, 2000. Detection and identification of gastrointestinal *Lactobacillus* species by using denaturing gradient gel electrophoresis and species-specific PCR primers. Applied and Environmental Microbiology, 66, 297-303.

ID 2969: *Lactobacillus rhamnosus* LR 04

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus rhamnosus* LR 04 (DSM 16605), ID 2969. 2011.
- 2 Dezi A, Carmagnola S, Ballarè M, Orsello M, Del Piano M, Capurso L, 2004. Probiotics and chronic diarrhoea in the elderly. Cibus, 8, 58-64.

ID 2970: *Lactobacillus salivarius* I 1794

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus salivarius* I1794, ID 2970. 2011.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus salivarius* I1794, using molecular methods.
- 3 Bonetti A, Morelli L, Campominosi E, 2002. Assessment of the persistence in the human intestinal tract of two probiotic lactobacilli *Lactobacillus salivarius* I 1794 and *Lactobacillus paracasei* I 1688. Microbial Ecology in Health and Disease, 14, 229-233.
- 4 Dondi G, 2004. Use of agents active against *Candida* in the treatment of disorders of the oral and intestinal mucosa, US2004/0043011A1, United States Patent and Trademark Office.

- 5 Dondi G, 2007. Use of agents active against Candida in the treatment of disorders of the oral and intestinal mucosa, EP1339419B1, European Patent Office.
- 6 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. Applied and Environmental Microbiology, 59, 945.
- 7 Morelli L, 1997. Microbiological analysis of 6 strains of lactobacillus for a patent deposit. Università Cattolica del Sacro Cuore di Piacenza.
- 8 Pedraglio G, 2004. Novel lactobacilli strains useful in the treatment of disorders of the gastrointestinal system, EP0861905B1, European Patent Office.
- 9 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of Lactobacillus spp. Isolated from Fecal and Vaginal Samples. Systematic and Applied Microbiology, 23, 504-509.

ID 2971: *Lactobacillus salivarius* I 1794

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus salivarius* I1794, ID 2971. 2011.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus salivarius* I1794, using molecular methods.
- 3 Castellazzi A, Avanzini MA, Oliveri M, Valsecchi C, Malfa P, Marseglia G, 2006. "In vitro" and "in vivo" immunomodulant attivity of PSMIX (*Lactobacillus paracasei* I 1688 and *Lactobacillus salivarius* I 1794). Poster at the 6th Annual Meeting of the Federation of Clinical Immunology Societies, San Francisco.
- 4 Castellazzi A, 2007. Final report on Florilac Trial. University of Pavia.
- 5 Castellazzi AM, Valsecchi C, Montagna L, Malfa P, Ciprandi G, Avanzini MA, Marseglia GL, 2007. In vitro activation of mononuclear cells by two probiotics: *Lactobacillus paracasei* I 1688, *Lactobacillus salivarius* I 1794, and their mixture (PSMIX). Immunological Investigations, 36, 413-421.
- 6 Dondi G and Malfa P, 2007. Use of specific lactic bacteria for the preparation of immunomodulating compositions, WO2007/015132A2, World Intellectual Property Organization.
- 7 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. Applied and Environmental Microbiology, 59, 945.
- 8 Morelli L, 1997. Microbiological analysis of 6 strains of lactobacillus for a patent deposit. Università Cattolica del Sacro Cuore di Piacenza.
- 9 Valsecchi C, Marseglia A, Licari A, Montagna L, Leone M, Marseglia G, Castellazzi AM, 2008. PSMIX nuova miscela brevettata a base di *L. paracasei* I-1688 e *L. salivarius* I-1794: attivita probiotiche e razionale di impiego clinico. Archives of Medical Therapy, 2, 9-14.
- 10 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. Systematic and Applied Microbiology, 23, 504-509.

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.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus paracasei* 11688, using molecular methods.
- 3 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus salivarius* CNCM 11794, using molecular methods.
- 4 Bonetti A, Morelli L, Campominosi E, 2002. Assessment of the persistence in the human intestinal tract of two probiotic lactobacilli *Lactobacillus salivarius* I 1794 and *Lactobacillus paracasei* I 1688. *Microbial Ecology in Health and Disease*, 14, 229-233.
- 5 Dondi G, 2004. Use of agents active against *Candida* in the treatment of disorders of the oral and intestinal mucosa, US2004/0043011A1, United States Patent and Trademark Office.
- 6 Dondi G, 2007. Use of agents active against *Candida* in the treatment of disorders of the oral and intestinal mucosa, EP1339419B1, European Patent Office.
- 7 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. *Applied and Environmental Microbiology*, 59, 945.
- 8 Morelli L, 1996. Identification of two strains of lactobacillus for a patent deposit. Universita Cattolica del sacro Cuore di Piacenza.
- 9 Morelli L, 1997. Microbiological analysis of 6 strains of lactobacillus for a patent deposit. Universita Cattolica del Sacro Cuore di Piacenza.
- 10 Pedraglio G, 2004. Novel lactobacilli strains useful in the treatment of disorders of the gastrointestinal system, EP0861905B1, European Patent Office.
- 11 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. *Systematic and Applied Microbiology*, 23, 504-509.

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.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus paracasei* 11688, using molecular methods.
- 3 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Lactobacillus salivarius* CNCM 11794, using molecular methods.
- 4 Castellazzi A, Avanzini MA, Oliveri M, Valsecchi C, Malfa P, Gianluigi Marseglia G, 2006. "In vitro" and "in vivo" immunomodulant activity of PSMIX (*Lactobacillus paracasei* I 1688 and *Lactobacillus salivarius* I 1794). *Clinical Immunology*, 119, 57.
- 5 Castellazzi A, 2007. Final report on Florilac Trial. University of Pavia.
- 6 Castellazzi AM, Valsecchi C, Montagna L, Malfa P, Ciprandi G, Avanzini MA, Marseglia GL, 2007. In vitro activation of mononuclear cells by two probiotics: *Lactobacillus paracasei* I 1688, *Lactobacillus salivarius* I 1794, and their mixture (PSMIX). *Immunological Investigations*, 36, 413-421.
- 7 Dondi G and Malfa P, 2007. Use of specific lactic bacteria for the preparation of immunomodulating compositions, WO2007/015132A2, World Intellectual Property Organization.

- 8 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. *Applied and Environmental Microbiology*, 59, 945.
- 9 Morelli L, 1996. Identification of two strains of lactobacillus for a patent deposit.
- 10 Morelli L, 1997. Microbiological analysis of 6 strains of lactobacillus for a patent deposit.
- 11 Valsecchi C, Marseglia A, Licari A, Montagna L, Leone M, Marseglia G, Castellazzi AM, 2008. PSMIX nuova miscela brevettata a base di *L. paracasei* I-1688 e *L. salivarius* I-1794: attivita probiotiche e razionale di impiego clinico. *Archives of Medical Therapy*, 2, 9-14.
- 12 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. *Systematic and Applied Microbiology*, 23, 504-509.

ID 2974: *Streptococcus thermophilus* BCCM/LMG P 18807

- 1 Dossier submitted by the competent Authority of Italy on *Streptococcus thermophilus* P18807, ID2974. 2011.
- 2 AAT, 2011. Report on confirmation of the taxonomic identity of the bacterial strain, *Streptococcus thermophilus* 118807, using molecular methods.
- 3 BCCM/LMG, 1999. Report on the determination of carbohydrate fermentation pattern SDS-PAGE protein profiling. Report 04/02/99.
- 4 Dondi G, 2000. Method for the selection of adhesive lactobacilli strains having therapeutical properties and strains obtained by said method, EP1046713A2, European Patent Office.
- 5 Elli M, Callegari ML, Ferrari S, Bessi E, Cattivelli D, Soldi S, Morelli L, Goupil Feuillerat N, Antoine JM, 2006. Survival of yogurt bacteria in the human gut. *Applied and Environmental Microbiology*, 72, 5113-5117.
- 6 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. *Applied and Environmental Microbiology*, 59, 945.
- 7 Moschetti, Blaiotta, Aponte, Catzeddu, Villani, Deiana, Coppola, 1998. Random amplified polymorphic DNA and amplified ribosomal DNA spacer polymorphism : powerful methods to differentiate *Streptococcus thermophilus* strains. *Journal of Applied Microbiology*, 85, 25-36.
- 8 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. *Systematic and Applied Microbiology*, 23, 504-509.

ID 2975: *Streptococcus thermophilus* BCCM/LMG P 18807

- 1 Dossier submitted by the competent Authority of Italy on *Streptococcus thermophilus* P18807, ID 2975. 2011.
- 2 AAT, 2011. Confirmation of the taxonomic identity of the bacterial strain, *Streptococcus thermophilus* 118807, using molecular methods.
- 3 BCCM/LMG, 1999. Determination of carbohydrate fermentation pattern SDS-PAGE protein profiling. Report 04/02/99.
- 4 Jensen MA, Webster JA, Straus N, 1993. Rapid identification of bacteria on the basis of polymerase chain reaction-amplified ribosomal DNA spacer polymorphisms. *Applied and Environmental Microbiology*, 59, 945.

- 5 Mastrandrea F, Coradduzza G, Serio G, Minardi A, Manelli M, Ardito S, Muratore L, 2004. Probiotics reduce the CD34+ hemopoietic precursor cell increased traffic in allergic subjects. European Annals of Allergy and Clinical Immunology, 36, 118-122.
- 6 Moschetti, Blaiotta, Aponte, Catzeddu, Villani, Deiana, Coppola, 1998. Random amplified polymorphic DNA and amplified ribosomal DNA spacer polymorphism: powerful methods to differentiate *Streptococcus thermophilus* strains. Journal of Applied Microbiology, 85, 25-36.
- 7 Ventura M, Casas IA, Morelli L, Callegari ML, 2000. Rapid Amplified Ribosomal DNA Restriction Analysis (ARDRA) Identification of *Lactobacillus* spp. Isolated from Fecal and Vaginal Samples. Systematic and Applied Microbiology, 23, 504-509.

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

- 1 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.
- 2 Alemka A, Clyne M, Shanahan F, Tompkins T, Corcionivoschi N, Bourke B, 2010. Probiotic Colonization of the Adherent Mucus Layer of HT29MTXE12 Cells Attenuates *Campylobacter jejuni* Virulence Properties. Infection and Immunity, 78, 2812-2822.
- 3 Cazzola M, Pham-Thi N, Kerihuel JC, Durand H, Bohbot S, 2010. Efficacy of a synbiotic supplementation in the prevention of common winter diseases in children: a randomized, double-blind, placebo-controlled pilot study. Therapeutic Advances in Respiratory Disease, 4, 271-278.
- 4 Cazzola M, Tompkins TA, Matera MG, 2010. Immunomodulatory impact of a synbiotic in Th1 and Th2 models of infection. Therapeutic Advances in Respiratory Disease, 4, 259.
- 5 Collins MD and Gibson GR, 1999. Probiotics, prebiotics, and synbiotics: approaches for modulating the microbial ecology of the gut. American Journal of Clinical Nutrition, 69, 1052S-1057S.
- 6 de Vrese M and Schrezenmeir J, 2002. Probiotics and non-intestinal infectious conditions. British Journal of Nutrition, 88 Suppl 1, S59-66.
- 7 Durand H and Diop L, 2006. Probiotics and intestinal health benefits. Medika, 32, 146-153.
- 8 Dykstra NS, Hyde L, Adawi D, Kulik D, Ahrne S, Molin G, Jeppsson B, MacKenzie A, Mack DR, 2011. Pulse Probiotic Administration Induces Repeated Small Intestinal Muc3 Expression in Rats. Pediatric Research, 69, 206-211.
- 9 Easo JG, Measham JD, Munroe J, Green-Johnson JM, 2002. Immunostimulatory actions of *Lactobacilli*: mitogenic induction of antibody production and spleen cell proliferation by *Lactobacillus delbrueckii* subsp. *bulgaricus* and *Lactobacillus acidophilus*. Food and Agricultural Immunology, 14, 73-83.
- 10 Fiander A, Bradley S, Johnson-Green PC, Green-Johnson JM, 2005. Effects of lactic acid bacteria and fermented milks on eicosanoid production by intestinal epithelial cells. Journal of Food Science, 70, 81-86.
- 11 Johnson-Henry KC, Nadjafi M, Avitzur Y, Mitchell DJ, Ngan BY, Galindo-Mata E, Jones NL, Sherman PM, 2005. Amelioration of the effects of *Citrobacter rodentium* infection in mice by pretreatment with probiotics. Journal of Infectious Diseases, 191, 2106-2117.
- 12 Johnson-Henry KC, Hagen KE, Gordonpour M, Tompkins TA, Sherman PM, 2007. Surface-layer protein extracts from *Lactobacillus helveticus* inhibit enterohaemorrhagic *Escherichia coli* O157:H7 adhesion to epithelial cells. Cellular Microbiology, 9, 356-367.
- 13 Kolida S, Tuohy K, Gibson GR, 2002. Prebiotic effects of inulin and oligofructose. British Journal of Nutrition, 87 Suppl 2, S193-197.

- 14 Naser SM, Hagen KE, Vancanneyt M, Cleenwerck I, Swings J, Tompkins TA, 2006. *Lactobacillus suntoryeus* Cachat and Priest 2005 is a later synonym of *Lactobacillus helveticus* (Orla-Jensen 1919) Bergey et al. 1925 (Approved Lists 1980). International Journal of Systematic and Evolutionary Microbiology, 56, 355-360.
- 15 Reid G, Sanders ME, Gaskins HR, Gibson GR, Mercenier A, Rastall R, Roberfroid M, Rowland I, Cherbut C, Klaenhammer TR, 2003. New scientific paradigms for probiotics and prebiotics. Journal of Clinical Gastroenterology, 37, 105-118.
- 16 Saavedra JM and Tscherne A, 2002. Human studies with probiotics and prebiotics: clinical implications. British Journal of Nutrition, 87 Suppl 2, S241-246.
- 17 Schrezenmeir J and de Vrese M, 2001. Probiotics, prebiotics, and synbiotics--approaching a definition. American Journal of Clinical Nutrition, 73, 361S-364S.
- 18 Sherman PM, Johnson-Henry KC, Yeung HP, Ngo PSC, Goulet J, Tompkins TA, 2005. Probiotics reduce enterohemorrhagic Escherichia coli O157: H7-and enteropathogenic E. coli O127: H6-induced changes in polarized T84 epithelial cell monolayers by reducing bacterial adhesion and cytoskeletal rearrangements. Infection and Immunity, 73, 5183.
- 19 Van Niel CW, Feudtner C, Garrison MM, Christakis DA, 2002. Lactobacillus therapy for acute infectious diarrhea in children: a meta-analysis. Pediatrics, 109, 678-684.
- 20 Wallace TD, Bradley S, Buckley ND, Green-Johnson JM, 2003. Interactions of lactic acid bacteria with human intestinal epithelial cells: effects on cytokine production. Journal of Food Protection, 66, 466-472.
- 21 Wine E, Gareau MG, Johnson-Henry K, Sherman PM, 2009. Strain-specific probiotic (*Lactobacillus helveticus*) inhibition of *Campylobacter jejuni* invasion of human intestinal epithelial cells. FEMS Microbiology Letters, 300, 146-152.

ID 3017: *Lactobacillus rhamnosus* CNCM I-1720, *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* subsp. *longum* CNCM I-3470 and *Saccharomyces boulardii* CNCM I-1079

- 1 Dossier submitted by the competent Authority of France on *Lactobacillus rhamnosus* CNCM I-1720, *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* ssp. *longum* CNCM I-3470 and *Saccharomyces boulardii* CNCM I-1079, ID 3017. 2011.
- 2 Adam J, Barret C, Barret-Bellet A, Benedetti E, Calendini A, Darchen P, Galibert JM, Guerci P, Guiot G, Haechler M, 1977. Controlled double-blind clinical trials of Ultra-Levure: multicentre study by 25 physicians in 388 cases. Gazette Medicale de France, 84, 2072-2078.
- 3 Alemba A, Clyne M, Shanahan F, Tompkins T, Corcionivoschi N, Bourke B, 2010. Probiotic Colonization of the Adherent Mucus Layer of HT29MTXE12 Cells Attenuates *Campylobacter jejuni* Virulence Properties. Infection and Immunity, 78, 2812-2822.
- 4 Biloo AG, Memon MA, Khaskheli SA, Murtaza G, Iqbal K, Saeed Shekhani M, Siddiqi AQ, 2006. Role of a probiotic (*Saccharomyces boulardii*) in management and prevention of diarrhoea. World Journal of Gastroenterology, 12, 4557-4560.
- 5 Bisson JF, Hidalgo S, Rozan P, Messaoudi M, 2010. Preventive Effects of Different Probiotic Formulations on Travelersâ€™ Diarrhea Model in Wistar Rats. Digestive Diseases and Sciences, 55, 911-919.
- 6 Buts JP, Keyser ND, Raedemaeker LD, 1994. *Saccharomyces boulardii* enhances rat intestinal enzyme expression by endoluminal release of polyamines. Pediatric Research, 36, 522-527.
- 7 Can M, Besirbellioglu BA, Avci IY, Beker CM, Pahsa A, 2006. Prophylactic *Saccharomyces boulardii* in the prevention of antibiotic-associated diarrhea: a prospective study. Medical Science Monitor: International Medical Journal of Experimental And Clinical Research, 12, PI19-PI22.

- 8 Castagliuolo I, LaMont JT, Nikulasson ST, Pothoulakis C, 1996. *Saccharomyces boulardii* protease inhibits *Clostridium difficile* toxin A effects in the rat ileum. *Infection and Immunity*, 64, 5225-5232.
- 9 Castagliuolo I, Riegler MF, Valenick L, LaMont JT, Pothoulakis C, 1999. *Saccharomyces boulardii* protease inhibits the effects of *Clostridium difficile* toxins A and B in human colonic mucosa. *Infection and Immunity*, 67, 302-307.
- 10 Chen X, Kokkotou EG, Mustafa N, Bhaskar KR, Sougioultzis S, O'Brien M, Pothoulakis C, Kelly CP, 2006. *Saccharomyces boulardii* inhibits ERK1/2 mitogen-activated protein kinase activation both in vitro and in vivo and protects against *Clostridium difficile* toxin A-induced enteritis. *Journal of Biological Chemistry*, 281, 24449-24454.
- 11 Cindoruk M, Erkan G, Karakan T, Dursun A, Unal S, 2007. Efficacy and Safety of *Saccharomyces boulardii* in the 14-day Triple Anti-Helicobacter pylori Therapy: A Prospective Randomized Placebo-Controlled Double-Blind Study. *Helicobacter*, 12, 309-316.
- 12 Cremonini F, Di Caro S, Covino M, Armuzzi A, Gabrielli M, Santarelli L, Nista EC, Cammarota G, Gasbarrini G, Gasbarrini A, 2002. Effect of different probiotic preparations on anti-Helicobacter pylori therapy-related side effects: a parallel group, triple blind, placebo-controlled study. *The American Journal of Gastroenterology*, 97, 2744-2749.
- 13 Czerucka D and Rampal P, 1999. Effect of *Saccharomyces boulardii* on cAMP-and Ca²⁺-dependent Cl⁻secretion in T84 cells. *Digestive Diseases and Sciences*, 44, 2359-2368.
- 14 Czerucka D, Dahan S, Mograbi B, Rossi B, Rampal P, 2000. *Saccharomyces boulardii* preserves the barrier function and modulates the signal transduction pathway induced in enteropathogenic *Escherichia coli*-infected T84 cells. *Infection and Immunity*, 68, 5998.
- 15 Dahan S, Dalmasso G, Imbert V, Peyron JF, Rampal P, Czerucka D, 2003. *Saccharomyces boulardii* interferes with enterohemorrhagic *Escherichia coli*-induced signaling pathways in T84 cells. *Infection and Immunity*, 71, 766-773.
- 16 D'Souza AL, Rajkumar C, Cooke J, Bulpitt CJ, 2002. Probiotics in prevention of antibiotic associated diarrhoea: meta-analysis. *British Medical Journal*, 324, 1361.
- 17 Duman DG, Bor S, e-ze^{1/4}temiz e, Sahin T, Oguz D, Istan F, Vural T, Sandkci M, Isksal F, Simsek I, 2005. Efficacy and safety of *Saccharomyces boulardii* in prevention of antibiotic-associated diarrhoea due to *Helicobacter pylori* eradication. *European Journal of Gastroenterology & Hepatology*, 17, 1357.
- 18 Dykstra NS, Hyde L, Adawi D, Kulik D, Ahrne S, Molin G, Jeppsson B, MacKenzie A, Mack DR, Pulse Probiotic Administration Induces Repeated Small Intestinal Muc3 Expression in Rats. *Pediatric Research*, 69, 206-211.
- 19 Gedek BR, 1999. Adherence of *Escherichia coli* serogroup O 157 and the *Salmonella Typhimurium* mutant DT 104 to the surface of *Saccharomyces boulardii*. *Mycoses*, 42, 261-264.
- 20 Girard P, Pansart Y, Lorette I, Gillardin JM, 2003. Dose-response relationship and mechanism of action of *Saccharomyces boulardii* in castor oil-induced diarrhea in rats. *Digestive Diseases and Sciences*, 48, 770-774.
- 21 Hennequin C, Thierry A, Richard GF, Lecointre G, Nguyen HV, Gaillardin C, Dujon B, 2001. Microsatellite typing as a new tool for identification of *Saccharomyces cerevisiae* strains. *Journal of Clinical Microbiology*, 39, 551-559.
- 22 Hochter W, Chase D, Hagenhoff G, 1990. *Saccharomyces boulardii* in acute adult diarrhoea: efficacy and tolerability of treatment. *Münchener Medizinische Wochenschrift*, 132, 188-192.
- 23 Jandu N, Zeng ZJ, Johnson-Henry KC, Sherman PM, 2009. Probiotics prevent enterohaemorrhagic *Escherichia coli* O157: H7-mediated inhibition of interferon-γ-induced tyrosine phosphorylation of STAT-1. *Microbiology*, 155, 531-540.

- 24 Johnson-Henry KC, Hagen KE, Gordonpour M, Tompkins TA, Sherman PM, 2007. Surface-layer protein extracts from *Lactobacillus helveticus* inhibit enterohaemorrhagic *Escherichia coli* O157: H7 adhesion to epithelial cells. *Cellular Microbiology*, 9, 356-367.
- 25 Kirchhelle A, Fruhwein N, Toburen D, 1996. Treatment of persistent diarrhea with *S. boulardii* in returning travelers. Results of a prospective study]. *Fortschritte der Medizin*, 114, 136-140.
- 26 Kollaritsch H, Kremsner P, Wiedermann G, Scheiner O, 1989. Prevention of traveller's diarrhea: comparison of different non-antibiotic preparations. *Travel Med Int*, 11, 9-17.
- 27 Kollaritsch H, Holst H, Grobara P, Wiedermann G, 1993. [Prevention of traveler's diarrhea with *Saccharomyces boulardii*. Results of a placebo controlled double-blind study]. *Fortschritte der Medizin*, 111, 152-156.
- 28 Lewis SJ, Potts LF, Barry RE, 1998. The lack of therapeutic effect of *Saccharomyces boulardii* in the prevention of antibiotic-related diarrhoea in elderly patients. *Journal of Infection*, 36, 171-174.
- 29 Mallie M, Van PN, Bertout S, Vaillant C, Bastide JM, 2001. Genotypic study of *Saccharomyces boulardii* compared to the *Saccharomyces sensu stricto* complex species. *Journal de Mycologie Medicale*, 11, 19-25.
- 30 Mansour-Ghanaei F, Dehbashi N, Yazdanparast K, Shafaghi A, 2003. Efficacy of *saccharomyces boulardii* with antibiotics in acute amoebiasis. *World Journal of Gastroenterology*, 9, 1832-1833.
- 31 Mattarelli P, Bonaparte C, Pot B, Biavati B, 2008. Proposal to reclassify the three biotypes of *Bifidobacterium longum* as three subspecies: *Bifidobacterium longum* subsp. *longum* subsp. nov., *Bifidobacterium longum* subsp. *infantis* comb. nov. and *Bifidobacterium longum* subsp. *suis* comb. nov. *International Journal of Systematic and Evolutionary Microbiology*, 58, 767-772.
- 32 McFarland LV, Surawicz CM, Greenberg RN, Fekety R, Elmer GW, Moyer KA, Melcher SA, Bowen KE, Cox JL, Noorani Z, 1994. A randomized placebo-controlled trial of *Saccharomyces boulardii* in combination with standard antibiotics for *Clostridium difficile* disease. *JAMA: the journal of the American Medical Association*, 271, 1913.
- 33 McFarland L, Surawicz C, Greenberg R, Elmer G, Moyer K, Melcher S, Bowen K, Cox J, 1995. Prevention of beta-lactam-associated diarrhea by *Saccharomyces boulardii* compared with placebo. *American Journal of Gastroenterology*, 90, 439-448.
- 34 McFarland LV, 2006. Meta-analysis of probiotics for the prevention of antibiotic associated diarrhea and the treatment of *Clostridium difficile* disease. *American Journal of Gastroenterology*, 101, 812-822.
- 35 McFarland LV, 2007. Meta-analysis of probiotics for the prevention of traveler's diarrhea. *Travel Medicine and Infectious Disease*, 5, 97-105.
- 36 McFarland LV, 2010. Systematic review and meta-analysis of *Saccharomyces boulardii* in adult patients. *World Journal of Gastroenterology*, 16, 2202-2222.
- 37 Naser SM, Hagen KE, Vancanneyt M, Cleenwerck I, Swings J, Tompkins TA, 2006. *Lactobacillus suntoryeus* Cachat and Priest 2005 is a later synonym of *Lactobacillus helveticus* (Orla-Jensen 1919) Bergey et al. 1925 (Approved Lists 1980). *International Journal of Systematic and Evolutionary Microbiology*, 56, 355-360.
- 38 Provencher C, LaPointe G, Sirois S, Van Calsteren MR, Roy D, 2003. Consensus-degenerate hybrid oligonucleotide primers for amplification of priming glycosyltransferase genes of the exopolysaccharide locus in strains of the *Lactobacillus casei* group. *Applied and Environmental Microbiology*, 69, 3299-3307.
- 39 Qamar A, Aboudola S, Warny M, Michetti P, Pothoulakis C, LaMont JT, Kelly CP, 2001. *Saccharomyces boulardii* stimulates intestinal immunoglobulin A immune response to *Clostridium difficile* toxin A in mice. *Infection and immunity*, 69, 2762-2765.

- 40 Roy D and Ward P, 2004. Comparison of fructose-1, 6-bisphosphatase gene (fbp) sequences for the identification of *Lactobacillus rhamnosus*. *Current Microbiology*, 49, 313-320.
- 41 Sezer A, Usta U, Cicin I, 2009. The effect of *Saccharomyces boulardii* on reducing irinotecan-induced intestinal mucositis and diarrhea. *Medical Oncology*, 26, 350-357.
- 42 Sherman PM, Johnson-Henry KC, Yeung HP, Ngo PSC, Goulet J, Tompkins TA, 2005. Probiotics reduce enterohemorrhagic *Escherichia coli* O157: H7-and enteropathogenic *E. coli* O127: H6-induced changes in polarized T84 epithelial cell monolayers by reducing bacterial adhesion and cytoskeletal rearrangements. *Infection and Immunity*, 73, 5183-5188.
- 43 Song MJ, Park DI, Park JH, Kim HJ, Cho YK, Sohn CI, Jeon WK, Kim BI, 2010. The Effect of Probiotics and Mucoprotective Agents on PPI-Based Triple Therapy for Eradication of *Helicobacter pylori*. *Helicobacter*, 15, 206-213.
- 44 Sougioultzis S, Simeonidis S, Bhaskar KR, Chen X, Anton PM, Keates S, Pothoulakis C, Kelly CP, 2006. *Saccharomyces boulardii* produces a soluble anti-inflammatory factor that inhibits NF-[kappa] B-mediated IL-8 gene expression. *Biochemical and Biophysical Research Communications*, 343, 69-76.
- 45 Surawicz CM, Elmer GW, Speelman P, McFarland LV, Chinn J, Van Belle G, 1989. Prevention of antibiotic-associated diarrhea by *Saccharomyces boulardii*: A prospective study. *Gastroenterology*, 96, 981.
- 46 Surawicz CM, McFarland LV, Greenberg RN, Rubin M, Fekety R, Mulligan ME, Garcia RJ, Brandmarker S, Bowen K, Borjal D, 2000. The search for a better treatment for recurrent *Clostridium difficile* disease: use of high-dose vancomycin combined with *Saccharomyces boulardii*. *Clinical Infectious Diseases*, 31, 1012.
- 47 Szajewska H and Mrukowicz J, 2005. Meta-analysis: non-pathogenic yeast *Saccharomyces boulardii* in the prevention of antibiotic-associated diarrhoea. *Alimentary Pharmacology & Therapeutics*, 22, 365-372.
- 48 Tlaskal P, Michkova E, Klazarova H, Jerabkova L, Nevoral J, Balackova J, Tejncka J, Valtrova V, Simandlova M, Kejvalova L, 1995. *Lactobacillus Acidophilus* in the Treatment of Children with Gastrointestinal Disease. *Cesko-Slovenska Pediatrie*, 51, 615-619.
- 49 Tlaskal P, 2005. Probiotics in the treatment of diarrhoeal disease of children. *NAFAS*, 3, 25-28.
- 50 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.
- 51 Verdu EF, Bercik P, Huang XX, Lu J, Al-Mutawaly N, Sakai H, Tompkins TA, Croitoru K, Tsuchida E, Perdue M, 2008. The role of luminal factors in the recovery of gastric function and behavioral changes after chronic *Helicobacter pylori* infection. *American Journal of Physiology-Gastrointestinal and Liver Physiology*, 295, G664-G670.
- 52 Wallace TD, Bradley S, Buckley ND, Green-Johnson JM, 2003. Interactions of lactic acid bacteria with human intestinal epithelial cells: effects on cytokine production. *Journal of Food Protection*, 66, 466-472.
- 53 Wine E, Gareau MG, Johnson-Henry K, Sherman PM, 2009. Strain-specific probiotic (*Lactobacillus helveticus*) inhibition of *Campylobacter jejuni* invasion of human intestinal epithelial cells. *FEMS Microbiology Letters*, 300, 146-152.
- 54 Yeung PSM, Sanders ME, Kitts CL, Cano R, Tong PS, 2002. Species-specific identification of commercial probiotic strains. *Journal of Dairy Science*, 85, 1039-1051.
- 55 Zanello G, Meurens F, Berri M, Salmon H, 2009. *Saccharomyces boulardii* effects on gastrointestinal diseases. *Current Issues in Molecular Biology*, 11, 47-58.

ID 3035: *Bifidobacterium adolescentis* BA 02

- 1 Dossier submitted by the competent Authority of Italy on *Bifidobacterium adolescentis* BA 02 (DSM 17103). ID 3035. 2011.
- 2 Del Piano M, Montino F, Carmagnola S, Anderloni A, Orsello M, Garello E, Sforza F, Ballare M, 2005. The use of probiotics in the treatment of constipation in the elderly. CIBUS, 1, 23-30.

ID 3047: *Bifidobacterium lactis* BS 01, *Lactobacillus rhamnosus* LR 04, *Lactobacillus rhamnosus* LR 05, *Lactobacillus plantarum* LP 01 and *Lactobacillus plantarum* LP 02

- 1 Dossier submitted by the competent Authority of Italy on *B. lactis* BS 01 (LMG P-21384) + *L. rhamnosus* LR 04 (DSM 16605) + LR 05 (DSM 19739) + *L. plantarum* LP 01 (LMG P-21021) and LP 02 (LMG P-21020), ID 3047. 2011.
- 2 Del Piano M, Carmagnola S, Anderloni A, Andorno S, Ballaré M, Balzarini M, Montino F, Orsello M, Pagliarulo M, Sartori M, 2010. The use of probiotics in healthy volunteers with evacuation disorders and hard stools: a double-blind, randomized, placebo-controlled study. Journal of Clinical Gastroenterology, 44, S30-34.
- 3 Del Piano M, Carmagnola S, Ballaré M, Sartori M, Orsello M, Balzarini M, Pagliarulo M, Tari R, Anderloni A, Strozzi GP, 2011. Is microencapsulation the future of probiotic preparations? Gut Microbes, 2, 120-123.
- 4 Pregliasco F, Anselmi G, Fonte L, Giussani F, Schieppati S, Soletti L, 2008. A new chance of preventing winter diseases by the administration of symbiotic formulations. Journal of Clinical Gastroenterology, 42 Suppl 3 Pt 2, S224-233.

ID 3055: *Lactobacillus paracasei* LPC 01

- 1 Dossier submitted by the competent Authority of Italy on *L. paracasei* LPC 01 (CNCM I-1390). ID 3055. 2011.
- 2 Andriulli A, Neri M, Loguercio C, Terreni N, Merla A, Cardarella MP, Federico A, Chilovi F, Milandri GL, De Bona M, Cavenati S, Gullini S, Abbiati R, Garbagna N, Cerutti R, Grossi E, 2008. Clinical trial on the efficacy of a new symbiotic formulation, Flortec, in patients with irritable bowel syndrome: a multicenter, randomized study. Journal of Clinical Gastroenterology, 42 Suppl 3 Pt 2, S218-223.
- 3 Caldarella MP, Balatsinou C, Milano A, Laterza F, Grossi E, Neri M, 2009. Effect of symbiotic formulation (FLORTEC) on visceral sensitivity and symptoms in patients with IBS with diarrhea. Cibus, 5, 43.
- 4 Cariello R, Tuccillo C, Romano A, Federico A, Mazzone G, Ribecco MT, Amoruso DC, Carteni M, De Magistris L, D'Argenio G, Loguercio C, 2009. Probiotic treatment with Flortec® reduces intestinal permeability and ameliorates CCL₄-induced rat liver fibrosis. Cibus, 5, 46.
- 5 Drago L, Gismondo MR, Lombardi A, de Haen C, Gozzini L, 1997. Inhibition of in vitro growth of enteropathogens by new *Lactobacillus* isolates of human intestinal origin. FEMS Microbiology Letters, 153, 455-463.
- 6 Elli M., Grossi E, Morelli L, 2009. Lessons from probiotics genome sequence: the example of *L. paracasei* B 20160.
- 7 Federico A, Tuccillo C, Grossi E, Abbiati R, Garbagna N, Romano M, Tiso A, Blanco Cdel V, Loguercio C, 2009. The effect of a new symbiotic formulation on plasma levels and peripheral blood mononuclear cell expression of some pro-inflammatory cytokines in patients with ulcerative colitis: a pilot study. European Review for Medical and Pharmacological Sciences, 13, 285-293.

- 8 Grossi E, Buresta R, Abbiati R, Cerutti R, 2010. Clinical Trial on the Efficacy of a New Symbiotic Formulation, Flortec, in Patients With Acute Diarrhea: A Multicenter, Randomized Study in Primary Care. *Journal of Clinical Gastroenterology*, 44, S35-41.
- 9 Milet E, Matteoli G, Iliev ID, Rescigno M, 2009. Comparison of the Immunomodulatory Properties of Three Probiotic Strains of Lactobacilli Using Complex Culture Systems: Prediction for In Vivo Efficacy. *PLoS ONE*, 4, e7056.
- 10 Morelli L, Zonenschain D, Callegari ML, Grossi E, Maisano F, Fusillo M, 2003. Assessment of a new symbiotic preparation in healthy volunteers: survival, persistence of probiotic strains and its effect on the indigenous flora. *Nutrition Journal*, 2, 11.
- 11 Morelli L, Garbagna N, Rizzello F, Zonenschain D, Grossi E, 2006. In vivo association to human colon of *Lactobacillus paracasei* B21060: map from biopsies. *Digestive and Liver Disease*, 38, 894-898.
- 12 Peluso I, Fina D, Caruso R, Stolfi C, Caprioli F, Fantini MC, Caspani G, Grossi E, Di Iorio L, Paone FM, Pallone F, Monteleone G, 2007. *Lactobacillus paracasei* subsp. *paracasei* B21060 suppresses human T-cell proliferation. *Infection and Immunity*, 75, 1730-1737.

ID 3056: *Bifidobacterium longum* W11

- 1 Dossier submitted by the competent Authority of Italy on *B. longum* W11 (LMG P-21586), ID 3056. 2011.
- 2 Amenta M, Cascio MT, Di Fiore P, Venturini I, 2006. Diet and chronic constipation. Benefits of oral supplementation with symbiotic zir fos (*Bifidobacterium longum* W11+ FOS Actilight). *Acta Biomedica*, 77, 157-162.
- 3 Cafaro D, Onofrio L, D'Agostino G, 2007. Combination therapy with symbiotics and local anti-inflammatories for red anusitis. *Minerva Gastroenterologica e Dietologica* , 53, 117-123.
- 4 Colecchia A, Vestito A, La Rocca A, Pasqui F, Nikiforaki A, Festi D, Symbiotic Study Group, 2006. Effetto di una preparazione simbiotica sulle manifestazioni cliniche della sindrome dell'intestino irritabile variante stipsi. Risultati di uno studio multicentrico, aperto, non controllato. *Minerva Gastroenterologica e Dietologica* , 52, 1-8.
- 5 Del Piano M, Ballare M, Montino F, Orsello M, Garello E, Ferrari P, Masini C, Strozzi GP, Sforza F, 2004. Clinical experience with probiotics in the elderly on total enteral nutrition. *Journal of Clinic Gastroenterology*, 38, S111-S114.
- 6 Dughera L, Elia C, Navino M, Cisaro F, ARMONIA Study Group, 2007. Effects of symbiotic preparations on constipated irritable bowel syndrome symptoms. *Acta Bio-Medica*, 78, 111-116.
- 7 Malaguarnera M, Greco F, Barone G, Gargante MP, Malaguarnera M, Toscano MA, 2007. *Bifidobacterium longum* with fructo-oligosaccharide (FOS) treatment in minimal hepatic encephalopathy: a randomized, double-blind, placebo-controlled study. *Diseases (Basel)*. *Digestive Diseases and Sciences*, 52, 3259-3265.
- 8 Morelli L, 2003. Analisi microbiologiche e genetiche che determinino la presenza del ceppo di *Bifidobacterium longum* contenuto nel prodotto Zir Fos in campioni fecali.
- 9 Orsi P and Pinazzi O, 2004. Effect of a symbiotic supplementation on reducing antibiotic side-effects during anti-*Helicobacter pylori* quadruple therapy. *Digestive and Liver Disease*, 36 (Suppl 2), S291.
- 10 Sarnelli G and et al, 2008. Effects of oral supplementation with the symbiotic (*bifidobacterium longum* w11 + fos actilight) on ibs with constipation: a randomized, dose finding trial, versus fibers. *Digestive and Liver Disease*, 40 Suppl 1, S141.

ID 3059: *Bifidobacterium lactis* BS 01, *Lactobacillus rhamnosus* LR 04 and *Lactobacillus plantarum* LP 02 and lactoferrin

- 1 Dossier submitted by the competent Authority of Italy on *B. lactis* BS 01 (LMG P-21384) + *L. rhamnosus* LR 04 (DSM 16605) + *L. plantarum* LP 02 (LMG P-21020) + Lactoferrin, ID 3059. 2011.
- 2 Del Piano M, Carmagnola S, Anderloni A, Andorno S, Ballare M, Balzarini M, Montino F, Orsello M, Pagliarulo M, Sartori M, 2010. The use of probiotics in healthy volunteers with evacuation disorders and hard stools: a double-blind, randomized, placebo-controlled study. *Journal of Clinical Gastroenterology*, 44, S30-34.
- 3 Pregliasco F, Anselmi G, Fonte L, Giussani F, Schieppati S, Soletti L, 2008. A new chance of preventing winter diseases by the administration of synbiotic formulations. *Journal of Clinic Gastroenterology*, 42 Suppl 3 Pt 2, S224-233.

ID 3061: *Lactobacillus casei* DG, CNCM I-1572

- 1 Dossier submitted by the competent Authority of Italy on *Lactobacillus casei* DG, CNCM I-1572, ID 3061. 2011.
- 2 Azienda ospedaliero universitaria consorziale policlinico di Bari, 2007. Studio clinico prot. DUO 05 Valutazione dell'effetto dei simbiotici sulla funzione intestinale dei pazienti con stipsi cronica idiomatica. Studio multicentrico, randomizzato, cross-over, indoppio cieco verso placebo. - *Lactobacillus casei* DG ed inulina (Enterolactis Duo) (Study in progress).
- 3 D'Incà R, Barollo M, Scarpa M, Grillo A, Brun P, Vettorato M, Castagliuolo I, Sturniolo G, 2011. Rectal Administration of *Lactobacillus casei* DG Modifies Flora Composition and Toll-Like Receptor Expression in Colonic Mucosa of Patients with Mild Ulcerative Colitis. *Digestive Diseases and Sciences*, 56, 1178-1187.
- 4 Drago L, De Vecchi E, Valli M, Nicola L, Lombardi A, Gismondo MR, 2002. Colonizzazione intestinale di *Lactobacillus casei* subsp.*casei* I-1572 CNCM (*L.casei* DG) in volontari sani e in topi Germ-Free. *Farmaci & Terapia*, 19, 72-76.
- 5 Tursi A, Brandimarte G, Giorgetti GM, Modeo ME, 2004. Effect of *Lactobacillus casei* supplementation on the effectiveness and tolerability of a new second-line 10-day quadruple therapy after failure of a first attempt to cure *Helicobacter pylori* infection. *Medical Science Monitor: International Medical Journal of Experimental and Clinical Research*, 10, CR662.
- 6 Tursi A, Brandimarte G, Giorgetti GM, Elisei W, 2006. Mesalazine and/or *Lactobacillus casei* in preventing recurrence of symptomatic uncomplicated diverticular disease of the colon: a prospective, randomized, open-label study. *Journal of Clinical Gastroenterology*, 40, 312.
- 7 Tursi A, Brandimarte G, Marco Giorgetti G, Elisei W, 2008. Mesalazine and/or *Lactobacillus casei* in maintaining long-term remission of symptomatic uncomplicated diverticular disease of the colon. *Hepato-gastroenterology*, 55, 916-920.

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

- 1 Dossier submitted by the competent Authority of France on *Bifidobacterium animalis* ssp. *lactis* Bf-6 and *Lactobacillus johnsonii* La-1 (ACD-1)(CLbA22), ID 4231. 2011.
- 2 BCCM/LMG, 2006. Accession form for public deposit . *Bifidobacterium anilmalis* subsp.*lactis*.
- 3 BCCM/LMG, 2009. BCCM/LMG bacteria catalogue - Strain details LMG 24384.
- 4 Cargill, 2011. 16S rRNA Gene Sequence Alignment Report. Strain La-1 (aslo referred to as ACD-1 and CLbA22).

- 5 Cargill, 2011. Rep-PCR of *L. johnsonii* La-a (ACD-1) compared to other Cargill thermophilic rod strains.
- 6 Cargill, 2011. Rep-PCR of Bf-6 compared to other commercial bifidobacteria strains.
- 7 Ehrmann M, 2006. Identification of strains.
- 8 Garrigues C, Johansen E, Pedersen MB, 2010. Complete genome sequence of *Bifidobacterium animalis* subsp. *lactis* BB-12, a widely consumed probiotic strain. *Journal of Bacteriology*, 192, 2467-2468.
- 9 Gevers D, Huys G, Swings J, 2001. Applicability of rep-PCR fingerprinting for identification of *Lactobacillus* species. *FEMS Microbiology Letters*, 205, 31-36.
- 10 Integrated Genomics Inc., 2011. Sequencing the genome of *Bifidobacterium animalis* ssp. *lactis* Bf-6.
- 11 Kogan SC, Doherty M, Gitschier J, 1987. An improved method for prenatal diagnosis of genetic diseases by analysis of amplified DNA sequences. *New England Journal of Medicine*, 317, 985-990.
- 12 MIDI LABS, 2011. Alignment Report - 500BP Identification.
- 13 MIDI LABS, 2011. Comparison Report - 500BP Identification.
- 14 Sun Z, Chen X, Wang J, Gao P, Zhou Z, Ren Y, Sun T, Wang L, Meng H, Chen W, 2010. Complete genome sequence of probiotic *Bifidobacterium animalis* subsp. *lactis* strain V9. *Journal of Bacteriology*, 192, 4080-4081.
- 15 Weisburg WG, Barns SM, Pelletier DA, Lane DJ, 1991. 16S ribosomal DNA amplification for phylogenetic study. *Journal of Bacteriology*, 173, 697-703.