Brussels, 12 June 2007

LIST OF REFERENCES Part 1

GENERAL SOURCES OF EVIDENCE

1. *Authoritative Bodies that have approved claims*

- **AFSSA**
  AFFSA's list of opinions related to human nutrition (FR)
  http://www.afssa.fr/Object.asp?IdObj=17334&Pge=0&CCH=070403112237:26:4&cwSID=BEA9A33C833E48A380BBDE26728C919B&AID=0

  Miscellaneous reports of AFFSA (some related to nutrition) (FR)
  http://www.afssa.fr/Object.asp?IdObj=164&Pge=0&CCH=070403112237:26:4&cwSID=BEA9A33C833E48A380BBDE26728C919B&AID=0

- **ANZFA** - Food Standards Australia, New Zealand http://www.foodstandards.gov.au/

- **CEDAP**. Avis de la commission interministérielle d'étude des produits destinés à une alimentation particulière (CEDAP) en date du 18 décembre 1996 sur les recommandations relatives au caractère non trompeur des seuils des allégations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Répression des fraudes) du 7 octobre 1997

- **CH** - Switzerland - Ordonnance du March 1995 sur les dennrées alimentaires et les objets usuels (ODAlOUs)
  http://www.admin.ch/ch/f/rs/c817_02.html
  http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr

- **FDA** Food and Drug Administration of the USA. Code of Federal Regulations; 21 CFR 101

- **FNFC/FOSHU** – Japan
  http://www.mhlw.go.jp/english/topics/foodsafety/fhc/index.html

- **JHCI** – Joint Health Claims Initiative – Final Technical Report – A List of Well Established Nutrient Function Statements
  http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf

- **NFA** – Terveysväitteiden valvontaopas, Finnish Food Authority Control guides number 2/2002
  http://www.palvelu.fi/evi/evi_material.php

- **NHPD** – Health Canada Permitted Health Claims
  http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/236932.html#Section-B.01.603

- **SNF** – Swedish Nutrition Foundation
  http://www.snf.ideon.se/snf/en/rh/Healh_claims_FF.htm

2. ***Reports, Scientific Reviews and Dietary Reference Values from Authoritative and other Scientific Bodies***

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- FAO/WHO. Human vitamin and mineral requirements. Report of a joint FAO/WHO expert consultation Bangkok, Thailand 2002.
- Institute of Medicine - USA

  1. *Institute of Medicine Dietary Reference Intakes for vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium and zinc.* Washington D.C. National Academy Press, 2001. http://books.nap.edu/openbook.php?isbn=0309072794
  2. *Institute of Medicine Dietary Reference Intakes for Vitamin C, Vitamin E, selenium and carotenoids. Washington D.C. National Academy Press, 2000.* http://books.nap.edu/openbook.php?isbn=0309069351
  3. *Institute of Medicine Dietary reference intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin and choline. Washington D.C. National Academy Press 2000a* http://books.nap.edu/openbook.php?isbn=0309065542
  4. *Institute of Medicine Dietary Reference Intakes for calcium, phosphorus, magnesium, vitamin D, and fluoride. Washington D.C. National Academy Press, 1997.* http://books.nap.edu/openbook.php?isbn=0309063507
  5. *Institute of Medicine Dietary Reference Intakes Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients) Washington D.C. National Academy 2005.* http://books.nap.edu/openbook.php?isbn=0309085373
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3. ***Text Books***

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VITAMIN A and Immune Function

Authoritative/Scientific Bodies

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  http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf
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VITAMIN B6 and Homocysteine

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VITAMIN B12 and Cognitive Function in Ageing

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CARBOHYDRATES - Low GI - Blood Glucose

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CARBOHYDRATES - Low GI - Cholesterol

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CARBOHYDRATES - Low GI - Satiety

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CARBOHYDRATES with a Low Glycaemic Response

Conditions of Use

The glycemic response is not more than half that of glucose, without increasing the fat content, assessed from blood glucose response curves (e.g. test food vs glucose) either based on a portion of the food providing 50g (minimum 10g) of total carbohydrates and dietary fibre (thus taking into account available carbohydrates and their replacements, e.g. polyols and dietary fibre) or based on the amount of carbohydrates in one serving of the food vs the equivalent amount of glucose.

Authoritative/Scientific Bodies

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CARBOHYDRATES with a Reduced Glycemic Response

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See as well references for "Carbohydrates with a low glycemic response".

CARBOHYDRATES and Physical Endurance

Authoritative/Scientific Body

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CARBOHYDRATE/GLUCOSE and Cognitive Performance

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CARBOHYDRATES – Non-Cariogenic / Absence of Fermentable

Authoritative/Scientific Bodies

General

- Swedish Nutrition Foundation (SNF)
- US FDA 21CFR §101.80

Isomaltulose

- FOSHU
- EU Novel Food Approval for Isomaltulose: Initial Assessment Report of the competent German Authority (BfR)
- US FDA 21CFR §101.80 (submitted)

Tagatose

- US FDA 21CFR §101.80

Polyols

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- FOSHU Japan: (1) FOSHU approved products classified by ingredients used and intended benefit or effect 1991-1997 at website of the International Association of Consumer Food Organisation at http://www.cspinet.org/reports/functionalfoods/table4.html; (2) website of the Japan Health Nutrition Food Association (JHNFA); (3) Shimizu, T. (2003) Health claims on functional foods: the Japanese regulations and an international comparison. Nutrition Research Reviews 16, 241-252. [Note: the Japanese name of isomalt is “hydrogenised Palatniose”]
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Isomalt

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Individual Studies

Isomaltulose

a) Human studies in situ (pH telemetry)

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POLYOLS and Remineralisation of Teeth

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POLYOLS and Low Glycaemic Properties

Authoritative/Scientific Bodies

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LIPID 1 – Unsaturates – Blood Cholesterol and Heart Health

Authoritative/Scientific Bodies

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LIPID 2 – LA (Omega 6) and LNA (Omega 3) – Artery / Heart Health

Expert Review

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LIPID 3 – LNA to LA Ratio

Authoritative/Scientific Bodies

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LIPID 4 - n3 LC PUFA - Brain Development / Cognitive Function

Authoritative/Scientific Bodies

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LIPID 5 – n3 LC PUFA - Cardiovascular / Heart Health

Expert Reviews

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LIPID 6 - n3 LC PUFA and Blood Pressure

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- Encyclopedia of Human Nutrition 1999 page 1039

Authoritative/Scientific Bodies

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DIETARY FIBRE and Bowel Function

Authoritative/Scientific Bodies

- SNF
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- JHCI
- NFA

1. INULIN - OLIGOFRUCTOSE and Bowel Function

Authoritative/Scientific Bodies

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Books

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Authoritative/Scientific Bodies

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3. RESISTANT STARCH and Bowel Function

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Human Studies

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Nyman, M; Asp, N G (1982): Fermentation of dietary fibre components in the rat intestinal tract. British Journal of Nutrition, 47, 357-366.

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Authoritative/Scientific Body

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DIETARY FIBRE and Satiety

Books

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- Diet & Health, Implications for Reducing Chronic Disease. National Research Council. National Academy Press. 1989, page 292.

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- Introduction to Human Nutrition. Edited on behalf of The Nutrition Society by Michael J. Gibney, Hester H. Vorster and Frans J. Kok. Blackwell Science, September 2002. page 77.
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Clinical Trial

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DIETARY FIBRE and Glycemic Response

1. FRUCTOLIGOSACCHARIDES FROM SUCROSE

Authoritative/Scientific Bodies

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Individual Studies

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2. ACACIA GUM

Individual Studies

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3. INULIN-OLIGOFRUCTOSE

Individual Studies

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4. OAT BETA-GLUCAN

Authoritative/Scientific Body

- Primaliv/OatWell® oat bran Müesli with 4 g oat beta-glucans lowers glucose and insulin responses after a bread meal http://www.hp-info.nu/prodsp/Finalreport_Primaliv.pdf

Human Intervention study

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5. OAT AND BARLEY BETA-GLUCAN and Blood Glucose Lowering

Review

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Clinical Trial

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Individual Studies

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- NL Profit/OatWell oat bran bread

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Oligofructose-enriched inulin: Increased Ca absorption

1. Scientific support for oligofructose-enriched inulin

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Authoritative/Scientific Bodies

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Authoritative/Scientific Bodies

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PROBIOTIC 10 – Bifidobacterium Breve I-3425 and Digestive Health

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PROBIOTIC 11 - Bifidobacterium Breve Yakult (BbY) and Digestive System / Intestinal Flora

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PROBIOTIC 13 – Bifidobacterium Longum I-3470 and Digestive Health

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Additional Human Studies

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PROBIOTIC 14 – Lactobacillus Acidophilus CNCM I-1722 and Digestive Health

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PROBIOTIC 15 – Lactobacillus Acidophilus CUL21 NCIMB 30156, Lactobacillus Acidophilus CUL 60 NCIMB 30157, Bifibobacterium Adolescentis CUL 17 NCIMB 30153, Bifiidobacterium Lactis (animalis ssp. lactis) CUL 34 NCIMB 30172 and Gut Flora

Individual Human Studies

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PROBIOTIC 16 – Lactobacillus Acidophilus Lafti L10 (CBS 116.411) and Digestive Health

Individual Human Study

- Survival of Lactobacillus acidophilus LAFTI® L10 and L. casei LAFTI® L26 in the human gastrointestinal tract and perceived effects on health, conducted at the UNSW by Welin A and Henriksson A – Internal DSM report

Animal Studies

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In Vitro Studies

- Gastro-intestinal survival test with LAFTI® L10 CG, conducted at the University of New South Wales (UNSW), Australia - Internal DSM report
- Dung et al. (Data on file) Survival of LAFTI® L10 in human gastric juice, conducted at the University of New South Wales – Internal DSM report
- In vitro study on inhibition of Helicobacter pylori by probiotic cultures, conducted at the UNSW – Internal DSM report
- Adhesion of probiotic cultures to Caco-2 cells, conducted at the UNSW - Internal DSM report

PROBIOTIC 17 – Lactobacillus Acidophilus Lafti L10 (CBS 116.411) and Intestinal Flora

Individual Human Study

- Survival of Lactobacillus acidophilus LAFTI® L10 and L. casei LAFTI® L26 in the human gastrointestinal tract and perceived effects on health, conducted at the UNSW by Welin A and Henriksson A – Internal DSM report

Animal Study

- Mahoney M et al. (2003) The effect of processed meat and meat starter cultures on gastro-intestinal colonization and virulence of Listeria monocytogenes in mice. International Journal of Food Microbiology 84:255-261

In Vitro Studies

- Gastro-intestinal survival test with LAFTI® L10 CG, conducted at the University of New South Wales (UNSW), Australia - Internal DSM report
- In vitro study on inhibition of Helicobacter pylori by probiotic cultures, conducted at the UNSW – Internal DSM report
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PROBIOTIC 19 – Lactobacillus Helveticus I-1722 and Digestive Health

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PROBIOTIC 20 – Lactobacillus Casei Lafti L26 (CBS 116.412) and Intestinal Flora

Individual Human Study

- Survival of Lactobacillus acidophilus LAFTI® L10 and L. casei LAFTI® L26 in the human gastrointestinal tract and perceived effects on health, conducted at the UNSW by Welin A and Henriksson A – Internal DSM report

Animal Studies

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In Vitro Study

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PROBIOTIC 21 – Lactobacillus Casei I-3429 and Digestive Health

Individual Human Studies

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PROBIOTIC 22 - Lactobacillus Casei Shirota (LcS) and Gut Health

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Individual Human Studies

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PROBIOTIC 23 - Lactobacillus Casei Shirota (LcS) and Digestive System / Bowel Habit

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PROBIOTIC 27 – Lactobacillus Helveticus CNCM I-1722 and Lactobacillus Rhamnosus CNCM I-1720 and Digestive System

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PROBIOTIC 28 - Lactobacillus Johnsonii La-19/CLbA5 and Bifidobacterium Animalis ssp. Lactis Bf-6/Bif-6/CB111 (Biogarde®/Bioghurt®/Bigarde®/Bighurt®-Cultures) and Intestinal Flora / Digestive Health

Authoritative/Scientific Bodies

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In Vitro Studies

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PROBIOTIC 29 - Lactobacillus Johnsonii NCC 533 (La1) (Pasteur Culture Collection CNCM I-1225) and Gut Health

Individual Human Studies

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PROBIOTIC 30 - Lactobacillus Paracasei NCC 2461 (ST11) (Pasteur Culture Collection CNCM I-2116) and Gut Health

Individual Human Study

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PROBIOTIC 31 – Lactobacillus Plantarum and Natural Defences / Digestive Health

Individual Human Studies

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PROBIOTIC 32 – Lactobacillus Plantarum 299v and Digestive System

Authoritative/Scientific Body

- Swedish Nutrition Foundation, Statement concerning the evaluation of the scientific documentation behind a product specific health claim, Proviva Fruit Drink with Lactobacillus plantarum 299v. 12 September 2003.

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PROBIOTIC 34 - Lactobacillus Rhamnosus ATCC53103 (LGG®) and Gastro-Intestinal Health

Authoritative/Scientific Bodies

- Ministry of Health and Welfare in Japan, approval as a functional ingredient for FOSHU granted in March 1994, and approval for an LGG®-fermented milk as a FOSHU product granted in May 1996.
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PROBIOTIC 38 – Sacharomyces Cerevisiae Var Boulardii and Digestive System

Meta-Analysis

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PROBIOTIC 39 – Streptococcus Thermophilus I-3428 and Digestive Health

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PROBIOTIC 40 - Bifidobacterium Animalis ssp. Lactis Bb-12® and Natural Defence/ Immune System

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PROBIOTIC 41 - Bifidobacterium Animalis ssp. Lactis BB-12, Lactobacillus Acidophilus LA-5, Lactbacillus Bulgaricus LBY-27 and Streptococcus Thermophilus STY-31 and Natural Defence / Immune System

Review

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PROBIOTIC 43 – Bifidobacterium Bifidum I-3426 and Immune Defenses / Support of Immunity

Reviews

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PROBIOTIC 44 – Bifidobacterium Breve I-3425 and Immune Defenses / Support of Immunity

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PROBIOTIC 45 – Bifidobacterium Infantis I-3424 (Rosell-33) and Immune Defenses / Support of Immunity

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PROBIOTIC 47 – Bifidobacterium Longum I-3470 and Immune Defenses / Support of Immunity

Individual Human Studies

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PROBIOTIC 48 – Lactobacillus Acidophilus CUL21 NCIMB 30156, Lactobacillus Acidophilus CUL 60 NCIMB 30157, Bifibobacterium Adolescentis CUL 17 NCIMB 30153, Bifiidobacterium Lactis (animalis ssp. lactis) CUL 34 NCIMB 30172 and Natural Defence/Immune System

Individual Human Studies

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PROBIOTIC 49 – Lactobacillus Acidophilus Lafti L10 (CBS 116.411) and Natural Defence / Immune System

Individual Human Studies

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Additional Human Study

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Animal Studies

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In Vitro Studies

- Adhesion of probiotic cultures to Caco-2 cells, conducted at the UNSW - Internal DSM report
- Dung et al. (Data on file) Survival of LAFTI® L10 in human gastric juice, conducted at the University of New South Wales – Internal DSM report
- Gastro-intestinal survival test with LAFTI® L10 CG, conducted at the University of New South Wales (UNSW), Australia - Internal DSM report
- In vitro study on inhibition of Helicobacter pylori by probiotic cultures, conducted at the UNSW – Internal DSM report

PROBIOTIC 50 - Lactobacillus Acidophilus NCFM ATCC SD5221 and Natural Resistance / Defence

Review

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PROBIOTIC 55 - Lactobacillus Casei Shirota (LcS) and Natural Resistance / Defence (enhance NK cell activity)

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PROBIOTIC 56 - Lactobacillus Casei Shirota (LcS) and Natural Defence (regulation of cell development)

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PROBIOTIC 57 - Lactobacillus Fermentum CECT5716 and Natural Defence / Immune System

Individual Human Studies

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PROBIOTIC 58 - Lactobacillus Gasseri CECT5714 and Lactobacillus Coryniformis CECT5711 and Natural Defence / Immune System

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PROBIOTIC 59 - Lactobacillus Gasseri PA 16/8, Bifidobacterium Bifidum MF 20/5 and Bifidobacterium Longum SP 07/3 and Natural Defence / Immune System

Individual Human Studies

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PROBIOTIC 60 - Lactobacillus Johnsonii La-19/CLbA5 and Bifidobacterium Animalis ssp. Lactis Bf-6/Bif-6/CB111 (Biogarde®/Bioghurt®/Bigarde®/Bighurt®-Cultures) and Natural / Immune Defenses

Authoritative/Scientific Bodies

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PROBIOTIC 61 - Lactobacillus Johnsonii NCC 533 (La1) (Pasteur Culture Collection CNCM I-1225) and Natural Defence / Immune System

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PROBIOTIC 67 - Lactobacillus Rhamnosus HN001 AGAL NM97/09514 and Natural Defence / Immune System

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PROBIOTIC 68 – Lactobacillus Rhamnosus I-1720 and Immune Defenses / Support of Immunity

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PROBIOTIC 70 - Lactobacillus Rhamnosus GR 1 (ATCC 55826) and Lactobacillus Reuteri RC-14 (ATCC 55845) and Vaginal Health/Flora

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PROBIOTIC 71 – Lactobacillus Acidophilus LA14 and Urogenital Tract / Natural Vaginal Defence

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PROBIOTIC 72 – Lactobacillus Rhamnosus and Urogenital Tract / Natural Vaginal Defence

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PROBIOTIC 73 – Lactobacillus Johnsonii NCC 533 (La1) (Pasteur Culture Collection CNCM I-1225) and Skin Health

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PROBIOTIC 74 – Lactobacillus Paracasei NCC 2461 (ST11) (Pasteur Culture Collection CNCM I-2116) and Skin Heath

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