Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
PROBIOTIC INGREDIENTS						

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	10. Lactobacillus paracasei ssp. paracasei CRL-431 (=L. casei 431)and Lactobacillus acidophilus					
		Natural defence / immune system	10E8-10E9 cfu/day			731

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Peer-reviewed scientific papers	Human studies: #407 Gaon, D., Garmendia, C., Murrielo, N.O., de Cucco Games, A., Cerchio, A., Quintas, R., Gonzalez, S.N., Oliver, G. Effect of Lactobacillus strains (L. casei and L. acidophilus Cerela) on bacterial overgrowth-related chronic diarrhea. 2002. Medicina, 62: 159-163. #333 Gonzalez, S., Cardozo, R., Apella, M., Oliver, G. Biotherapeutic role of fermented milk. 1995. Biotherapy, 8: 129-134. #419 Gaon D, Garcia H, Winter L, Rodriguez N, Quintas R, Gonzalez SN, Oliver G. Effect of Lactobacillus strains and Saccharomyces boulardii on persistent diarrhea in children. Medicina, 63: 293-298 #462 de Vrese M, Rautenberg P, Laue C, Koopmans M, Herremans T, Schrezenmeir J. Probiotic bacteria stimulate virus-specific neutralizing antibodies following a booster polio vaccination. Eur J Nutr 2004, 394 Other human studies: #501 Christensen HR, Larsen CN, Kæstel P, Rosholm LB, Sternberg C, Michaelsen KF, Frøkiær H. 2006. Immunomodulatory potential of supplementation with probiotics: a dose-response study in healthy young adults. FEMS Immunology & Medical Microbiology 47(3): p. 380-390. Animal studies: #222 Perdigon, G., Alvarez, S., Nader de Macias, M., Roux, M., Pesce de Ruiz Holgado, A. The oral administration of lactic acid bacteria increase the mucosal intestinal immunity in response to enteropathogens. 1990. Journal of Food Protection, 53 (5): 404-410. #244 Perdigon, G., Nader de Macia, M., Alvarez, S., Oliver, G., Pesce de Ruiz Holgado, A. Prevention of gastrointestinal infection using	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					immunobiological methods with milk fermented with Lactobacillus casei and Lactobacillus acidophilus. 1990. Journal of Dairy Research, 57: 255-264. #245 Perdigon, G., Alvarez, S., Medici, M., Pesce de Ruiz Holgado, A. Influence of the use of Lactobacillus casei as an oral adjuvant on the levels of secretory IgA during an infection with Salmonella typhimurium. 1993. Food & Agricultural Immunology, 5: 27-37. #293 Perdigon, G., Nader de Macias, M.E., Alvarez, S., Oliver, G., Pesce de Ruiz Holgado, A. Systemic augmentation of the immune response in mice by feeding fermented milk with Lactobacillus casei and Lactobacillus acidophilus. 1988. Immunology, 63: 17-23. # 298 Nader de Macias, M.E., Romero, C., Apella, M.C., Gonzalez, S.N., Oliver, G. Prevention of infection produced by Escherichia coli and Listeria monocytogenes by feeding milk fermented with Lactobacilli. 1993. Journal of Food Protection, 56 (5): 401-405. #299 Perdigon, G., Alvarez, S., Gobbato, N., de Budeguer, M.V., de Ruiz Holgado, A.A.P. Comparative effect of the adjuvant capacity of Lactobacillus casei and lipopolysaccharide on the intestinal secretory antibody response and resistance to Salmonella infection in mice. 1995. Food & Agricultural Immunology, 7: 283-294. #300 Perdigon, G., Medici, M., Bibas Bonet de Jorrat, M.E., Valverde de Budeguer, M., Pesce de Ruiz Holgado, A. Immunomodulating effects of lactic acid bacteria on mucosal and tumoral immunity. 1993. Int. J. Immunotherapy, IX (1): 29-52 #301 Perdigon, G., Alvarez, S., Pesce de Ruiz Holgado, A. Immunoadjuvant activity of oral Lactobacillus casei: influence of dose on the	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

secretory immune response and protective capacity in intestinal infections. 1991. Journal of Dairy Research, 58: 485-496.
#302 Perdigon, G., Nader de Macias, M.E., Alvarez, S., Oliver, G., Pesce de Ruiz Holgado, A. Effect of perorally administered lactobacilli on macrophage activation in mice. 1986. Infection and Immunity, 53 (2): 404-410
#303 Perdigon, G.,Nader de Macias, M.E., Alvarez, S., Medici, M., Oliver, G., Pesce de Ruiz Holgado, A. Effect of a mixture of Lactobacillus casei and Lactobacillus acidophilus administered orally on the immune system in mice. 1986. Journal of Food Protection, 49 (12): 986-989

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#336 Macias, M., Apella, M., Romero, N., Gonzalez, S., Oliver, G. Inhibition of Shigella sonnei by Lactobacillus casei and Lactobacillus acidophilus. 1992. Journal of Applied Bacteriology, 73: 407-411

#340 de Petrino, S., Eugenia, M., de Jorrat, B., de Budeguer, M., Perdigon, G. Influence of the oral administration of different latic acid bacteria on intestinal microflora and IgA-secreting cells in mice treated with ampicillin. 1997. Food and Agricultural Immunology, 9: 265-275.
#377 Perdigon, G., Vintini, E., Alvarez, S., Medina, M., Medici, M. Study of the possible mechanisms involved in the mucosal immune system activation by lactic acid bacteria. 1999. Journal of Dairy Science, 82: 1108-1114
#404 Cano, P.G., Agüero, G., Perdigón, G. Adjuvant effects of Lactobacillus casei added to a renutrition diet in a malnourished mouse model. 2002. Biocell, 26(1):35-48.
#405 Vitiñi, E., Alvarez, S., Medina, M.,

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Medici, M., de Buduguer, M.V., Perdigón, G. Gut mucosal immunostimulation by lactic acid bacteria. 2000. Biocell, 24(3): 223-232. #418 Perdigon G, Maldonado Galdeano C, Valdez JC, Medici M. Interaction of lactic acid bacteria with the gut immune system. Eur J Clin Nutr. 2002 Dec;56 Suppl 4:S21-6. Maldonado Galdeano C and Perdigon G. 2004. Role of viability of probiotic strains in their persistence in the gut and in mucosal immune stimulation. J. Appl. Microbiol. 7, 673-681 #474 Villena, J., Racedo S., Agüero G., Bru E., Medina M., Alvarez S. 2005. Lactobacillus casei improves resistance to pneumococcal respiratory infection in malnourished mice. J. Nutr. 135: 1462-1469 #557 Agüero G, Villena J, Racedo S, Haro S, Alvarez S. 2006. Beneficial immunomodulatory activity of Lactobacillus casei in malnourished mice pneumonia: effect on inflammation and coagulation. Nutrition 22; 810-819. In vitro studies: #297 Apella, M.C., Gonzalez, S.N., Nader de Macias, M.E., Romero, N., Oliver, G. In vitro studies on the inhibition of the growth of Shigella sonnei by Lactobacillus casei and Lactobacillus acidophilus. 1992. Journal of Applied Bacteriology, 73: 480-483. #328 Gonzalez, S., Apella, M., Romero, N., Macias, M., Oliver, G. Inhibition of enteropathogens by lactobacilli strains used in fermented milk. 1993. Journal of Food Protection, 56 (9): 773-776. # 335 Ambrosini, V., Gonzalez, S., Perdigon, G., Holgado, A., Oliver, G. Chemical composition of the cell wall of lactic acid bacteria and related species. 1996. C.P. Bulletin, 44 (12): 2263-2267.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					#338 Ambrosini, V., Gonzalez, S., Holgado, A., Oliver, G. Study of the morphology of the cell walls of some strains of lactic acid bacteria and related species. 1998. Journal of Food Protection, 61 (5): 557-562. #167 Hatcher, G., Lambrecht, R. Augmentation of macrophage phagocytic activity by cell-free extracts of selected lactic acid-producing bacteria. 1993. Journal of Dairy Science, 76: 2485-2492. #215 Miettinen, M., Vuopio-Varkila, J., Varkila, K. Production of human tumor necrosis factor alpha, interleukin-6 and interleukin 10 is induced by lactic acid bacteria. 1996. Infection and Immunity, 64 (12): 5403-5405. #486 Ding W, Wang H, Griffiths MW. 2005. Probiotics down-regulate flaA ó28 promotor in Campylobacter jejuni.J. Food Prot. 68 (11): 2295-2300.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	A combination of the probiotics: Lactobacillus casei F19, Lactobacillus plantarum 2592, Leuconostoc mesenteroides 77:1, Pediococcus pentosaceus 16:1					
		Natural defence/immune system	Dose comparable to studies.			779

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Scientific investigations	Quin-Liu., Z. P. Duan, D. K. Ha, S. Bengmark, J. Kurtovic, and S. Riordan. Synbiotic Modulation of the Gut flora: Effect on Minimal Hepatic Encephalopathy (MHE) in patients with cirrhosis. 2004. Hepatology 39: 1441-1449. Peluso I., Fina D., Caruso R., Stolfi C., Caprioli F., Fantini M.C., Caspani G., Grossi E., Di Iorio L., Paone F.M., Pallone F., Monteleone G.. 2007. Lactobacillus paracsei ssp paracasei B21060 supressess human T-cell proliferation. Infect. Immunity 75:1730-1737. Rayes N., D. Seehofer, T. Theruvath, R. A. Schiller, J. M. Langrehr, S. Jonas, S. Bengmark, and P. Neuhaus. 2005. Supply of pre- and probiotics reduces bacterial infection rates after liver transplantation – a randomized, double blind trial. Am. J. Transplantations 5:125-130. Riordan S. m., N. Skinner, A. Nagaree, H. McCallum, C. J. McIvaer, J. Kurtovic, J. A. Hamilton, S. Bengmark, R. Williams, and K. Visvanathan. 2003. Peripheral blood mononuclear cell expression of toll-like receptors and relation to cytokine levels in cirrhosis. Hepatology 37:1154-1164. Spindler-Vesel A., Bengmark S., Vovk I., Kompan L. 2007. Synbiotics, prebiotics, glutamine, or peptide in early enteral nutrition: A randomized study in traumatic patients. J. Parenteral and Enteral Nutrition 31:1-8	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	A combination of three probiotic ingredients; Lactobacillus casei F19, Bifidobacterium lactis Bb12 and Lactobacillus acidophilus La5					
		Intestinal flora/digestive health:	Daily intake 1x10E10 cfu of each probiotic strain			777

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Scientific investigations Scientific reviews	Black F, Einarsson K, Lidbeck A, Orrhage K, Nord CE 1991 Effect of lactic acid producing bacteria on the human intestinal microflora during ampicillin treatment SWcand J Infect Dis 23:247-254 Jernberg C, Sullivan A, Edlund C, Jansson JK. 2005 Monitoring of antibiotic-induced alterations in the human intestinal microflora and detection of probiotic strains by use of terminal restriction fragment length polymorphism. Appl Environ Microbiol. 71:501-6. Lidbeck A, Edlund C, Gustafsson JA, Kager L, Nord CE. 1988 Impact of Lactobacillus acidophilus on the normal intestinal microflora after administration of two antimicrobial agents. Infection. 16:329-36. Nord CE, Lidbeck A, Orrhage K, Sjostedt S. 1997 Oral supplementation with lactic acid-producing bacteria during intake of clindamycin. Clin Microbiol Infect. 3:124-132. Orrhage K, Brismar B, Nord CE 1994 Effets of supplements with Bifidobacterium longum and Lactobacillus acidophilus on the intestinal microbiota during administration of clindamycin. Microb Ecol Health Dis 7:17-25. Sullivan A, Barkholt L, Nord CE. 2003 Lactobacillus acidophilus, Bifidobacterium lactis and Lactobacillus F19 prevent antibiotic-associated ecological disturbances of Bacteroides fragilis in the intestine. J Antimicrob Chemother. 52:308-11. Crittenden, R., Saarela, M., Mättö, J., Ouwehand, A.C., Salminen, S., Pelto, L., Vaughan, E.E., de Vos, W.M., von Wright, A.,	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Fondén, R., Mattila-Sandholm, T. 2002. Lactobacillus paracasei subsp. paracasei F19: survival, ecology and safety in the human intestinal tract - a survey of feeding studies within the PROBDEMO project. Microbial Ecology in Health and Disease Suppl. (Lactobacillus F19 – Closing the broken circle) 3:22-26. Sullivan, Å., Palmgren, A.C., Nordh, C.E. 2001. Effect of Lactobacillus paracasei on intestinal colonisation of Lactobacilli, Bifidobacteria and Clostridium difficile in elderly persons. Anerobe 07: 67-70. Sullivan, Å., Bennet, R., Viitanen, M., Palmgren, A.C., Nord, C.E. 2002. Influence of Lactobacillus F19 on intestinal microflora in children and elderly persons and impact on Helicobacter pylori infections. Microbial Ecology in Health and Disease Suppl. (Lactobacillus F19 – Closing the broken circle) 3:17-21.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	A combination of three probiotic strains: **-Lactobacillus gasseri 57C** **-Lactobacillus fermentum 57A** **-Lactobacillus plantarum 57B** **Trade name of the food supplement:** **prOVag**					
		Helps in maintaining balanced vaginal flora and pH	One dose must contain 1 billion (at least 108 CFU) lyophilized lactic acid bacteria strains in the following proportion: 50% Lactobacillus gasseri 57C, 25% Lactobacillus fermentum 57A, 25% Lactobacillus plantarum 57B. To also present a statement which conveys that pregnant or lactating women should consult with a physician prior to taking prOVag. The following statements should be included on the product: 1 capsule daily Do not exceed recommended daily dosage Store in refrigerator (2°C-8°C).	Biochemistry and Biophysics Institute (Polish Academy of Science) in Warsaw.	Additional information: Sequential data of Lactobacillus bacteria strains marked as 57A, 57B, 57C, , Biochemistry and Biophysics Institute (Polish Academy of Science) in Warsaw.	651

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				List of publications	1. Andreu A., tapleton A., Fennel C., Hillier S., Stamm W. Hemagglutination, adherence and surface properties of vaginal Lactobacillus species. J Infect Dis 1995; 171: 1237- 43. 2. Antonio MA, Hillier SL. DNA fingerprinting of Lactobacillus crispalus strain CTV-04 repetitive element sequence-based PCR analysis in a pilot study on vaginal colonization. J Clin Microbiol 2003, 41:1881-1887. 3. Assim B., Kilic E. Some probiotic properties of vaginal lactobacilli isolated from healthy women. Jpn. J. Infect. Dis., 59, 249-253, 2006. 4. Boskey E.R., Telsch K.M., Whaley K.J., Moench T.R., Cone R.A. Acid production by vaginal flora in vitro is consistent with the rate and extent of vaginal acidification. Infect Immunity 1999, 67: 5170- 5175. 8. Herra CM, Cafferkey MT, Keane CT. The in vitro susceptibilities of vaginal lactobacilli to four broad- spectrum antibiotics, as determined by the agar dilution and E test methods. J Antimicrob Chemother 1995, 35: 775- 783. 9. Hilton E, Isenberg HD, Alperstein P, France K, Borenstein MT. Ingestion of yogurt containing Lactobacillus acidophilus as prophylaxis for candidal vaginitis. Ann Intern Med 1992; 116: 353-357. 10. Joint FAO/WHO Working Group Report on drafting guidelines for the evaluation of probiotics in food. London, Ontario, Canada, April 30 and May 1; 2002; 1- 11. 11. Lankaputra W.E., Shah N.P.: Survival of Lactobacillus acidophilus and Bifidobacterium sp. in the presence of acid and bile salts. Cult. Dairy Prod. J. 1995, 30: 2-7. 13. McGroarty J.A. Probiotics use of lactobacilli in the human female urogenital tract, FEMS Immunology and Medical Microbiology 6, 25 1-	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

264, 1993.
14. Perenc M. Fungal infections of vagina and vulva in practice of family doctor. Family Doctor, 03/2007, 316-322.
15. Reid G, Bruce AW, Frazer N, Heinemann C, Owen J, Henning B. Oral probiotics can resolve urogenital infections. FEMS Immunol Med Microbiol 2001; 30: 49-52.
16. Reid G, Bruce AW. Urogenital infections in women: can probiotics help? Postgrad Med J 2003; 79: 428-432. 2001; 30: 49-52.
17. Reid G, Charbonneau D, Erb J. Kochanowski B, Beuerman D, Poehner R, Bruce AW. Oral use of Lactobacillus rhamnosus GR-1 and L. fermentum RC-14 significantly alters vaginal flora: randomized, placebo-controlled trial in 64 healthy women. FEMS Immunol Med Microbiol 2003; 35: 13 1-134.
18. Reid G. Probiotic agents to protect the urogenital tract against infection. Am J Clin Nutr 73, 2001; 437- 43.
19. Reid G. Probiotics for urogenital health. Nutrition Clin Care 2002, 1: 3- 8
20. Reid G., Bruce A. Selection of Lactobacillus strains for urogenital probiotic applicatons. J Infect Dis 2001;183: 77- 80.
21. Reid G., Buerman D., Heinemann C., et al. Probiotic Lactobacillus dose required to restore and maintain a normal vaginal flora, FEMS Immunol Med Microb 2001, 32, 37- 41.
22. Reid G., Burton J., Devillard E. The rationale for probiotics in female urogenital healthcare. Med Gen Med 2004; 6: 49.
23. Reid G., McGroarty JA., Angotti R., Cook R. Lactobacillus ihibitor production against Escherichia coli and coaggregation ability with uropathogens. Can J Microl 34, 1988: 344-351.
24. Reid G., Soboh F., Bruce A., Mittelman M.

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Effect of nutrient composition on the in vitro growth of urogenital lactobacilli and uropathogens. Can J Microb 1998, 44: 866-871. 26. Sobel JD, Zervos M, Reed BD, Hooton T, Soper D, Nyirjesy P, Heine MW, Willems J, Panzer H. Fluconazole susceptibility of vaginal isolates obtained from women with complicated Candida vaginitis: clinical implications. Antimicrob Agents Chemother 2003;47:34-8. . 33. Strus M., Kucharska A., Kukla T.G., Brzychczy- Wlóch M., Maresz K., Heczko P.B. The in vitro activity of vaginal Lactobacillus with probiotic properties against Candida. Infect Dis Obstet Gynecol 2005, 13: 69-77. 35. Strus M., Malinowska M., The range of antagonist properties of Lactobacillus bacteria on etiological factors of bacterial vaginosis. Appl Environ Microbiol, 1999, 5 1,47-57.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	A'Biotica / Lacidofil:					
		Maintains a healthy intestinal microflora balance during and after antibiotic therapy.	Daily dose must provide 2 or more billion Colony Forming Units of the Lactobacilli probiotic bacteria. For use everyday during antibiotic therapy and a few days afterwards. Take probiotics separately from ingestion of antibiotics. To present a safety statement: It is not recommended to give Probiotics to severely immunosuppressed patients, post cardiac surgery patients, patients with pancreatic dysfunction or patients with blood in the stool unless under a doctor's care.	British Medical Journal – Meta Analysis of Nine randomised, double blind, placebo controlled trials of probiotics. European Journal of Nutrition – PASSCLAIM Report The Journal of Pediatrics – Expert Study Pediatrics – Randomised Clinical Study	D'Souza AL, Rajkumar C, Cooke J, Bulpitt CJ. Probiotics in prevention of antibiotic associated diarrhoea: meta-analysis. BMJ 2002; 324: 1361-1364 http://www.bmj.com/cgi/content/full/324/7350/1361 Cummings, J.H. et al (2004) PASSCLAIM – Gut Health & Immunity. European Journal of Nutrition [Suppl 2], 43: 11/118- 11/173 (http://europe.ilsi.org/activities/ecprojects/PASSCLAIM/passpubs.htm) Vanderhoof JA, Whitney DB, Antonson DL, et al. Lactobacillus rhamnosus (GG) in the prevention of antibiotic-associated diarrhea in children. J Pediatrics 1999; 135: 564-8. http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=ShowDetailView&TermToSearch=10547243&ordinalpos=2&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum Arvola T. Laiho K, Torkelli S. et al. Prophylactic Lactobacillus rhamnosus (GG) reduces antibiotic-associated diarrhea in children with respiratory infections: a randomized study. Pediatrics 1999; 104(5): e64. http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=ShowDetailView&TermToSearch=10545590&ordinalpos=2&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum	875

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Journal of the Medical Association of Thailand – Expert Report Journal of Alimentary pharmacology & therapeutics – Meta-analysis Journal of Food Protection – Expert Analysis National Institute of Agronomic Research – Expert Report	Jirapinyo P, Thamonsiri N, Densupsoontorn N, et al. Prevention of antibiotic-accosiated diarrhoea in infants by probiotics. J Med Assoc Thai 2002; 85 (Suppl 2): S739-S42. http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=ShowDetailView&TermToSearch=12403254&ordinalpos=7&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum Cremonini F, di Caro S, Nista EC, et al. Meta-analysis: the effect of probiotic administration on antibiotic-associated diarrhoea. Aliment Pharmacol Ther.2002 Aug;16(8):1461-7 http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=ShowDetailView&TermToSearch=12182746&ordinalpos=6&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum Wallace TD, Bradley S, Buckley ND, and Green-Johnson JM (2003) Interactions of lactic acid bacteria with human intestinal epithelial cells: effects on cytokine production. Journal of Food Protection, 66, 3; 446-472. (http://apt.allenpress.com/perlserv/?request=get-abstract&issn=0362-028X&volume=066&issue=03&page=0466&ct=1)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bacillus subtilis					
		Maintenance of healthy Immune system	At least 107 cfu / day			947

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks & peer reviewed journal articles	Cario E. (2005). Bacterial interactions with cells of the intestinal mucosa: Toll-like receptors and NOD2. Gut. 2005 Aug;54(8):1182-93. Epub 2005 Apr 19. Review. Salinas I, Cuesta A, Esteban MA, Meseguer J. (2005). Dietary administration of Lactobacillus delbrueckii and Bacillus subtilis, single or combined, on gilthead seabream cellular innate immune responses. Fish Shellfish Immunol. 2005 Jul;19(1):67-77. Duc le H, Hong HA, Cutting SM. (2003). Germination of the spore in the gastrointestinal tract provides a novel route for heterologous antigen delivery. Vaccine. 2003 Oct 1;21(27-30):4215-24 Barnes AGC, Cerovic V, Hobson P and Klavinskis LS. (2006). Bacillus subtilis spores: a novel microparticle adjuvant which can instruct a balanced Th1 and Th2 immune response to specific antigen. 2006. Paper under submission Barnes AGC, Cerovic V, Perumal D, Dar N, Hobson P and Klavinskis LS. (2007). Bacillus subtilis spores promote dendritic cell priming through a phagocytosis / TLR2 dependant mechanism. 2007. Paper under submission O'Riordan M, Yi CH, Gonzales R, Lee KD, Portnoy DA. (2002). Innate recognition of bacteria by a macrophage cytosolic surveillance pathway. Proc Natl Acad Sci U S A. 2002 Oct 15;99(21):13861-6. Epub 2002 Oct 1. Abrahams VM, Bole-Aldo P, Kim YM, Straszewski-Chavez SL, Chaiworapongsa T,	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Romero R, Mor G. (2004). Divergent trophoblast responses to bacterial products mediated by TLRs. J Immunol. 2004 Oct 1;173(7):4286-96. As listed by A Green	
		Intestinal / digestive health	At least 10[7] cfu / day			694

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Peer reviewed journal articles.	Barefoot, S.F., Nettles, C.G. (1993). Antibiosis revisited: bacteriocins produced by dairy starter cultures. Journal of Dairy Science, 76 (8) :2366-79. Review. Casula, G. & Cutting, S. M. (2002). Bacillus probiotics: spore germination in the gastrointestinal tract. Applied and Environmental Microbiology, 68 (5), 2344-2352. D'Arienzo, R., Maurano, F., Mazzarella, G., Luongo, D., Stefanile, R., Ricca, E. & Rossi, M. (2006). Bacillus subtilis spores reduce susceptibility to Citrobacter rodentium-mediated enteropathy in a mouse model. Research in Microbiology, 157, 891-897. Hoa, N. T., Baccigalupi, L., Huxham, A., Smertenko, A., Van, P. H., Ammendola, S., Ricca, E. & Cutting, S. M. (2000). Characterization of Bacillus species used for oral bacteriotherapy and bacterioprophylaxis of gastrointestinal disorders. Applied and Environmental Microbiology, 66, 5241-5247. Hong, H. A., Duc, L. H. & Cutting, S. M. (2005). The use of bacterial spore formers as probiotics. FEMS Microbiology Reviews, 29, 813-835. La Ragione, R. M., Casula, G., Cutting, S. M. & Woodward, M. (2001). Bacillus subtilis spores competitively exclude Escherichia coli 070:K80 in poultry. Veterinary Microbiology, 79, 133-142. La Ragione, R. M. & Woodward, M. J. (2003). Competitive exclusion by Bacillus subtilis spores of Salmonella enterica serotype Enteritidis and Clostridium perfringens in young chickens. Veterinary Microbiology, 94, 245-256. Mazza, P. (1994). The use of Bacillus subtilis as an antidiarrhoeal microorganism. Bollettino Chimico Farmaceutico, 133, 3-18.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Sanders, M. E., Morelli, L. & Tompkins, T. A. (2003). Sporeformers as human probiotics: Bacillus, Sporolactobacillus, and Brevibacillus. Comprehensive Reviews in Food Science and Food Safety, 2, 101-110. Sorokulova, I.B., Pinchuk, I.V., Denayrolles, M., Osipova I.G., Huang, J.M., Cutting S.M., Urdaci, M.C. (2007). The safety of two Bacillus probiotic strains for human use. Digestive Diseases and Science, in press.	
		Immune function	At least 10[7] cfu / day			695

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks, peer reviewed journal articles.	Abrahams, V.M., Bole-Aldo, P., Kim, Y.M., Straszewski-Chavez, S.L., Chaiworapongsa, T., Romero, R., Mor, G. (2004). Divergent trophoblast responses to bacterial products mediated by TLRs. Journal of Immunology, 173 (7), 4286-96. Barnes, A.G.C., Cerovic, V., Hobson, P. & Klavinskis, L.S. (2007). Bacillus subtilis spores: a novel microparticle adjuvant which can instruct a balanced Th1 and Th2 immune response to specific antigen. European Journal of Immunology, 37 (6),1538-47. Cario, E. (2005). Bacterial interactions with cells of the intestinal mucosa: Toll-like receptors and NOD2. Gut, 54 (8), 1182-93. Coppi, F., Ruoppolo, M., Mandressi, A., Bellorofonte, C., Gonnella, G. & Trinchieri, A. (1985). Results of treatment with Bacillus subtilis spores (Enterogermina) after antibiotic therapy in 95 patients with infection calculosis. Chemioterapia, 4 (6), 467-70. Duc, L. H., Hong, H. A. & Cutting, S. M. (2003). Germination of the spore in the gastrointestinal tract provides a novel route for heterologous antigen presentation. Vaccine, 21, 4215-4224. Duc, L. H., Hong, H. A., Barbosa, T. M., Henriques, A. O. & Cutting, S. M. (2004). Characterization of Bacillus probiotics available for human use. Applied and Environmental Microbiology, 70, 2161-2171. Duc, L. H., Hong, H. A., Uyen, N. Q. & Cutting, S. M. (2004). Intracellular fate and immunogenicity of B. subtilis spores. Vaccine, 22, 1873-1885. Hartmann, J. (2003). Immunostimulation by Bacillus subtilis preparations. Explore, 12 (1). Hoa, N. T., Baccigalupi, L., Huxham, A., Smertenko, A., Van, P. H., Ammendola, S., Ricca, E. & Cutting, S. M. (2000). Characterization of Bacillus species used for	

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Hong, H. A. & Duc, L. H. (2004). The fate of ingested spores. In Bacterial spore formers: probiotics and emerging applications, pp. 107-112. Edited by E. Ricca, A.O. Henriques & S. M. Cutting: Horizon Bioscience.
Hong, H. A., Duc, L. H. & Cutting, S. M. (2005). The use of bacterial spore formers as probiotics. FEMS Microbiology Reviews, 29, 813-835.
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O'Riordan, M., Yi, C.H., Gonzales, R., Lee, K.D., Portnoy, D.A. (2002). Innate recognition of bacteria by a macrophage cytosolic surveillance pathway. Proceedings of the National Academy of Sciences of the United States of America, 99 (21), 13861-6.

Rhee, K. J., Sethupathi, P., Driks, A., Lanning, D. K. & Knight, K. L. (2004). Role of commensal bacteria in development of gut-associated lymphoid tissues and preimmune antibody repertoire. Journal of Immunology, 172, 1118-1124.
Salinas, I., Cuesta, A., Esteban, M.A. & Meseguer, J. (2005). Dietary administration of Lactobacillus delbrueckii and Bacillus subtilis, single or combined, on gilthead seabream cellular innate immune responses. Fish and Shellfish Immunology, 19 (1), 67-77.
Sanders, M. E., Morelli, L. & Tompkins, T. A. (2003). Sporeformers as human probiotics: Bacillus, Sporolactobacillus, and Brevibacillus. Comprehensive Reviews in Food Science and Food Safety, 2, 101-110.

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Sorokulova, I.B., Pinchuk, I.V., Denayrolles, M., Osipova I.G., Huang, J.M., Cutting S.M., Urdaci, M.C. (2007). The safety of two Bacillus probiotic strains for human use. Digestive Diseases and Science, in press. Tam, N. M. K., Uyen, N. Q., Hong, H. A., Duc, L. H., Hoa, T. T., Serra, C. H., Henriques, A. O. & Cutting, S. M. (2006). The intestinal life cycle of Bacillus subtilis and close relatives. Journal of Bacteriology, 188, 2692-2700.	
		Contains Probiotic	At least 10[7] cfu / day			696

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Peer reviewed journal articles and scientific opinions by official scientific bodies.	Casula, G. & Cutting, S. M. (2002). Bacillus probiotics: spore germination in the gastrointestinal tract. Applied and Environmental Microbiology, 68 (5), 2344-2352. Green, D.H., Wakeley, P.R., Page, A., Barnes, A., Baccigalupi, L., Ricca, E. & Cutting S.M. (1999). Characterization of two Bacillus probiotics. Applied and Environmental Microbiology, 65 (9), 4288-91. Hoa, N. T., Baccigalupi, L., Huxham, A., Smertenko, A., Van, P. H., Ammendola, S., Ricca, E. & Cutting, S. M. (2000). Characterization of Bacillus species used for oral bacteriotherapy and bacterioprophylaxis of gastrointestinal disorders. Applied and Environmental Microbiology, 66, 5241-5247. Hong, H. A., Duc, L. H. & Cutting, S. M. (2005). The use of bacterial spore formers as probiotics. FEMS Microbiology Reviews, 29, 813-835. Pinchuk, I.V., Bressollier, P., Verneuil, B., Fenet, B., Sorokulova, I.B., Mégraud, F., Urdaci, M.C. (2001). In vitro anti-Helicobacter pylori activity of the probiotic strain Bacillus subtilis 3 is due to secretion of antibiotics. Antimicrobial Agents and Chemotherapy, 45 (11), 3156-61. Sanders, M. E., Morelli, L. & Tompkins, T. A. (2003). Sporeformers as human probiotics: Bacillus, Sporolactobacillus, and Brevibacillus. Comprehensive Reviews in Food Science and Food Safety, 2, 101-110. Sorokulova, I.B., Pinchuk, I.V., Denayrolles, M., Osipova I.G., Huang, J.M., Cutting S.M., Urdaci, M.C. (2007). The safety of two Bacillus probiotic strains for human use. Digestive Diseases and Science, in press.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					WHO definition of probiotic FAO/WHO (2001). Guidelines for the evaluation of probiotics in food. Joint FAO/WHO working group report on drafting guidelines for the evaluation of probiotics in food. London, Ontario, Canada, April 30 and May 1, 2002.	
		Beneficial effect on intestinal microflora, gut integrity, digestion	At least 107 cfu / day	Textbooks & peer reviewed journal articles	Barefoot SF, Nettles CG.(1993). Antibiosis revisited: bacteriocins produced by dairy starter cultures. J Dairy Sci. 1993 Aug;76(8):2366-79. Review. La Ragione RM, Casula G, Cutting SM, Woodward MJ. (2001). Bacillus subtilis spores competitively exclude Escherichia coli O78:K80 in poultry. Vet Microbiol. 2001 Mar 20;79(2):133-42. D'Arienzo R, Maurano F, Mazzarella G, Luongo D, Stefanile R, Ricca E, Rossi M. (2006). Bacillus subtilis spores reduce susceptibility to Citrobacter rodentium-mediated enteropathy in a mouse model. Res Microbiol. 2006 Nov;157(9):891-7. Epub 2006 Sep 26. As listed by A Green	933
		Contains Probiotic that confers a benefit on the host	At least 107 cfu / day	Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	WHO definition of probiotic FAO/WHO (2001). Guidelines for the Evaluation of Probiotics in Food. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, April 30 and May 1, 2002 Green DH, Wakeley PR, Page A, Barnes A, Baccigalupi L, Ricca E, Cutting SM. (1999). Characterization of two Bacillus probiotics. Appl Environ Microbiol. 1999 Sep;65(9):4288-91.	919

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bacillus subtilis HU58					
		Intestinal / digestive health	At least 10[7] cfu / day	Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	Tam, N. M. K., Uyen, N. Q., Hong, H. A., Duc, L. H., Hoa, T. T., Serra, C. H., Henriques, A. O. & Cutting, S. M. (2006). The intestinal life cycle of Bacillus subtilis and close relatives. Journal of Bacteriology, 188, 2692-2700.	701
		Contains Probiotic	At least 10[7] cfu / day	Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	Tam, N. M. K., Uyen, N. Q., Hong, H. A., Duc, L. H., Hoa, T. T., Serra, C. H., Henriques, A. O. & Cutting, S. M. (2006). The intestinal life cycle of Bacillus subtilis and close relatives. Journal of Bacteriology, 188, 2692-2700. WHO definition of probiotic FAO/WHO (2001). Guidelines for the evaluation of probiotics in food. Joint FAO/WHO working group report on drafting guidelines for the evaluation of probiotics in food. London, Ontario, Canada, April 30 and May 1, 2002.	703
		Immune function	At least 10[7] cfu / day	Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	Tam, N. M. K., Uyen, N. Q., Hong, H. A., Duc, L. H., Hoa, T. T., Serra, C. H., Henriques, A. O. & Cutting, S. M. (2006). The intestinal life cycle of Bacillus subtilis and close relatives. Journal of Bacteriology, 188, 2692-2700	702

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bacillus subtilis Natto					
		Contains Probiotic	At least 10[7] cfu / day	Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	Hong, H. A., Duc, L. H. & Cutting, S. M. (2005). The use of bacterial spore formers as probiotics. FEMS Microbiology Reviews, 29, 813-835. Hosoi, T., Ametani, A., Kiuchi, K. & Kaminogawa, S. (2000). Improved growth and viability of lactobacilli in the presence of Bacillus subtilis (natto), catalase, or subtilisin. Canadian Journal of Microbiology, 46 (10), 892-897. Hosoi, T. & Kiuchi, K. (2004). Production and probiotic effects of Natto. pp. 143-154. Edited by E. Ricca, A. O. Henriques & S. M. Cutting. Wymondham, UK: Horizon Bioscience. Sanders, M. E., Morelli, L. & Tompkins, T. A. (2003). Sporeformers as human probiotics: Bacillus, Sporolactobacillus, and Brevibacillus. Comprehensive Reviews in Food Science and Food Safety, 2, 101-110. WHO definition of probiotic FAO/WHO (2001). Guidelines for the evaluation of probiotics in food. Joint FAO/WHO working group report on drafting guidelines for the evaluation of probiotics in food. London, Ontario, Canada, April 30 and May 1, 2002.	700
		Intestinal / digestive health	At least 10[7] cfu / day	Textbooks, peer reviewed journal articles.	Hosoi, T. & Kiuchi, K. (2004). Production and probiotic effects of Natto. pp. 143-154. Edited by E. Ricca, A. O. Henriques & S. M. Cutting. Wymondham, UK: Horizon Bioscience. Ozawa, K., Yagu-Uchi, K., Yamanaka, K., Yamashita, Y., Ueba, K. & Miwatani, T. (1979). Bacillus natto and Streptococcus faecalis on growth of Candida albicans. Microbiology and Immunology, 23, 1147-1156.	697

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Immune function	At least 10[7] cfu / day	Textbooks, peer reviewed journal articles.	Hong, H. A., Duc, L. H. & Cutting, S. M. (2005). The use of bacterial spore formers as probiotics. FEMS Microbiology Reviews, 29, 813-835. Hosoi, T., Ametani, A., Kiuchi, K. & Kaminogawa, S. (1999). Changes in fecal microflora induced by intubation of mice with Bacillus subtilis (natto) spores are dependent upon dietary components. Canadian Journal of Microbiology, 45, 59-66. Hosoi, T. & Kiuchi, K. (2004). Production and probiotic effects of Natto. pp. 143-154. Edited by E. Ricca, A. O. Henriques & S. M. Cutting. Wymondham, UK: Horizon Bioscience. Inooka, S., Uehara, S. & Kimura, M. (1986). The effect of Bacillus natto on the T and B lymphocytes from spleens of feeding chickens. Poultry Science, 65, 1217-1219.	698
		Heart health	At least 10[7] cfu / day			699

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Peer reviewed journal articles.	Omura, K., Hitosugi, M., Zhu, X., Ikeda, M., Maeda, H. & Tokududome, S. (2005). A newly derived protein from Bacillus subtilis natto with both antithrombotic and fibrinolytic effects. Journal of Pharmacological Sciences, 99 (3), 247-251. Pais, E., Alexy, T., Holsworth, R.E. & Meiselman, H.J. (2006). Effects of nattokinase, a pro-fibrinolytic enzyme, on red blood cell aggregation and whole blood viscosity. Clinical Hemorheology Microcirculation, 35 (1-2), 139-42. Peng, Y., Yang, X. & Zhang, Y. (2005). Microbial fibrinolytic enzymes: an overview of source, production, properties, and thrombolytic activity in vivo. Applied Microbiology and Biotechnology, 69 (2), 126-32. Tai, M-W. & Sweet, B.V. (2006). Nattokinase for prevention of thrombosis. American Journal of Health System Pharmacy, 63 (12),1121-1123.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bacilus subtilis BP6					
		Intestinal / digestive health	at least 10[7] cfu/day	Nutrition Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	203
				Reviews	-Hong HA, Duc LH, and Cutting SM. The use of bacterial spore formers as probiotics. FEMS Microbiology Reviews 2005; 29: 813-835.	
				Reviews	-Mazza M. The use of Bacillus subtilis as an antidiarrhoeal microorganism. Boll. Chim. Farmaceutico 1994; 133(1): 3-18.	
				Reviews	-Sanders ME, Morelli L, and Tompkins TA. Sporeformers as human probiotics: Bacillus, Sporolactobacillus, and Brevibacillus. Comprehensive Reviews in Food Science and Food Safety 2003; 2: 101-110.	
				Textbook	-Sensei S, In Bacterial spore formers. Probiotics and emerging applications, Chapter 11, pp. 131-141. Eds. Ricca D, Henriques AO and Cutting SM. Horizon Biosceince, Wymondham (UK).	
				Animal and In Vitro Studies	-Pinchuk IV, Bressollier P, Verneuil B, Fenet B, et al. In vitro anti-Helicobacter pylori activity of the probiotic strain Bacillus subtilis 3 is due to secretion of antibiotics. Antimicrobial Agents and Chemotherapy 2001; 45(11): 3156-3161.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Animal and In Vitro Studies	-Teo AY and Tan HM. Inhibition of Clostridium perfringens by a novel strain of Bacillus subtilis isolated from the gastrointestinal tracts of healthy chickens. Applied and Environmental Microbiology 2005; 71(8): 4185-4190.	
				Animal and In vitro Studies, Individual Human Study	- inical and Vaccine Immunology. 13 (3): 365 -375 Bruzzese E, Canani RB, De Marco G, Guarino A. Microflora in inflammatory bowel diseases: a pediatric perspective. J Clin Gastroenterol. 2004 Jul;38(6 Suppl):S91-3. Individual Human Study Mullie C, Yazourh A, Thibault H, Odou MF, Singer E, Kalach N, Kremp O, Romond MB. 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. Pediatr Res. 2004 Nov;56(5):791-5. Epub 2004 Sep 3.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium animalis Lafti B94 (CBS118.529)					
		Intestinal flora	at least 10[11]cfu/day	Individual Human Study	-Su P et al. (2005) Detection and Quantification of Bifidobacterium lactis LAFTI® B94 in human faecal samples from a consumption trial. FEMS Microbiology Letters 244:99-103.	204
				Animal Studies	-Crittenden R et al. (2005) Probiotic Research in Australia, New Zealand and the Asia-Pacific Region. Current Pharmaceutical Design, 11, 37-53	
				Animal Studies	-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	-Crittenden RG et al. (2001) Selection of a bifidobacterium strain to complement resistant starch in a synbiotic yoghurt. Journal of Applied Mircrobiology 90: 268-278	
				In Vitro Studies	-In vitro study on inhibition of Helicobacter pylori by probiotic cultures, conducted at the UNSW - Internal DSM report	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium animalis ssp. lactis Bb-12 ®					
		Natural defence / immune system	at least 10[9] cfu/day yoghurt daily consumption 10E9 - 10E10 cfu/day			242

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual human studies	Individual Human Studies Fukushima, Y., Kawata, Y., Hara, H., Terada, A., Mitsuoka, T. Effect of a probiotic formula on intestinal immunoglobulin A production in healthy children. 1998. International Journal of Food Microbiology, 42: 39-44. Isolauri, E., Arvola, T., Sutas, Y., Moilanen, E., Salminen, S. Probiotics in the management of atopic eczema. 2000. Clinical and Experimental Allergy, 30: 1604-1610. Link-Amster, H., Rochat, F., Saudan, K.Y., Mignot, O., Aeschlimann, J.M. Modulation of a specific humoral immune response and changes in intestinal flora mediated through fermented milk intake. 1994. FEMS Immunology and Medical Microbiology, 10: 55-64. Schiffrin, E.J., Rochat, F., Link-Amster, H., Aeschlimann, J.M., Donnet-Hughes, A. Immunomodulation of human blood cells following the ingestion of lactic acid bacteria. 1995. Journal of Dairy Science, 78: 491-497. Animal Studies Miettinen, M., Alander, M., von Wright, A., Buopio-Varkila, J., Marteau, P., Veld, J., Mattila-Sandholm, T. The survival of and cytokine induction by lactic acid bacteria after passage through a gastrointestinal model. 1998. Microbial Ecology in Health and Disease, 10: 141-147. Wagner, R.D., Pierson, C., Warner, T., Dohnalek, M., Farmer, J., Roberts, L., Hilty, M., Balish, E. Biotherapeutic effects of probiotic bacteria on candidiasis in immunodeficient mice. 1997. Infection and Immunity, 65(10): 4165-4172.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					In Vitro Studies Commane D.M., Shortt C.T., Silvi S., Cresci A., Hughes R.M., Rowland I.R. 2005. Effects of fermentation products of pro- and prebiotics on trans-epithelial electrical resistance in an in vitro model of the colon. Nutrition and Cancer. 51(1): 102-109 Kankaanpaa P, Sutas Y, Salminen S, Isolauri. 2003. Homogenates derived from probiotic bacteria provide down-regulatory signals for peripheral blood mononuclear cells. Food Chemistry 83, 269-277. Matsumoto M, Benno Y. 2006. Anti-inflammatory metabolite production in the gut from the consumption of probiotic yoghurt containing Bifidobacterium animalis subsp. lactis LKM 512. Biosci. Biotechnol. Biochem. 70(6), 1287-1292. Miettinen, M., Alander, M., von Wright, A., Buopio-Varkila, J., Marteau, P., Veld, J., Mattila-Sandholm, T. The survival of and cytokine induction by lactic acid bacteria after passage through a gastrointestinal model. 1998. Microbial Ecology in Health and Disease, 10: 141-147. Pessi T, Sutas Y, Saxelin M, Kallionen H, Isolauri E. 1999. Antiproliferative effects of homogenates derived from five strains of candidate probiotic bacteria. Applied and Environmental Microbiology, 65 (11), 4725-4728. Zeuthen LH, Christensen HR, Frokiaer H. 2006. Lactic acid bacteria inducing a weak interleukin-12 and Tumour Necrosis Factor Alpha response in human dendritic cells inhibit strongly stimulating lactic acid bacteria but act synergistically with Gram-Negative bacteria. Clinical and Vaccine Immunology. 13 (3): 365-375	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human Studies	#509 Rautava S, Arvilommi H, Isolauri E. 2006. Specific probiotics in enhancing maturation of IgA responses in formula-fed infants. Pediatric Research 60(2): 222-225. #200 Saavedra, J.M., Bauman, N.A., Oung, I., Perman, J.A., Yolken, R.H. Feeding of Bifidobacterium bifidum and Streptococcus thermophilus to infants in hospital for prevention of diarrhea and shedding of rotavirus. 1994. The Lancet, 344: 1046-1049. #437 Chouraqui JP, Van Egroo LD, Fichot MC. 2004. Acidified milk formula supplemented with bifidobacterium lactis: Impact on infant diarrhea in residential care settings. Journal of Pediatric Gastroenterology and Nutrition 38:288 -292. #501 Christensen HR, Larsen CN, Kæstel P, Rosholm LB, Sternberg C, Michaelsen KF, Frøkiær H. 2006. Immunomodulatory potential of supplementation with probiotics: a dose-response study in healthy young adults. FEMS Immunology & Medical Microbiology 47(3): p. 380-390.	
		Intestinal flora/digestive system	at least 10[9] cfu/day	Individual Human Studies	-Alander M, Matto J, Kneifel W et al. 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 2001;11:817-25.	205
				Individual Human Studies	-Malinen E, Matto J, Salmitie M, Alander M, Saarela M, Palva A. PCR-ELISA II: Analysis of Bifidobacterium populations in human faecal samples from a consumption trial with Bifidobacterium lactis Bb-12 and a galacto-oligosaccharide preparation. Syst Appl Microbiol. 2002 Aug;25(2):249-58. Erratum in: Syst Appl Microbiol. 2003 Mar;26(1):154-5.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Human Studies	-Masako Shioya, Keisuke Nakaoka, Rei Igarashi, Naomine Iizuka, Tadashi Abe and Yoshimi Benno. Effect of fermented milk containing Bifidobacterium lactis FK 120 on the fecal flora and fecal properties in healthy female volunteers. Journal of Nutritional Food 3 (1), 7-18, 2000. Japanese studies, basis for FOSHU approval in Japan.	
				Individual Human Studies	-Masako Shioya, Keisuke Nakaoka, Naomine Iizuka and Yoshimi Benno. Effect of fermented milk containing Bifidobacterium lactis FK 120 on the fecal flora, with special reference to Bifidobacterium species, and the fecal properties in healthy volunteers. Journal of Nutritional Food 3 (1), 19-32, 2000. Japanese studies, basis for FOSHU approval in Japan	
				Individual Human Studies	-Masako Shioya, Keisuke Nakaoka, Naomine Iizuka, Mutsuku Sato and Yoshimi Benno. Effect of fermented milk containing Bifidobacterium lactis FK 120 on the fecal flora, with special reference to Bifidobacterium species, and the fecal properties in elderly volunteers. Journal of Nutritional Food 3 (1), 33-44, 2000. Japanese studies, basis for FOSHU approval in Japan	
				Individual Human Studies	-Matsumoto, M., Tadenuma, T., Nakamure, K., Kume, H., Imai, T., Kihara, R., Watanabe, M., and Benno, Effect of Bifidobacterium lactis LKM 512 Yogurt on Fecal Microflora in Middle to Old Aged Persons Y. Microbial Ecol Health Dis 12, 77-80. 2000.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Human Studies	-Matsumoto M. and Benno Y. Consumption of Bifidobacterium lactis LKM512 yogurt reduces gut mutagenicity by increasing gut polyamine contents in healthy adult subjects. Mutation Research 2004. 568; 147-153	
				Individual Human Studies	-Matsumoto M, Ohishi H, Benno Y. Impact of LKM512 yogurt on improvement of intestinal environment of the elderly FEMS Immunol.Med Microbiol. 2001;31:181-6.	
				Individual Human Studies	-Ouwehand AC, Kurvinen T, Rissanen P. Use of a probiotic Bifidobacterium in a dry food matrix, an in vivo study. Int J Food Microbiol. 2004 Aug 15;95(1):103-6.	
				Individual Human Studies	-Satokari RM, Vaughan EE, Akkermans AD, Saarela M, de Vos WM. Polymerase chain reaction and denaturing gradient gel electrophoresis monitoring of fecal bifidobacterium populations in a prebiotic and probiotic feeding trial. Syst.Appl.Microbiol.2001;24:227-31.	
				Individual Human Studies	-Schiffrin E.J., F. Rochat, H. Link-Amster, J. M. Aeschlimann, and A. Donnet-Hughes. Immunomodulation of Human Blood Cells Following the Ingestion of Lactic Acid Bacteria. J. Dairy Sci. 1995 78: 491-497	
				In Vitro Studies	-Matsumoto, M., H. Tani, H. Ono, Y. Benno. 2002. Adhesive property of Bifidobacterium lactis LKM512 and predominant bacteria of intestinal microflora to human intestinal mucin. Current Microbiology, 44, 212-215.	
				In Vitro Studies	-Vinderola CG, Reinheimer JA. 2003. Lactic acid starter and probiotic bacteria: a comparative "in vitro" study of probiotic characteristics and biological barrier resistance. Food research International 36: 895-904.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human Studies	Pitkälä KH, Strandberg, Finne-Sover UH, Ouwehand AC, Poussa T, Salminen, S. Fermented cereal with specific Bifidobacteria normalizes bowel movements in elderly nursing home residents. A randomized, controlled trial. The Journal of Nutrition, Health & Aging 11(4), 2007 # 657 Nishida S, Gotou M, Akutsu S, Ono M, Hitomi Y, Nakamura T, Iino H. Effect of yoghurt containing Bifidobacterium lactis BB-12 on improvement of defecation and fecal microflora of healthy female adults. Milk Science 53(2), 71 -80, 2004 (Japanese paper, basis for FOSHU approval, translated into English) # 658 Uchida K, Akashi K, Kusunoki I, Ikeda T, Katano N, Motoshima H, Benno Y. Effect of fermented milk containing Bifidobacterium lactis BB-12 on stool frequency, defecation, fecal microbiota and safety of excessive ingestion in healthy female students. Journal of Nutritional Food 8(1), 39-51, 2005 (Japanese paper, basis for FOSHU approval, translated into English) # 654 Murakami T, Miyahira H, Yukisato S, Nakamura R, Kanno H, Kotakemori M, Kamei T, Kobayashi O. Safety and effect of yoghurt containing Bifidobacterium lactis BB-12 on improvement of defecation and fecal microflora in healthy volunteers. Journal of Nutritional Food 9(1), 15-26, 2006 (Japanese paper, basis for FOSHU approval, translated into English) # 655 Matsumoto M, Imai T, Hironaka T, Kume H, Watanabe M, Benno Y. Effect of yoghurt with Bifidobacterium lactis LKM512 in improving fecal microflora and defecation of healthy volunteers. Intestine Microbiology Magazine 14, 97-102, 2001 (Japanese paper, basis for FOSHU approval, translated into English) Larsen CN, Nielsen S, Kæstel P, Brockmann E,	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Bennedsen M, Christensen HR, Eskesen DC, Jacobsen BL, Michaelsen KF. 2006. Dose-response study of probiotic bacteria Bifidobacterium animalis subsp. lactis BB-12 and Lactobacillus paracasei subsp. paracasei CRL-341 in healthy young adults. European Journal of Clinical Nutrition 60 (11): p. 1284-1293.	
				Animal Studies	Lesniewska V, Rowland I, Laerke HN, Grant G, Naughton PJ. 2006. Relationship between dietary-induced changes in intestinal commensal microflora and duodenojujenal myoelectric activity monitored by radiotelemetry in the rat in vivo. Experimental Physiology 91(1): 229-237.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium animalis ssp. lactis BB-12 ® and Lactobacillus acidophilus LA-5 ®					
		Maintains the balance of the intestinal flora of the digestive system	Consumption of >10e8 cfu/day of BB-12® and LA-5®			706

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Peer-reviewed scientific journals Human, animal and in vitro studies	Kirjavainen P (1998) The ability of probiotic bacteria to bind to human intestinal mucus. FEMS Microbiology Letters 167, 185-189. Larson C (2006) Dose response study of probiotic bacteria B. animalis BB12 and L. paracasei CRL-341 in healthy young adults. European J Clin Nutrition 60, 1284-1293. Silva A (1999) Protective effect of bifidus milk on the experimental infection with S. typhimurium in mice. J. Applied Microbiology 86, 331-336. Langhendries J (1995) Effect of fermented infant formula containing viable Bifidobacteria on the fecal flora composition and pH of healthy full term infants. J. Pediatric Gastroenterology & Nutrition 21, 177-181. Fukushima Y (1997) Effect of follow up formula containing Bifidobacteria on fecal flora and metabolites in healthy children. Bioscience Microflora 16, 65-72. Fukushima Y (1998) Effect of probiotic formula on intestinal Ig A production in healthy children. Int J Food Microbiology 42, 39-41. Chumchalova J (1995) Characterization of acidocin CH5, a saccharolytic sensitive bacteriocin of L. acidophilus LA5. Chem Microbiol Technol Lebensm 17, 145-150. Nord C (1997) Oral supplementation with lactic acid producing bacteria during intake of clindomycin. Clinical Microbiology & Infection 3, 124-132.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium animalis ssp. lactis BB-12, Lactobacilus acidophilus LA-5, Lactbacilus bulgaricus LBY-27 and Streptococcus thermophilus STY-31					
		Natural defence / immune system	at least 10[9] cfu/day 10e9 - 10e10 cfu/day			243

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human study Animal study In vitro study	Review Lewis, S.J., Freedman, A.R. Review article: The use of biotherapeutic agents in the prevention and treatment of gastrointestinal disease. 1998. Aliment Pharmacol Ther, 12: 807-822. Clinical Trials Anderson ADG, McNaught CE, Jain PK, MacFie J. 2004. Randomised clinical trial of synbiotic therapy in elective surgical patients. Gut, 53, 241-245 Anderson ADG, McNaught CE, MacFie J, Tring I, Barker P, Mitchell CJ. 2003. Randomized clinical trial of multimodal optimization and standard perioperative surgical care. British Journal of Surgery, 90; 1497-1504. Gatt M, Anderson ADG, Reddy BS, Hayward-Sampson P, tring IC, MacFie J. 2005. Randomized clinical trial of multimodal optimization of surgical care in patients undergoing major colonic resection. British Journal of Surgery, 92, 1354-1362 Jain PK, McNaught CE, Anderson ADG, MacFie J, Mitchell CJ. 2004. Influence of synbiotic containing Lactobacillus acidophilus La5, Bifidobacterium lactic Bb12, Streptococcus thermophilus, Lactobacillus bulgaricus and oligofructose on gut barrier function and sepsis in critically ill patients: a randomised controlled trial. Clinical Nutrition 23; 467-475	
				Human Studies	#186 Nord, C.E., Lidbeck, A., Orrhange, K., Sjostedt, S. Oral supplementation with lactic acid bacteria during intake of clindamycin. 1997. Clinical Microbiology and Infection, 3 (1): 124-132.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium animalis ssp. lactis BB-12® and Lactobacilus acidophilus La-5®					
		Natural defence / immune system	at least 4,6x10[9] cfu/day 10E9 cfu/day or more			244

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human study Animal study In vitro study	Individual Human Studies Black, F.T., Einarsson, K., Lidbeck, A., Orrhage, K., Nord, C.E. Effect of lactic acid producing bacteria on the human intestinal microflora during ampicillin treatment. 1991. Scand. J. Infect. Dis., 23: 247-254. Juntunen, M., Kirjavainen, P.V., Ouwehand, A.C., Salminen, S.J., Isolauri, E. Adherence of probiotic bacteria to human intestinal mucus in healthy infants and during rotavirus infection. 2001. Clinical and Diagnostic Laboratory Immunology 8: 293-296. Sheu BY, Cheng H-C, Kao A-W, Wang S-T, Yang Y-J, Yang H-B, Wu J-J. 2006. Pretreatment with Lactobacillus- and Bifidobacterium-containing yogurt can improve the efficacy of Quadruple therapy in eradicating residual Helicobacter pylori infection after failed triple therapy. Am J Clin Nutr 83: 864-9. Sheu BS, J Wu, CY Lo, HW Wu, JH Chen, YS Lin & MD Lin. 2002. Impact of supplement with Lactobacillus- and Bifidobacterium-containing yoghurt on triple therapy for Helicobacter pylori eradication. Aliment. Pharmacol. Ther. 16, 1669-1675. Wang KY, Li SN, Liu CS, Perng DS, Su YC, Wu DC, Jan CM, Lai CH, Wang TN, Wang WM. 2004. Effects of ingesting Lactobacillus- and Bifidobacterium-containing yoghurt in subjects with colonized Helicobacter pylori. Am. J. Clin. Nutr. 80; 737-41. Animal Study Tejada-Simon, M.V., Lee, J.H., Ustunol, Z., Pestka, J.J. Ingestion of yogurt containing Lactobacillus acidophilus and Bifidobacterium to potentiate Immunoglobulin A responses to cholera toxin in mice. 1999. Journal of Dairy Science, 82: 649-660.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					In Vitro Study Hutt P, Shchepetova J, Loivukene K, Kullisaar T, Mikelsaar M. 2006. Antagonistic activity of probiotic lactobacilli and bifidobacteria against entero- and uropathogens. Journal of Applied Microbiology 100: 1324-1332.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium animalis ssp. lactis BB-12® and Lactobacilus LA-5®					
		Digestive health/Intestinal Flora	at least 10[9] cfu/day	Individual Human Studies	-Black, F.T., Einarsson, K., Lidbeck, A., Orrhage, K., Nord, C.E. Effect of lactic acid producing bacteria on the human intestinal microflora during ampicillin treatment. 1991. Scand. J. Infect. Dis., 23: 247-254	206
				Individual Human Studies	-Laake, K.O., Bjorneklett, A., Bakka, A., Midtvedt, T., Norin, K.E., Eide, T.J., Jacobsen, M.B., Lingaas, E., Axelsen, A.K., Lotveit, T., Vatn, M.H. Influence of fermented milk on clinical state, fecal bacterial counts and biochemical characteristics in patients with ileal- pouch-anal anastomosis. 1999. Microbial Ecology in Health and Disease, 11: 211-217.	
				Individual Human Studies	-Laake KO, Line PD, Aabakken L, Lotveit T, Bakka A, Eide J, Roseth A, Grzyb K, Bjorneklett A, Vatn MH. 2003. Assessment of Mucosal inflammation and circulation in response to probiotics in patients operated with ileal pouch anal anastomosis for ulcerative colitis. Scand J Gastroenterol.: 4; 409-414.	
				Individual Human Studies	-Laake, K.O., P.D. Line, K. Grzyb, G. Aamodt, L. Aabakken, A. Roset, A.B. Hvinden, A. Bakka, J. Eide, A. Bjorneklett, M.H. Vatn. 2004. Assessment of mucosal inflammation and blood flow in response to four weeks intervention with probiotics in patients operated with a J-configurated Ileal-Pouch-Anal-Anastomosis (IPAA). Scand. J. Gastroenterol. (12) 1228-1235.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Human Studies	-Laake K.O., Bjorneklett A., Aamodt G., Aabakken L., Jacobsen, M., Bakka, A., Vatn, M.H. 2005. Outcome of four weeks intervention with probiotics on symptoms and endoscopic appearance after surgical reconstruction with a J-configurated ileal-pouch-anal-anastomosis in ulcerative colitis. Scandinavian Journal of Gastroenterology (40) 43-51.	
				Individual Human Studies	-Masako Shioya, Keisuke Nakaoka, Rei Igarashi, Naomine Iizuka, Tadashi Abe and Yoshimi Benno. Effect of fermented milk containing Bifidobacterium lactis FK 120 on the fecal flora and fecal properties in healthy female volunteers. Journal of Nutritional Food 3 (1), 7-18, 2000.	
				Individual Human Studies	-Masako Shioya, Keisuke Nakaoka, Naomine Iizuka and Yoshimi Benno. Effect of fermented milk containing Bifidobacterium lactis FK 120 on the fecal flora, with special reference to Bifidobacterium species, and the fecal properties in healthy volunteers. Journal of Nutritional Food 3 (1), 19-32, 2000.	
				Individual Human Studies	-Masako Shioya, Keisuke Nakaoka, Naomine Iizuka, Mutsuku Sato and Yoshimi Benno. Effect of fermented milk containing Bifidobacterium lactis FK 120 on the fecal flora, with special reference to Bifidobacterium species, and the fecal properties in elderly volunteers. Journal of Nutritional Food 3 (1), 33-44, 2000.	
				Individual Human Studies	-Nord, C.E., Lidbeck, A., Orrhange, K., Sjostedt, S. Oral supplementation with lactic acid bacteria during intake of clindamycin. 1997. Clinical Microbiology and Infection, 3 (1): 124-132.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Human Studies	-Sheu BS, J Wu, CY Lo, HW Wu, JH Chen, YS Lin & MD Lin. 2002. Impact of supplement with Lactobacillus- and Bifidobacterium-containing yoghurt on triple therapy for Helicobacter pylori eradication. Aliment. Pharmacol. Ther. 16, 1669-1675	
				Individual Human Studies	-Wildt S, Munck LK, Vinter-Jensen L, Hansen BF, Nordgaard-Lassen I, Christensen S, Avnstroem S, Rasmussen SN, Rumessen J. 2006. Probiotic treatment of collagenous colitis: A randomized, double-blind, placebo-controlled trial with L. acidophilus and Bifidobacterium animalis subsp. lactis. Inflamm Bowel Dis 12 (5): 395-401.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human Studies	Pitkälä KH, Strandberg, Finne-Sover UH, Ouwehand AC, Poussa T, Salminen, S. Fermented cereal with specific Bifidobacteria normalizes bowel movements in elderly nursing home residents. A randomized, controlled trial. The Journal of Nutrition, Health & Aging 11(4), 2007 # 657 Nishida S, Gotou M, Akutsu S, Ono M, Hitomi Y, Nakamura T, Iino H. Effect of yoghurt containing Bifidobacterium lactis BB-12 on improvement of defecation and fecal microflora of healthy female adults. Milk Science 53(2), 71 -80, 2004 (Japanese paper, basis for FOSHU approval, translated into English) # 658 Uchida K, Akashi K, Kusunoki I, Ikeda T, Katano N, Motoshima H, Benno Y. Effect of fermented milk containing Bifidobacterium lactis BB-12 on stool frequency, defecation, fecal microbiota and safety of excessive ingestion in healthy female students. Journal of Nutritional Food 8(1), 39-51, 2005 (Japanese paper, basis for FOSHU approval, translated into English) # 654 Murakami T, Miyahira H, Yukisato S, Nakamura R, Kanno H, Kotakemori M, Kamei T, Kobayashi O. Safety and effect of yoghurt containing Bifidobacterium lactis BB-12 on improvement of defecation and fecal microflora in healthy volunteers. Journal of Nutritional Food 9(1), 15-26, 2006 (Japanese paper, basis for FOSHU approval, translated into English) # 655 Matsumoto M, Imai T, Hironaka T, Kume H, Watanabe M, Benno Y. Effect of yoghurt with Bifidobacterium lactis LKM512 in improving fecal microflora and defecation of healthy volunteers. Intestine Microbiology Magazine 14, 97-102, 2001 (Japanese paper, basis for FOSHU approval, translated into English)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Animal Study	Lesniewska V, Rowland I, Laerke HN, Grant G, Naughton PJ. 2006. Relationship between dietary-induced changes in intestinal commensal microflora and duodenojujenal myoelectric activity monitored by radiotelemetry in the rat in vivo. Experimental Physiology 91(1): 229-237.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium animalis ssp. lactis BB-12® and Lactobacilus paracasei ssp. paracasei CRL -431® (=L. casei 431)					
		Digestive system/Intestinal Flora	at least 10[8] cfu/day	Individual Human Study	-Larsen CN, Nielsen S, Kaestel P, Brockmann E, Bennedsen M, Christensen HR, Eskesen DC, Jacobsen BL, Michaelsen KF. 2006. Dose-response study of probiotic bacteria Bifidobacterium animalis subsp. lactis BB-12 and Lactobacillus paracasei subsp. paracasei CRL-341 in healthy young adults. European Journal of Clinical Nutrition 60 : 1284-1293.	207
				In Vitro Study	-Zeuthen LH, Christensen HR, Frokiaer H. 2006. Lactic acid bacteria inducing a weak interleukin-12 and Tumour Necrosis Factor Alpha response in human dendritic cells inhibit strongly stimulating lactic acid bacteria but act synergistically with Gram-Negative bacteria. Clinical and Vaccine Immunology. 13 (3): 365-375.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Other Studies	Human studies: # 653 Pitkälä KH, Strandberg, Finne-Sover UH, Ouwehand AC, Poussa T, Salminen, S. Fermented cereal with specific Bifidobacteria normalizes bowel movements in elderly nursing home residents. A randomized, controlled trial. The Journal of Nutrition, Health & Aging 11(4), 2007 # 657 Nishida S, Gotou M, Akutsu S, Ono M, Hitomi Y, Nakamura T, Iino H. Effect of yoghurt containing Bifidobacterium lactis BB-12 on improvement of defecation and fecal microflora of healthy female adults. Milk Science 53(2), 71 -80, 2004 (Japanese paper, basis for FOSHU approval, translated into English) # 658 Uchida K, Akashi K, Kusunoki I, Ikeda T, Katano N, Motoshima H, Benno Y. Effect of fermented milk containing Bifidobacterium lactis BB-12 on stool frequency, defecation, fecal microbiota and safety of excessive ingestion in healthy female students. Journal of Nutritional Food 8(1), 39-51, 2005 (Japanese paper, basis for FOSHU approval, translated into English) # 654 Murakami T, Miyahira H, Yukisato S, Nakamura R, Kanno H, Kotakemori M, Kamei T, Kobayashi O. Safety and effect of yoghurt containing Bifidobacterium lactis BB-12 on improvement of defecation and fecal microflora in healthy volunteers. Journal of Nutritional Food 9(1), 15-26, 2006 (Japanese paper, basis for FOSHU approval, translated into English) # 655 Matsumoto M, Imai T, Hironaka T, Kume H, Watanabe M, Benno Y. Effect of yoghurt with Bifidobacterium lactis LKM512 in improving fecal microflora and defecation of healthy volunteers. Intestine Microbiology Magazine 14, 97-102, 2001 (Japanese paper, basis for FOSHU approval, translated into English)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Other human studies: #531 Masako Shioya, Keisuke Nakaoka, Rei Igarashi, Naomine Iizuka, Tadashi Abe and Yoshimi Benno. Effect of fermented milk containing Bifidobacterium lactis FK 120 on the fecal flora and fecal properties in healthy female volunteers. Journal of Nutritional Food 3 (1), 7-18, 2000. (Japanese study, to be translated into English) #530 Masako Shioya, Keisuke Nakaoka, Naomine Iizuka and Yoshimi Benno. Effect of fermented milk containing Bifidobacterium lactis FK 120 on the fecal flora, with special reference to Bifidobacterium species, and the fecal properties in healthy volunteers. Journal of Nutritional Food 3 (1), 19-32, 2000. (Japanese study, to be translated into English) #206 Schiffrin E.J., F. Rochat, H. Link-Amster, J. M. Aeschlimann, and A. Donnet¬Hughes. Immunomodulation of Human Blood Cells Following the Ingestion of Lactic Acid Bacteria. J. Dairy Sci. 1995 78: 491-497 #395 Satokari RM, Vaughan EE, Akkermans AD, Saarela M, de Vos WM. Polymerase chain reaction and denaturing gradient gel electrophoresis monitoring of fecal bifidobacterium populations in a prebiotic and probiotic feeding trial. Syst.Appl.Microbiol.2001;24:227-31. #408 Matsumoto, M., Tadenuma, T., Nakamure, K., Kume, H., Imai, T., Kihara, R., Watanabe, M., and Benno, Effect of Bifidobacterium lactis LKM 512 Yogurt on Fecal Microflora in Middle to Old Aged Persons Y. Microbial Ecol Health Dis 12, 77-80. 2000. #416 Alander M, Matto J, Kneifel W et al. Effect of galacto-oligosaccharide supplementation on human faecal microflora and on survival and persistence of Bifidobacterium lactis Bb-12 in the	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

gastrointestinal tract. International Dairy Journal 2001;11:817-25.
#417 Malinen E, Matto J, Salmitie M, Alander M, Saarela M, Palva A. PCR-ELISA II: Analysis of Bifidobacterium populations in human faecal samples from a consumption trial with Bifidobacterium lactis Bb-12 and a galacto¬oligosaccharide preparation. Syst Appl Microbiol. 2002 Aug;25(2):249-58. Erratum in: Syst Appl Microbiol. 2003 Mar;26(1):154-5.
#444 Ouwehand AC, Kurvinen T, Rissanen P. Use of a probiotic Bifidobacterium in a dry food matrix, an in vivo study. Int J Food Microbiol. 2004 Aug 15;95(1):103-6.
#455 Matsumoto M. and Benno Y. Consumption of Bifidobacterium lactis LKM512 yogurt reduces gut mutagenicity by increasing gut polyamine contents in healthy adult subjects. Mutation Research 2004. 568; 147-153
#500 Larsen CN, Nielsen S, Kæstel P, Brockmann E, Bennedsen M, Christensen HR, Eskesen DC, Jacobsen BL, Michaelsen KF. 2006. Dose-response study of probiotic bacteria Bifidobacterium animalis subsp. lactis BB-12 and Lactobacillus paracasei subsp. paracasei CRL-341 in healthy young adults. European Journal of Clinical Nutrition 60 (11): p. 1284-1293.
Animal studies:
#505 Lesniewska V, Rowland I, Laerke HN, Grant G, Naughton PJ. 2006. Relationship between dietary-induced changes in intestinal commensal microflora and duodenojujenal myoelectric activity monitored by radiotelemetry in the rat in vivo. Experimental Physiology 91(1): 229-237.
In vitro studies:
#410 Matsumoto, M., H. Tani, H. Ono, Y.

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Benno. 2002. Adhesive property of Bifidobacterium lactis LKM512 and predominant bacteria of intestinal microflora to human intestinal mucin. Current Microbiology, 44, 212-215. #439 Vinderola CG, Reinheimer JA. 2003. Lactic acid starter and probiotic bacteria: a comparative "in vitro" study of probiotic characteristics and biological barrier resistance. Food research International 36: 895-904.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium animalis ssp. lactis BB-12®, Lactobacilus acidophilus LA-5®, Lactbacilus bulgaricus LBY-27® and Streptococcus thermophilus STY-31®					
		Gut flora	at least 10[9] cfu/day 10E9 -10E10 cfu/day	Review	-Lewis, S.J., Freedman, A.R. Review article: The use of biotherapeutic agents in the prevention and treatment of gastrointestinal disease. 1998. Aliment Pharmacol Ther, 12: 807-822.	208
				Clinical Trials	-Anderson ADG, McNaught CE, Jain PK, MacFie J. 2004. Randomised clinical trial of synbiotic therapy in elective surgical patients. Gut, 53, 241-245	
				Clinical Trials	-Anderson ADG, McNaught CE, MacFie J, Tring I, Barker P, Mitchell CJ. 2003. Randomized clinical trial of multimodal optimization and standard perioperative surgical care. British Journal of Surgery, 90; 1497-1504.	
				Clinical Trials	-Gatt M, Anderson ADG, Reddy BS, Hayward-Sampson P, tring IC, MacFie J. 2005. Randomized clinical trial of multimodal optimization of surgical care in patients undergoing major colonic resection. British Journal of Surgery, 92, 1354-1362	
				Clinical Trials	-Jain PK, McNaught CE, Anderson ADG, MacFie J, Mitchell CJ. 2004. Influence of synbiotic containing Lactobacillus acidophilus La5, Bifidobacterium lactic Bb12, Streptococcus thermophilus, Lactobacillus bulgaricus and oligofructose on gut barrier function and sepsis in critically ill patients: a randomised controlled trial. Clinical Nutrition 23; 467-475	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Human Study	-Black, F.T., Anderson, P.L., Orskov J., Orskov, F., Gaarslev, K., Laulund, S. Prophylactic efficacy of lactobacilli on traveler's diarrhea. 1989. Travel Medicine, 333-335.	
				Human Studies	Nord, C.E., Lidbeck, A., Orrhange, K., Sjostedt, S. Oral supplementation with lactic acid bacteria during intake of clindamycin. 1997. Clinical Microbiology and Infection, 3 (1): 124-132.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium animalis ssp. lactis CNCM I-2494 / DN-173 010					
		Intestinal transit	at least 10[10] cfu/ day fermented milk product daily consumption	Authoritative/Scientific Bodies	-Afssa report - Jean-Christophe Bocld & Carole Thomann - Effect of prebiotics and probiotics on flora and immunity in adults - February 2005	209
				Authoritative/Scientific Bodies	-Brazilian official approval Agencia Nacional de Vigilancia Sanitaria (Brazil) approval 15/01/2004	
				Authoritative/Scientific Bodies	-Netherland Official approval = The Netherlands Nutrition Centre- Assessment Report 13-4-2004	
				Reviews	-Cummings JH, Macfarlane GT. Role of intestinal bacteria in nutrient metabolism. Clinical Nutrition 1997; 16: 3-11.	
				Reviews	-Cummings JH, Antoine JM, Azpiroz F, Bourdet-Sicard R, Brandtzaeg P, Calder PC, Gibson GR, Guarner F, Isolauri E, Pannemans D, Shortt C, Tuijtelaars S, Watzl B. gut health and immunity. Eur J Nutr. 2004 Jun;43 Suppl 2:II118-II173. Review	
				Reviews	-De Roos NM, Katan MB. Effects of probiotic bacteria on diarrhea, lipid metabolism, and carcinogenesis: a review of papers published between 1988 and 1998. Am J Clin Nutr 2000;71(2):405-11.	
				Reviews	-Goldin BR. Health benefits of probiotics. Br J Nutr 1998;80(4):S203-7.	
				Reviews	-Locke GR, Pemberton JH, Phillips SF. American Gastroenterological Association Technical review on constipation. Gastroenterology 2000;119(6):1766-78.	
				Reviews	-Mitsuoka, T. Bifidobacteria and their role in human health. J Ind Microbiol 1990; 6: 263-8.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Reviews	-Picard C. Review article : bifidobacteria as probiotic agents - physiological effects and clinical benefits. Aliment Pharmacol Therm 2005;22: 495-512	
				Individual Human Studies	-Berrada N, Lemeland JF, Laroche G, Thouvenot P, Piaia M. Bifidobacterium from fermented milks: survival during gastric transit. J Dairy Sci 1991;74(2):409-13.	
				Individual Human Studies	-Bouvier M, Meance S, Bouley C, Berta J-L, Grimaud J-C. Effects of consumption of a milk fermented by the probiotic strain Bifidobacterium animalis DN-173 010 on colonic transit times in healthy humans. Bioscience Microflora 2001;20 (2):43-8.	
				Individual Human Studies	-Duez H, Pelletier C, Cools S, Aissi E, Cayuela C, Gavini F, Bouquelet S, Neut C, Mengaud J. A colony immunoblotting method for quantitative detection of a Bifidobacterium animalis probiotic strain in human faeces. J Appl Microbiol 2000;88(6):1019-27.	
				Individual Human Studies	-Marteau P, Cuillerier E, Meance S, Gerhardt MF, Myara A, Bouvier M, Bouley C,Tondu F, Bommelaer G, Grimaud JC. Bifidobacterium animalis strain DN-173 010 shortens the colonic transit time in healthy women: a double-blind, randomized, controlled study. Aliment Pharmacol Ther 2002;16(3):587-93.	
				Individual Human Studies	-Meance S, Cayuela C, Raimondi A, Turchet P, Lucas C, Antoine J-M. Recent advances in the use of functional foods: effects of the commercial fermented milk with Bifidobacterium animalis strain DN-173 010 and yoghurt strains on gut transit time in the elderly. Microbial Ecology in Health and Disease 2003;15:15-22.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Human Studies	-Meance S, Cayuela C, Turchet P, Raimondi A, Lucas C, Antoine J-M. A fermented milk with a Bifidobacterium probiotic strain DN-173 010 shortened oro-fecal gut transit time in elderly. Microbial Ecology in Health and Disease 2001;13:217-22.	
				Individual Human Studies	-Pochart P, Marteau P, Bouhnik Y, Goderel I, Bourlioux P, Rambaud JC. Survival of bifidobacteria ingested via fermented milk during their passage through the human small intestine: an in vivo study using intestinal perfusion. Am J Clin Nutr. 1992 Jan;55(1):78-80.	
				Additional Human Studies	-Cummings JH, Bingham SA, Heaton KW, Eastwood MA.. Fecal weight, colon cancer risk, and dietary intake of nonstarch polysaccharides (dietary fiber). Gastroenterology. 1992 Dec;103(6):1783-9. Gastroenterol 1992; 103:1783-9.	
				Additional Human Studies	-Hopkins MJ, Sharp R, MacFarlane GT. Age and disease related changes in intestinal bacterial populations assessed by cell culture, 16S rRNA abundance, and community cellular fatty acid profiles. Gut 2001; 48: 198-205.	
				Additional Human Studies	-Lampe JW, Fredstrom SB, Slavin JL, Potter JD. Sex differences in colonic function: a randomised trial. Gut. 1993 Apr;34(4):531-6.	
				Additional Human Studies	-Lewis SJ, Heaton KW. The metabolic consequences of slow colonic transit. Am J Gastroenterol. 1999;94(8):2010-6.	
				Additional Human Studies	-Probert CJ, Emmett PM, Heaton KW. Intestinal transit time in the population calculated from self made observations of defecation. J Epidemiol Community Health. 1993 Aug;47(4):331-3.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Additional Human Studies	-Probert CS, Emmett PM, Cripps HA, Heaton KW. Evidence for the ambiguity of the term constipation: the role of irritable bowel syndrome. Gut. 1994 Oct;35(10):1455-8.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium bifidum					
		Beneficial effect on intestinal microflora, gut integrity, digestion	At least 107 cfu / day	Textbooks & peer reviewed journal articles	Madsen, KL. (2001). The use of probiotics in gastrointestinal disease. Can J Gastroenterol. 2001 Dec;15(12):817-22. de Vrese M, Winkler P, Rautenberg P, Harder T, Noah C, Laue C, Ott S, Hampe J, Schreiber S, Heller K and 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. Clin Nutr. 2005 Aug;24(4):481-91. Epub 2005 Apr 21. Madden JA, Plummer SF, Tang J, Garaiova I, Plummer NT, Herbison M, Hunter JO, Shimada T, Cheng L and Shirakawa T. (2005). Effect of probiotics on preventing disruption of the intestinal microflora following antibiotic therapy: a double-blind, placebo-controlled pilot study. Int Immunopharmacol. 2005 Jun;5(6):1091-7. Bartosch S, Woodmansey EJ, Paterson JC, McMurdo ME and Macfarlane GT. (2005). Microbiological effects of consuming a synbiotic containing Bifidobacterium bifidum, Bifidobacterium lactis, and oligofructose in elderly persons, determined by real-time polymerase chain reaction and counting of viable bacteria. Clin Infect Dis. 2005 Jan 1;40(1):28-37. Epub 2004 Dec 6 As listed by A Green	932
		Digestive Balance	Probiotic (when administered in adequate amounts, must	Overview of evidence Human trials	Kailasapathy K et al., Immunology & Cell Biology 2000; 78(1):80-88	2,301

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 10 million bacteria per portion/dose			
		Immune support	Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with			2,302

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 10 million bacteria per portion/dose	Review article Human studies National Institute of Health Public Access Manuscript Overview of evidence Human trials	Roberfroid MB Am J Clin Nutr 2000;(71 suppl):1682S-7S Brown AC et al., Nutr Clin Care 2004;7(2): 56-68 Gomes AMP et al., Trends in Food Science & Technology 1999; 10: 139-157	
		Contains Probiotic that confers a benefit on the host	At least 107 cfu / day			918

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	WHO definition of probiotic FAO/WHO (2001). Guidelines for the Evaluation of Probiotics in Food. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, April 30 and May 1, 2002. Gorbach SL and Goldin BR. (1992). Nutrition and the gastrointestinal microflora. Nutr Rev. 1992 Dec;50(12):378-81 Rolfe, RD. (2000). The role of probiotic cultures in the control of gastrointestinal health. J Nutr. Feb;130(2S Suppl): 396S-402S. Fuller, R and Perdigon, G. (2003). Gut flora, nutrition, immunity and Health. Edited by R Fuller and G Perdigon. Blackwell Publishing.	
		Maintenance of healthy Immune system	At least 107 cfu / day			946

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks & peer reviewed journal articles	PDR (Physician's Desk Reference) For Nutritional Supplements (2001) Sheldon Saul Hendler and David Rorvik (Eds); Montvale NJ; Medical Economics Company. Park JH, Um JI, Lee BJ, Goh JS, Park SY, Kim WS, Kim PH. (2002). Encapsulated Bifidobacterium bifidum potentiates intestinal IgA production. Cell Immunol. 2002 Sep;219(1):22-7 Kim HS and Gilland SE (1983). Lactobacillus acidophilus as a dietary adjunct ofr milk to aid lactose digestion in humans; J Dairy Sci 1983 May; 66 (5): 959-66 de Vrese M, Winkler P, Rautenberg P, Harder T, Noah C, Laue C, Ott S, Hampe J, Schreiber S, Heller K and 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. Clin Nutr. 2005 Aug;24(4):481-91. Epub 2005 Apr 21. Schiffrin EJ, Brassart D, Servin AL, Rochat F, Donnet-Hughes A. (1997). Immune modulation of blood leukocytes in humans by lactic acid bacteria: criteria for strain selection. Am J Clin Nutr. 1997 Aug;66(2):515S-520S As listed by A Green	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium bifidum CNCM I-373					
		Digestive health	at least 10[9] cfu/day daily intake	Nutrition Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	210
				Textbook	-Shils, Shike, et al. (2005). Modern Nutrition in Health and Disease. Lippincott Williams & Wilkins (LWW).	
				Reviews	-Naidu, A. S., W. R. Bidlack, et al. (1999). "Probiotic spectra of lactic acid bacteria (LAB)." Crit Rev Food Sci Nutr 39(1): 13-126.	
				Reviews	-Roberfroid, M. B. (2000). "Prebiotics and probiotics: are they functional foods?" Am J Clin Nutr 71(6 Suppl): 1682S-7S; discussion 1688S-90S.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium bifidum I-3426					
		Digestive health	at least 1x10[9] cfu/day	Reviews	-Collins MD, Gibson GR. Probiotics, prebiotics, and synbiotics: approaches for modulating the microbial ecology of the gut. Am J Clin Nutr. 1999 May;69(5):1052S-1057S.	211
				Reviews	-Kramer S, Bischoff SC. Therapeutic possibilities of probiotics in antibiotic-related diarrhea. MMW Fortschr Med. 2006 Aug 31;148(35-36):28-30.	
				Reviews	-Szajewska H, Mrukowicz JZ. Probiotics in the treatment and prevention of acute infectious diarrhea in infants and children: a systematic review of published randomized, double-blind, placebo-controlled trials. J Pediatr Gastroenterol Nutr. 2001 Oct;33 Suppl 2:S17-25.	
				Individual Human Study	-Saavedra JM, Bauman NA, Oung I, Perman JA, Yolken RH. Feeding of Bifidobacterium bifidum and Streptococcus thermophilus to infants in hospital for prevention of diarrhoea and shedding of rotavirus. Lancet. 1994 Oct 15;344(8929):1046-9	
		Immune defenses / support of immunity	at least 1x10[9] cfu/day			245

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human studies Review articles	Reviews Bruzzese E, Canani RB, De Marco G, Guarino A. Microflora in inflammatory bowel diseases: a pediatric perspective. J Clin Gastroenterol. 2004 Jul;38(6 Suppl):S91-3. Szajewska H, Mrukowicz JZ. Probiotics in the treatment and prevention of acute infectious diarrhea in infants and children: a systematic review of published randomized, double-blind, placebo-controlled trials. J Pediatr Gastroenterol Nutr. 2001 Oct;33 Suppl 2:S17-25. Individual Human Studies Kalliomaki M, Salminen S, Arvilommi H, Kero P, Koskinen P, Isolauri E. Probiotics in primary prevention of atopic disease: a randomised placebo-controlled trial. Lancet. 2001 Apr 7;357(9262):1076-9. Weston S, Halbert A, Richmond P, Prescott SL. Effects of probiotics on atopic dermatitis: a randomised controlled trial. Arch Dis Child. 2005 Sep;90(9):892-7. Epub 2005 Apr 29.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium breve					
		Beneficial effect on intestinal microflora, gut integrity, digestion	At least 107 cfu / day	Textbooks & peer reviewed journal articles	Araki K, Shinozaki T, Irie Y and Miyazawa Y. (1999). Trial of oral administration of Bifidobacterium breve for the prevention of rotavirus infections. Kansenshogaku Zasshi. 1999 Apr;73(4):305-10. Thibault H, Aubert-Jacquin C and Goulet O. (2004). Effects of long-term consumption of a fermented infant formula (with Bifidobacterium breve c50 and Streptococcus thermophilus 065) on acute diarrhea in healthy infants. J Pediatr Gastroenterol Nutr. 2004 Aug;39(2):147-52. As listed by A Green	929
		Contains Probiotic that confers a benefit on the host	At least 107 cfu / day	Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	WHO definition of probiotic FAO/WHO (2001). Guidelines for the Evaluation of Probiotics in Food. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, April 30 and May 1, 2002. Gorbach SL and Goldin BR. (1992). Nutrition and the gastrointestinal microflora. Nutr Rev. 1992 Dec;50(12):378-81 Rolfe, RD. (2000). The role of probiotic cultures in the control of gastrointestinal health. J Nutr. Feb;130(2S Suppl): 396S-402S. Fuller, R and Perdigon, G. (2003). Gut flora, nutrition, immunity and Health. Edited by R Fuller and G Perdigon. Blackwell Publishing.	915

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Maintenance of healthy Immune system	At least 107 cfu / day	Textbooks & peer reviewed journal articles	Indrio F, Ladisa G, Mautone A, Montagna O. (2007). Effect of a Fermented Formula on Thymus Size and Stool pH in Healthy Term Infants. Pediatr Res. 2007 Jul;62(1):98-100 Fujii T, Ohtsuka Y, Lee T, Kudo T, Shoji H, Sato H, Nagata S, Shimizu T, Yamashiro Y. (2006). Bifidobacterium breve enhances transforming growth factor beta1 signaling by regulating Smad7 expression in preterm infants. J Pediatr Gastroenterol Nutr. 2006 Jul;43(1):83-8. Yasui H, Shida K, Matsuzaki T, Yokokura T. (1999). Immunomodulatory function of lactic acid bacteria. Antonie Van Leeuwenhoek. Babinska I, Rotkiewicz T, Otrocka-Domagala I. (2005). The effect of Lactobacillus acidophilus and Bifidobacterium spp. administration on the morphology of the gastrointestinal tract, liver and pancreas in piglets. : Pol J Vet Sci. 2005;8(1):29-35. As listed by A Green	943

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium breve I-3425					
		Digestive health	at least 1x10[9] cfu/day	Individual Human Studies	-Kajander K, Korpela R. Clinical studies on alleviating the symptoms of irritable bowel syndrome. Asia Pac J Clin Nutr. 2006;15(4):576-80.	212
				Individual Human Studies	-Myllyluoma E, Veijola L, Ahlroos T, Tynkkynen S, Kankuri E, Vapaatalo H, Rautelin H, Korpela R. Probiotic supplementation improves tolerance to Helicobacter pylori eradication therapy--a placebo-controlled, double-blind randomized pilot study. Aliment Pharmacol Ther. 2005 May 15;21(10):1263-72.	
				Individual Human Studies	-Uchida K, Takahashi T, Inoue M, Morotomi M, Otake K, Nakazawa M, Tsukamoto Y, Miki C, Kusunoki M. Immunonutritional effects during synbiotics therapy in pediatric patients with short bowel syndrome. Pediatr Surg Int. 2007 Jan 5; [Epub ahead of print]	
				Individual Human Studies		

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium breve Yakult (BbY)					
		Digestive system / Intestinal flora	at least 1x10[9] cfu/day	Reviews	-Nomoto K. (2005); Prevention of infection by probiotics. J. bioscience and bioengineering 100: 583-592.	213
				Reviews	-Tanaka, R. Clinical applications of Bifidobacterium in humans Research of Bifidobacteria, T. Mitsuoka (editor), 221-228 (1994)	
				Individual Human Studies	-Asahara, T. et al, The effects of Bifidobacteria-fermented milk on human urinary mutagenicity, which increases following ingestion of cooked ground beef. Journal of Intestinal Bacteriology, 12, 89-96 (1999)	
				Individual Human Studies	-Kado Y. et al. Survival of a probiotic Bifidobacterium breve strain Yakult in the human gastrointestinal tract. Journal of Intestinal Microbiology, 1992, 15, 9-14.	
				Individual Human Studies	-Kitajima, H., et al. Early administration of Bifidobacterium breve to preterm infants: randomised controlled trial. Arch Dis Child Fetal Neonatal Ed. 76(2): F101-7. (1997)	
				Individual Human Studies	-Matsui, T. et al Effect of Bifidus yogurt on the defecation frequency of the elderly. Journal of Nutrition, 58, 213-218 (2000)	
				Individual Human Studies	-Takano, K. et al Effect of intestinal bacteria on the secretory immunological competence of the digestive tract. Pediatrics, 27, 1081-1086 (1986)	
				Individual Human Studies	-Tanaka, R. et al. Effects of administration of TOS and Bifidobacterium breve 4006 on the human fecal flora. Bifid. Microflora, 2, 17-24 (1983)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Human Studies	-Tanaka, R. et al. Investigation of the stool frequency in elderly who are bed ridden and its improvements by ingesting of Bifidus yogurt. Japanese Journal of Geriatric Gerontology Society, 19, 577-582 (1982)	
				Individual Human Studies	-Tanaka, R. et al. Research relating to the implantation of Bifidobacterium - Administration effects of B.bifidum 4007 and B.breve 4006 in infants and adults Clinical Pediatrics, 33, 2483-2492 (1980)	
				Individual Human Studies	-Tohyama K (1993); Suppression of intestinal putrefactive fermentation by Bifidobacterium breve. Bifidobacteria, 6, 151-160.	
				Individual Human Studies	-Yasui, H. et al. Detection of Bifidobacterium strains that induce large quantities of IgA. Microbial Ecol. Health Dis., 5, 155-162 (1992)	
				Individual Human Studies	-Yasui, H. et al. Enhancement of immune response in Peyer's patch cells cultured with Bifidobacterium breve. J. Dairy Sci., 74, 1187-1195 (1991)	
				Individual Human Studies	-Yasui, H. et al. Immunogenicity of Bifidobacterium breve and change in antibody production in Peyer's patches after oral administration. J. Dairy Sci., 72, 30-35 (1989)	
				Additional Human Studies	-Horita, M. Intestinal flora and infection of newborn infants, Journal of infection, 57, 405-418 (1983)	
				Additional Human Studies	-Hotta M. et al. Clinical effects of Bifidobacterium preparations on pediatric intractable diarrhea. Keio J. Med. 36: 298-314 (1987)	
				Additional Human Studies	-Ishikawa, H. et al. Randomized controlled trial of the effect of Bifidobacterium-fermented milk on ulcerative colitis. J. Amer. Coll. Nutr., 22, 56-63 (2002)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Additional Human Studies	-Kan, T. et al. Research relating to the implantation of Bifidobacterium - Administration effects of B.bifidum 4002 in bottle-fed infants, Clinical Pediatrics, 30, 1947-1953 (1977)	
				Additional Human Studies	-Kanamori, Y., et al. A novel synbiotic therapy dramatically improved the intestinal function of a pediatric patient with laryngotracheo-esophageal cleft (LTEC) in the intensive care unit. Clin Nutr. 21:527-30 (2002)	
				Additional Human Studies	-Kanamori, Y., et al. Anaerobic dominant flora was reconstructed by synbiotics in an infant with MRSA enteritis. Pediatr Int. 45(3): 359-62 (2003)	
				Additional Human Studies	-Kanamori, Y., et al. Combination therapy with Bifidobacterium breve, Lactobacillus casei, and gakactooligosaccharides dramatically improved the intestinal function in a girl with short bowel syndrome: A novel synbiotics therapy for intestinal failure. Digestive Diseases and Science 46: 2010-2016 (2001)	
				Additional Human Studies	-Kitajima, H., et al. Early administration of Bifidobacterium breve to preterm infants: randomised controlled trial. Arch Dis Child Fetal Neonatal Ed. 76(2): F101-7. (1997)	
				Additional Human Studies	-Koizumi, T. et al Effect of Bifidobacterium breve administration on endotoxic in cirrhosis patients and its assessment Tomotari Mitsuoka (editor), Intestinal flora and adult diseases, p. 155-173, Japan Scientific Societies Press (1985)	
				Additional Human Studies	-Koizumi, T. et al Effect of Bifidobacterium preparation BBG02 on hepatic encephalopathy. Sougou Rinshou 29(9): 2473-2478 (1980)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Additional Human Studies	-Tanaka, R. et al Effect of Bifidobacterium preparation administration on antibiotic-associated intractable diarrhea. Tomotari Mitsuoka (editor), Intestinal flora and infection, p. 43-64, Japan Scientific Societies Press (1986)	
				Additional Human Studies	-Tojo, M. et al. The effect of Bifidobacterium breve administration on Campylobacter enteritis. Acta Paediatr. Jpn., 29, 160-167 (1987)	
				Animal Studies	-Asahara, T. et al., Antibacterial effect of fermented milk containing Bifidobacterium breve, Bifidobacterium bifidum and Lactobacillus acidophilus against indigenous Escherichia coli infection in mice. Microb. Ecol. Health Dis., 13, 16-24 (2001)	
				Animal Studies	-Asahara, T. et al., Increased resistance of mice to Salmonella enterica serovar Typhimurium infection by synbiotic administration of Bifidobacteria and transgalactosylated oligosaccharides, J. Appl. Microbiol., 91, 985-996 (2001)	
				Animal Studies	-Asahara, T. et al., Intestinal colonization by probiotic Bifidobacteria protects mice from lethal infection with Shiga-toxin producing Escherichia coli O157:H7. Infect. Immun., in press.	
				Animal Studies	-Matsumoto, S. et al. Preventive effects of Bifidobacterium- and Lactobacillus-fermented milk on the development of inflammatory bowel disease in senescence-accelerated mouse P1/Yit strain mice. Digestion, 64, 92-99 (2001)	
				Animal Studies	-Yasui, H. et al. Passive protection against rotavirus-induced diarrhea of mouse pups born to and nursed by dams fed Bifidobacterium breve YIT4064. J. Infect. Dis., 172, 403-409 (1995)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				In Vitro Study	-Morotomi, M. et al. In vitro binding of potent mutagenic pyrolyzates to intestinal bacteria. J. Natl. Cancer Inst., 77, 195-201 (1986).	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium infantis					
		Contains Probiotic that confers a benefit on the host	At least 107 cfu / day	Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	WHO definition of probiotic FAO/WHO (2001). Guidelines for the Evaluation of Probiotics in Food. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, April 30 and May 1, 2002. Gorbach SL and Goldin BR. (1992). Nutrition and the gastrointestinal microflora. Nutr Rev. 1992 Dec;50(12):378-81 Rolfe, RD. (2000). The role of probiotic cultures in the control of gastrointestinal health. J Nutr. Feb;130(2S Suppl): 396S-402S. Fuller, R and Perdigon, G. (2003). Gut flora, nutrition, immunity and Health. Edited by R Fuller and G Perdigon. Blackwell Publishing.	916
		Maintenance of healthy Immune system	At least 107 cfu / day			944

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks & peer reviewed journal articles	O'Hara AM, O'Regan P, Fanning A, O'Mahony C, Macsharry J, Lyons A, Bienenstock J, O'Mahony L, Shanahan F. (2006). Functional modulation of human intestinal epithelial cell responses by Bifidobacterium infantis and Lactobacillus salivarius. Immunology. 2006 Jun;118(2):202-15. Sheil B, MacSharry J, O'Callaghan L, O'Riordan A, Waters A, Morgan J, Collins JK, O'Mahony L, Shanahan F. (2006). Role of interleukin (IL-10) in probiotic-mediated immune modulation: an assessment in wild-type and IL-10 knock-out mice. Clin Exp Immunol. 2006 May;144(2):273-80 O'Mahoney et al (2005). Lactobacillus and bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles. Gastroenterology. 2005 Mar;128(3):783-5. As listed by A Green	
		Improved Intestinal Flora balance	At least 1 x 107 CFU daily	Reviews	Picard, C., Fioramonti, J., Francois, A., Robinson, T., Neant, F., and Manuchansky, C. Review article: bifidobacteria as probiotic agents - physiological effects and clinical benefits. Alimentary Pharmacology and Therapeutics, 2005; 22 (6):495-512. Mitsuoka, T. Bifidobacteria and their role in human health. J Ind Microbiol 1990; 6: 263-8. ESSENTIAL, DIGESTION, ALL Naidu A.S., W.R. Bidlack, and Clemens, R.A. Probiotic spectra of lactic acid bacteria. In Clydesdale, F.M. Critical Reviews in Food Science and Nutrition, 1999: 13-126.	824

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Beneficial effect on intestinal microflora, gut integrity, digestion	At least 107 cfu / day	Textbooks & peer reviewed journal articles.	Chaitow, L and Trenev, N. (1990). Probiotics. Thorsons O'Mahoney et al (2005). Lactobacillus and bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles. Gastroenterology. 2005 Mar;128(3):783-5. Whorwell et al (2006) Efficacy of an Encapsulated Probiotic Bifidobacterium infantis 35624 in Women with Irritable Bowel Syndrome; The American Journal of Gastroenterology, Volume 101, Number 7, July 2006, pp. 1581-1590(10) As listed by A Green	930
	Bifidobacterium infantis I- 3424					
		Immune defenses / support of immunity	at least 1x10[9] cfu/day	Human study Review article	Review Bruzzese E, Canani RB, De Marco G, Guarino A. Microflora in inflammatory bowel diseases: a pediatric perspective. J Clin Gastroenterol. 2004 Jul;38(6 Suppl):S91-3. Individual Human Study Mullie C, Yazourh A, Thibault H, Odou MF, Singer E, Kalach N, Kremp O, Romond MB. 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. Pediatr Res. 2004 Nov;56(5):791-5. Epub 2004 Sep 3.	247

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium infantis UCC35624					
		Immune Response	At least 1 x 107 CFU daily	Human Intervention Studies - Randomized Controlled Trials	O'Mahony, L., J. McCarthy, P. Kelly, G. Hurley, F. Luo, K. Chen, G. O'Sullivan, B. Kiely, J.K. Collins, F. Shanahan and E.M.M. Quigley. 2005. Lactobacillus and Bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles. Gastroenterology 2005. 128: 541-551.	834
				Human Intervention Studies - Physiologic	Chen K, Luo F, Hendrix S, Altringer L, Charbonnneau D, Poehner R, Carryl O, Trowbridge M, O'Mahony L, Shanahan F, Quigley E. Modulation of cytokine profiles in healthy and IBS subjects following supplementation with the unique probiotic strain, Bifidobacterium infantis 35624 Gastroenterology 2005; 128: A-661 (Abstract W1674)	
				Animal studies	Sheil B, MacSharry J, O'Callaghan L, O' Riordan A, Waters A, Morgan J, O'Mahony L, Collins JK, Shanahan F. Role of IL-10 in probiotic-mediated immune modulation: an assessment in wild-type and IL-10 Knock-out mice. Clinical and Experimental Immunology,144:273–280.	
					McCarthy J, O'Mahony L, O'Callaghan L, Shiel B, Vaughan EE, Fitzsimons N, Fitzgibbon J, O' Sullivan GC, Kiely B, Collins JK, Shanahan F. Double blind, placebo controlled trial of two probiotic strains in interleukin 1- knockout mice and mechanistic link with Cytokine balance. GUT 2003;52:975-980.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Probiotic mechanism of action - in vitro studies	O'Mahony L, O'Callaghan L, McCarthy J, Shilling D, Kavanagh E, Kirwan W, Redmond H, Collins J, Shanahan F. Differential cytokine response from dendritic cells to commensal and pathogenic bacteria in different lymphoid compartments in humans. AJP - GI 290:839-845, 2006.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Probiotic functionality - critical reviews	Quigley EMM & Flourie B. Probiotics and irritable bowel syndrome: a rationale for their use and an assessment of the evidence to date. Neurogastroenterol Motil (2006) Volume 19, Issue 3, March 2007, Pages 166-172 Quigley EMM. The use of probiotics in functional bowel disease. Gastroenterol Clin N Am 2005. 34:533-545. Picard, C., Fioramonti, J., Francois, A., Robinson, T., Neant, F., and Manuchansky, C. Review article: bifidobacteria as probiotic agents - physiological effects and clinical benefits. Alimentary Pharmacology and Therapeutics, 2005; 22 (6):495-512. Mitsuoka, T. Bifidobacteria and their role in human health. J Ind Microbiol 1990; 6: 263-8. Naidu A.S., W.R. Bidlack, and Clemens, R.A. Probiotic spectra of lactic acid bacteria. In Clydesdale, F.M. Critical Reviews in Food Science and Nutrition, 1999: 13-126. Arunachalam KD. Role of bifidobacteria in Nutrition, Medicine and Technology. Nutrition Research 1999; 19(10)1559-1597. Tannock GW. What immunologists should know about bacterial communities of the human bowel. Seminars in Immunology, 2007;19:94-105. Salminen, S., Gueimonde, M., and Isolauri, E.. Probiotics That Modify Disease Risk. Journal of Nutrition, 2005;135 (5):1294-1298. Reid G, Jass J, Sebulsky M and McCormick J. Potential uses of probiotics in clinical practice,	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Clin Microbiol Rev, 2003; 16(4): 658-672. Verdu E., Collins S. Irritable bowel syndrome. Best Practice & Research Clinical Gastroenterology, 2004; 18 (2): 315-321. Saxelin M., Tynkkynen S., Mattila-Sandholm T., and Willem M. de Vos. Probiotic and other functional microbes: from markets to mechanisms. Current Opinion in Biotechnology, 2005; 16 (2):204-211. Mombelli B. and Gismondo, M.R.. The use of probiotics in medical practice. International Journal of Antimicrobial Agents, 2000; 16 (4):531-536. Shanahan F. The host-microbe interface within the gut. Best Pract Res Clin Gastroenterol, 2002; 16(6):915-31. Dunne C, Murphy L, Flynn S, O'Mahony L, O' Halloran S, Feeney M, Morrissey D, Thornton G, Fitzgerald G, Daly C, Kiely B, Quigley EMM, O"Sullivan GC, Shanahan F, Collins JK. Probiotics: from myth to reality. Demonstration of functionality in animal models of disease and in human clinical trials. Antonie van Leeuwenhoek. 76:279-92, 1999.	
		Build and maintain normal digestive health	At least 1 x 107 CFU daily			826

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human Intervention Studies - Randomized Controlled Trials	O'Mahony, L., J. McCarthy, P. Kelly, G. Hurley, F. Luo, K. Chen, G. O'Sullivan, B. Kiely, J.K. Collins, F. Shanahan and E.M.M. Quigley. 2005. Lactobacillus and Bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles. Gastroenterology 2005. 128: 541-551. Whorwell PJ, Altringer L, Morel J, Bond Y, Charbonneau D, O'Mahony L, Kiely B, Shanahan F, Quigley EM. Efficacy of an encapsulated probiotic Bifidobacterium infantis 35624 in women with irritable bowel syndrome. Am J Gastroenter 2006 Jul;101(7):1581-90.	
				Human Intervention Studies -Physiologic	Chen K, Luo F, Hendrix S, Altringer L, Charbonnneau D, Poehner R, Carryl O, Trowbridge M, O'Mahony L, Shanahan F, Quigley E. Modulation of cytokine profiles in healthy and IBS subjects following supplementation with the unique probiotic strain, Bifidobacterium infantis 35624 Gastroenterology 2005; 128: A-661 (Abstract W1674) Charbonneau DL, Altringer LA, Carryl OR, Chen KS, Kidd KJ, Darcy T, Fawcett DH, Trowbridge MM, Jang C, Luo F, Poehner RD, Meller ST Fecal flora effects following oral supplementation with Bifidobacteria infantis 35624 in healthy and IBS subjects. World Congress of Gastroenterology, Montreal, Canada September 2005.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				critical reviews	Quigley EMM & Flourie B. Probiotics and irritable bowel syndrome: a rationale for their use and an assessment of the evidence to date. Neurogastroenterol Motil (2006) Volume 19, Issue 3, March 2007, Pages 166-172 Quigley EMM. The use of probiotics in functional bowel disease. Gastroenterol Clin N Am 2005. 34:533-545. Picard, C., Fioramonti, J., Francois, A., Robinson, T., Neant, F., and Manuchansky, C. Review article: bifidobacteria as probiotic agents - physiological effects and clinical benefits. Alimentary Pharmacology and Therapeutics, 2005; 22 (6):495-512. Mitsuoka, T. Bifidobacteria and their role in human health. J Ind Microbiol 1990; 6: 263-8. Naidu A.S., W.R. Bidlack, and Clemens, R.A. Probiotic spectra of lactic acid bacteria. In Clydesdale, F.M. Critical Reviews in Food Science and Nutrition, 1999: 13-126. Arunachalam KD. Role of bifidobacteria in Nutrition, Medicine and Technology. Nutrition Research 1999; 19(10)1559-1597. Salminen, S., Gueimonde, M., and Isolauri, E.. Probiotics That Modify Disease Risk. Journal of Nutrition, 2005;135 (5):1294-1298. Reid G, Jass J, Sebulsky M and McCormick J. Potential uses of probiotics in clinical practice, Clin Microbiol Rev, 2003; 16(4): 658-672. Orrhage K and Nord CE. Bifidobacteria and Lactobacilli in human health. Drugs Exptl. Clin. Res., 2000; XXVI: 95-111.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Verdu E., Collins S. Irritable bowel syndrome. Best Practice & Research Clinical Gastroenterology, 2004; 18 (2): 315-321. Dunne C. Adaptation of bacteria to the intestinal niche: Probiotics and gut disorder. Inflamm Bowel Dis 2001;7:136-145. Mombelli B. and Gismondo, M.R.. The use of probiotics in medical practice. International Journal of Antimicrobial Agents, 2000; 16 (4):531-536. Rolfe RD. The role of probiotic cultures in the control of gastrointestinal health. Journal of Nutrition, 2000; 130:396S-402S. Shanahan F. The host-microbe interface within the gut. Best Pract Res Clin Gastroenterol, 2002; 16(6):915-31. T. S. King, M. Elia, and J. O. Hunter. Abnormal colonic fermentation in irritable bowel syndrome. The Lancet 352, 1998: 1187-1189. Dunne C, Murphy L, Flynn S, O'Mahony L, O' Halloran S, Feeney M, Morrissey D, Thornton G, Fitzgerald G, Daly C, Kiely B, Quigley EMM, O"Sullivan GC, Shanahan F, Collins JK. Probiotics: from myth to reality. Demonstration of functionality in animal models of disease and in human clinical trials. Antonie van Leeuwenhoek. 76:279-92, 1999.	
		Normalizes digestive health for overall natural balance and well-being	At least 1 x 107 CFU daily			841

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human Intervention Studies - Randomized Controlled Trials	O'Mahony, L., J. McCarthy, P. Kelly, G. Hurley, F. Luo, K. Chen, G. O'Sullivan, B. Kiely, J.K. Collins, F. Shanahan and E.M.M. Quigley. 2005. Lactobacillus and Bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles. Gastroenterology 2005. 128: 541-551. Whorwell PJ, Altringer L, Morel J, Bond Y, Charbonneau D, O'Mahony L, Kiely B, Shanahan F, Quigley EM. Efficacy of an encapsulated probiotic Bifidobacterium infantis 35624 in women with irritable bowel syndrome. Am J Gastroenter 2006 Jul;101(7):1581-90.	
				Human Intervention Studies Physiologic	Chen K, Luo F, Hendrix S, Altringer L, Charbonnneau D, Poehner R, Carryl O, Trowbridge M, O'Mahony L, Shanahan F, Quigley E. Modulation of cytokine profiles in healthy and IBS subjects following supplementation with the unique probiotic strain, Bifidobacterium infantis 35624 Gastroenterology 2005; 128: A-661 (Abstract W1674) Charbonneau DL, Altringer LA, Carryl OR, Chen KS, Kidd KJ, Darcy T, Fawcett DH, Trowbridge MM, Jang C, Luo F, Poehner RD, Meller ST Fecal flora effects following oral supplementation with Bifidobacteria infantis 35624 in healthy and IBS subjects. World Congress of Gastroenterology, Montreal, Canada September 2005.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Animal studies	Sheil B, MacSharry J, O'Callaghan L, O' Riordan A, Waters A, Morgan J, O'Mahony L, Collins JK, Shanahan F. Role of IL-10 in probiotic-mediated immune modulation: an assessment in wild-type and IL-10 Knock-out mice. Clinical and Experimental Immunology,144:273–280. McCarthy J, O'Mahony L, O'Callaghan L, Shiel B, Vaughan EE, Fitzsimons N, Fitzgibbon J, O' Sullivan GC, Kiely B, Collins JK, Shanahan F. Double blind, placebo controlled trial of two probiotic strains in interleukin 1- knockout mice and mechanistic link with Cytokine balance. GUT 2003;52:975-980. Symonds E, O'Mahony C, O'Mahony D, O'Mahony L, Shanahan F. Probiotic Prevention of Digestive Enzyme Damage in a Mouse Model of Salmonella Gastroenterology 2007:132:A714 (Abstract W1575).	
				Probiotic mechanism of action - in vitro studies	O'Mahony L, O'Callaghan L, McCarthy J, Shilling D, Kavanagh E, Kirwan W, Redmond H, Collins J, Shanahan F. Differential cytokine response from dendritic cells to commensal and pathogenic bacteria in different lymphoid compartments in humans. AJP - GI 290:839-845, 2006. O'Mahony C, Scully P, O'Mahony D, Lyons A, O'Sullivan D, Macsharry J, Kiely B, Shanahan F, O'Mahony L Commensal Microbiota, Including Probiotics, Promote T Regulatory Cells and Attenuation of Inflammatory Responses to Murine Salmonella Infection. Gastroenterology 2007:132:A401 (Abstract M1695).	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Probiotic functionality - critical reviews	Quigley EMM & Flourie B. Probiotics and irritable bowel syndrome: a rationale for their use and an assessment of the evidence to date. Neurogastroenterol Motil (2006) Volume 19, Issue 3, March 2007, Pages 166-172 Quigley EMM. The use of probiotics in functional bowel disease. Gastroenterol Clin N Am 2005. 34:533-545. Picard, C., Fioramonti, J., Francois, A., Robinson, T., Neant, F., and Manuchansky, C. Review article: bifidobacteria as probiotic agents - physiological effects and clinical benefits. Alimentary Pharmacology and Therapeutics, 2005; 22 (6):495-512. Mitsuoka, T. Bifidobacteria and their role in human health. J Ind Microbiol 1990; 6: 263-8. Naidu A.S., W.R. Bidlack, and Clemens, R.A. Probiotic spectra of lactic acid bacteria. In Clydesdale, F.M. Critical Reviews in Food Science and Nutrition, 1999: 13-126. Arunachalam KD. Role of bifidobacteria in Nutrition, Medicine and Technology. Nutrition Research 1999; 19(10)1559-1597. Tannock GW. What immunologists should know about bacterial communities of the human bowel. Seminars in Immunology, 2007;19:94-105. Salminen, S., Gueimonde, M., and Isolauri, E.. Probiotics That Modify Disease Risk. Journal of Nutrition, 2005;135 (5):1294-1298. Reid G, Jass J, Sebulsky M and McCormick J. Potential uses of probiotics in clinical practice,	

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Clin Microbiol Rev, 2003; 16(4): 658-672.

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Mombelli B. and Gismondo, M.R.. The use of probiotics in medical practice. International Journal of Antimicrobial Agents, 2000; 16 (4):531-536.

Rolfe RD. The role of probiotic cultures in the control of gastrointestinal health. Journal of Nutrition, 2000; 130:396S-402S.

Shanahan F. The host-microbe interface within the gut. Best Pract Res Clin Gastroenterol, 2002; 16(6):915-31.

King TS, Elia M, and Hunter JO. Abnormal colonic fermentation in irritable bowel syndrome. The Lancet 352, 1998: 1187-1189.

Dunne C, Murphy L, Flynn S, O'Mahony L, O' Halloran S, Feeney M, Morrissey D, Thornton G, Fitzgerald G, Daly C, Kiely B, Quigley EMM, O"Sullivan GC, Shanahan F, Collins JK. Probiotics: from myth to reality. Demonstration of functionality in animal models of disease and in human clinical trials. Antonie van Leeuwenhoek. 76:279-92, 1999.

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Promotes healthy gut transit for improved comfort	At least 1 x 107 CFU daily	Human Intervention Studies - Randomized Controlled Trials	O'Mahony, L., J. McCarthy, P. Kelly, G. Hurley, F. Luo, K. Chen, G. O'Sullivan, B. Kiely, J.K. Collins, F. Shanahan and E.M.M. Quigley. 2005. Lactobacillus and Bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles. Gastroenterology 2005. 128: 541-551. Whorwell PJ, Altringer L, Morel J, Bond Y, Charbonneau D, O'Mahony L, Kiely B, Shanahan F, Quigley EM. Efficacy of an encapsulated probiotic Bifidobacterium infantis 35624 in women with irritable bowel syndrome. Am J Gastroenter 2006 Jul;101(7):1581-90.	839
				Human Intervention Studies - Physiologic	Charbonneau DL, Altringer LA, Carryl OR, Chen KS, Kidd KJ, Darcy T, Fawcett DH, Trowbridge MM, Jang C, Luo F, Poehner RD, Meller ST Fecal flora effects following oral supplementation with Bifidobacteria infantis 35624 in healthy and IBS subjects. World Congress of Gastroenterology, Montreal, Canada September 2005.	

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		Promotes optimal Digestive function	At least 1 x 107 CFU daily	Human Intervention Studies - Randomized Controlled Trials	O'Mahony, L., J. McCarthy, P. Kelly, G. Hurley, F. Luo, K. Chen, G. O'Sullivan, B. Kiely, J.K. Collins, F. Shanahan and E.M.M. Quigley. 2005. Lactobacillus and Bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles. Gastroenterology 2005. 128: 541-551. Whorwell PJ, Altringer L, Morel J, Bond Y, Charbonneau D, O'Mahony L, Kiely B, Shanahan F, Quigley EM. Efficacy of an encapsulated probiotic Bifidobacterium infantis 35624 in women with irritable bowel syndrome. Am J Gastroenter 2006 Jul;101(7):1581-90.	838
				Human Intervention Studies - Physiologic	Charbonneau DL, Altringer LA, Carryl OR, Chen KS, Kidd KJ, Darcy T, Fawcett DH, Trowbridge MM, Jang C, Luo F, Poehner RD, Meller ST Fecal flora effects following oral supplementation with Bifidobacteria infantis 35624 in healthy and IBS subjects. World Congress of Gastroenterology, Montreal, Canada September 2005.	

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		Promotes Gut Barrier Function	At least 1 x 107 CFU daily	Human Intervention Studies - Randomized Controlled Trials	O'Mahony, L., J. McCarthy, P. Kelly, G. Hurley, F. Luo, K. Chen, G. O'Sullivan, B. Kiely, J.K. Collins, F. Shanahan and E.M.M. Quigley. 2005. Lactobacillus and Bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles. Gastroenterology 2005. 128: 541-551.	837
				Human Intervention Studies - Physiologic	Chen K, Luo F, Hendrix S, Altringer L, Charbonnneau D, Poehner R, Carryl O, Trowbridge M, O'Mahony L, Shanahan F, Quigley E. Modulation of cytokine profiles in healthy and IBS subjects following supplementation with the unique probiotic strain, Bifidobacterium infantis 35624 Gastroenterology 2005; 128: A-661 (Abstract W1674) Charbonneau DL, Altringer LA, Carryl OR, Chen KS, Kidd KJ, Darcy T, Fawcett DH, Trowbridge MM, Jang C, Luo F, Poehner RD, Meller ST Fecal flora effects following oral supplementation with Bifidobacteria infantis 35624 in healthy and IBS subjects. World Congress of Gastroenterology, Montreal, Canada September 2005.	

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				Animal studies	Sheil B, MacSharry J, O'Callaghan L, O' Riordan A, Waters A, Morgan J, O'Mahony L, Collins JK, Shanahan F. Role of IL-10 in probiotic-mediated immune modulation: an assessment in wild-type and IL-10 Knock-out mice. Clinical and Experimental Immunology,144:273–280. McCarthy J, O'Mahony L, O'Callaghan L, Shiel B, Vaughan EE, Fitzsimons N, Fitzgibbon J, O' Sullivan GC, Kiely B, Collins JK, Shanahan F. Double blind, placebo controlled trial of two probiotic strains in interleukin 1- knockout mice and mechanistic link with Cytokine balance. GUT 2003;52:975-980. Symonds E, O'mahony C, O'mahony D, O'mahony L, Shanahan F. Probiotic Prevention of Digestive Enzyme Damage in a Mouse Model of Salmonella Gastroenterology 2007:132:A714 (Abstract W1575).	
				Probiotic mechanism of action - in vitro studies	O'Mahony L, O'Callaghan L, McCarthy J, Shilling D, Kavanagh E, Kirwan W, Redmond H, Collins J, Shanahan F. Differential cytokine response from dendritic cells to commensal and pathogenic bacteria in different lymphoid compartments in humans. AJP - GI 290:839-845, 2006. O'mahony C, Scully P, O'mahony D, Lyons A, O'sullivan D, Macsharry J, Kiely B, Shanahan F, O'mahony L Commensal Microbiota, Including Probiotics, Promote T Regulatory Cells and Attenuation of Inflammatory Responses to Murine Salmonella Infection. Gastroenterology 2007:132:A401 (Abstract M1695).	

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		Promotes digestive regularity	At least 1 x 107 CFU daily			840

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human Intervention Studies - Randomized Controlled Trials	O'Mahony, L., J. McCarthy, P. Kelly, G. Hurley, F. Luo, K. Chen, G. O'Sullivan, B. Kiely, J.K. Collins, F. Shanahan and E.M.M. Quigley. 2005. Lactobacillus and Bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles. Gastroenterology 2005. 128: 541-551. Whorwell PJ, Altringer L, Morel J, Bond Y, Charbonneau D, O'Mahony L, Kiely B, Shanahan F, Quigley EM. Efficacy of an encapsulated probiotic Bifidobacterium infantis 35624 in women with irritable bowel syndrome. Am J Gastroenter 2006 Jul;101(7):1581-90.	
				Human Intervention Studies - Physiologic	Charbonneau DL, Altringer LA, Carryl OR, Chen KS, Kidd KJ, Darcy T, Fawcett DH, Trowbridge MM, Jang C, Luo F, Poehner RD, Meller ST Fecal flora effects following oral supplementation with Bifidobacteria infantis 35624 in healthy and IBS subjects. World Congress of Gastroenterology, Montreal, Canada September 2005.	

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		Improved Intestinal Flora balance	At least 1 x 107 CFU daily	Human Intervention Trials	O'Mahony, L., J. McCarthy, P. Kelly, G. Hurley, F. Luo, K. Chen, G. O'Sullivan, B. Kiely, J.K. Collins, F. Shanahan and E.M.M. Quigley. 2005. Lactobacillus and Bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles. Gastroenterology 2005. 128: 541-551. Whorwell PJ, Altringer L, Morel J, Bond Y, Charbonneau D, O'Mahony L, Kiely B, Shanahan F, Quigley EM. Efficacy of an encapsulated probiotic Bifidobacterium infantis 35624 in women with irritable bowel syndrome. Am J Gastroenter 2006 Jul;101(7):1581-90.	825

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Physiologic and RCT	Chen K, Luo F, Hendrix S, Altringer L, Charbonnneau D, Poehner R, Carryl O, Trowbridge M, O'Mahony L, Shanahan F, Quigley E. Modulation of cytokine profiles in healthy and IBS subjects following supplementation with the unique probiotic strain, Bifidobacterium infantis 35624 Gastroenterology 2005; 128: A-661 (Abstract W1674) Charbonneau DL, Altringer LA, Carryl OR, Chen KS, Kidd KJ, Darcy T, Fawcett DH, Trowbridge MM, Jang C, Luo F, Poehner RD, Meller ST Fecal flora effects following oral supplementation with Bifidobacteria infantis 35624 in healthy and IBS subjects. World Congress of Gastroenterology, Montreal, Canada September 2005.	
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				Critical Reviews	Quigley EMM & Flourie B. Probiotics and irritable bowel syndrome: a rationale for their use and an assessment of the evidence to date. Neurogastroenterol Motil (2006) Volume 19, Issue 3, March 2007, Pages 166-172 Quigley EMM. The use of probiotics in functional bowel disease. Gastroenterol Clin N Am 2005. 34:533-545. Picard, C., Fioramonti, J., Francois, A., Robinson, T., Neant, F., and Manuchansky, C. Review article: bifidobacteria as probiotic agents - physiological effects and clinical benefits. Alimentary Pharmacology and Therapeutics, 2005; 22 (6):495-512. Mitsuoka, T. Bifidobacteria and their role in human health. J Ind Microbiol 1990; 6: 263-8. Naidu A.S., W.R. Bidlack, and Clemens, R.A. Probiotic spectra of lactic acid bacteria. In Clydesdale, F.M. Critical Reviews in Food Science and Nutrition, 1999: 13-126. Arunachalam KD. Role of bifidobacteria in Nutrition, Medicine and Technology. Nutrition Research 1999; 19(10)1559-1597. Salminen, S., Gueimonde, M., and Isolauri, E.. Probiotics That Modify Disease Risk. Journal of Nutrition, 2005;135 (5):1294-1298. Reid G, Jass J, Sebulsky M and McCormick J. Potential uses of probiotics in clinical practice, Clin Microbiol Rev, 2003; 16(4): 658-672. Orrhage K and Nord CE. Bifidobacteria and Lactobacilli in human health. Drugs Exptl. Clin. Res., 2000; XXVI: 95-111.	

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		Promotion of healthy digestion	At least 1 x 107 CFU daily			831

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					Nutrition, 2000; 130:396S-402S. Shanahan F. The host-microbe interface within the gut. Best Pract Res Clin Gastroenterol, 2002; 16(6):915-31.	
		Optimal Digestive Balance	At least 1 x 107 CFU daily	Human Intervention Studies - Randomized Controlled Trials	O'Mahony, L., J. McCarthy, P. Kelly, G. Hurley, F. Luo, K. Chen, G. O'Sullivan, B. Kiely, J.K. Collins, F. Shanahan and E.M.M. Quigley. 2005. Lactobacillus and Bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles. Gastroenterology 2005. 128: 541-551. Whorwell PJ, Altringer L, Morel J, Bond Y, Charbonneau D, O'Mahony L, Kiely B, Shanahan F, Quigley EM. Efficacy of an encapsulated probiotic Bifidobacterium infantis 35624 in women with irritable bowel syndrome. Am J Gastroenter 2006 Jul;101(7):1581-90.	829
				Human Intervention Studies - Physiologic	Chen K, Luo F, Hendrix S, Altringer L, Charbonnneau D, Poehner R, Carryl O, Trowbridge M, O'Mahony L, Shanahan F, Quigley E. Modulation of cytokine profiles in healthy and IBS subjects following supplementation with the unique probiotic strain, Bifidobacterium infantis 35624 Gastroenterology 2005; 128: A-661 (Abstract W1674) Charbonneau DL, Altringer LA, Carryl OR, Chen KS, Kidd KJ, Darcy T, Fawcett DH, Trowbridge MM, Jang C, Luo F, Poehner RD, Meller ST Fecal flora effects following oral supplementation with Bifidobacteria infantis 35624 in healthy and IBS subjects. World Congress of Gastroenterology, Montreal, Canada September 2005.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Probiotic mechanism of action - in vitro studies	O'Mahony L, O'Callaghan L, McCarthy J, Shilling D, Kavanagh E, Kirwan W, Redmond H, Collins J, Shanahan F. Differential cytokine response from dendritic cells to commensal and pathogenic bacteria in different lymphoid compartments in humans. AJP - GI 290:839-845, 2006.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Critical reviews	Quigley EMM & Flourie B. Probiotics and irritable bowel syndrome: a rationale for their use and an assessment of the evidence to date. Neurogastroenterol Motil (2006) Volume 19, Issue 3, March 2007, Pages 166-172 Quigley EMM. The use of probiotics in functional bowel disease. Gastroenterol Clin N Am 2005. 34:533-545. Picard, C., Fioramonti, J., Francois, A., Robinson, T., Neant, F., and Manuchansky, C. Review article: bifidobacteria as probiotic agents - physiological effects and clinical benefits. Alimentary Pharmacology and Therapeutics, 2005; 22 (6):495-512. Mitsuoka, T. Bifidobacteria and their role in human health. J Ind Microbiol 1990; 6: 263-8. Naidu A.S., W.R. Bidlack, and Clemens, R.A. Probiotic spectra of lactic acid bacteria. In Clydesdale, F.M. Critical Reviews in Food Science and Nutrition, 1999: 13-126. Arunachalam KD. Role of bifidobacteria in Nutrition, Medicine and Technology. Nutrition Research 1999; 19(10)1559-1597. Salminen, S., Gueimonde, M., and Isolauri, E.. Probiotics That Modify Disease Risk. Journal of Nutrition, 2005;135 (5):1294-1298. Reid G, Jass J, Sebulsky M and McCormick J. Potential uses of probiotics in clinical practice, Clin Microbiol Rev, 2003; 16(4): 658-672. Orrhage K and Nord CE. Bifidobacteria and Lactobacilli in human health. Drugs Exptl. Clin. Res., 2000; XXVI: 95-111.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Dunne C. Adaptation of bacteria to the intestinal niche: Probiotics and gut disorder. Inflamm Bowel Dis 2001;7:136-145. Rolfe RD. The role of probiotic cultures in the control of gastrointestinal health. Journal of Nutrition, 2000; 130:396S-402S. King TS, Elia M, and Hunter JO. Abnormal colonic fermentation in irritable bowel syndrome. The Lancet 352, 1998: 1187-1189.	
		Promotes improved Intestinal transit	At least 1 x 107 CFU daily	Human Intervention Studies - Randomized Controlled Trials	O'Mahony, L., J. McCarthy, P. Kelly, G. Hurley, F. Luo, K. Chen, G. O'Sullivan, B. Kiely, J.K. Collins, F. Shanahan and E.M.M. Quigley. 2005. Lactobacillus and Bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles. Gastroenterology 2005. 128: 541-551. Whorwell PJ, Altringer L, Morel J, Bond Y, Charbonneau D, O'Mahony L, Kiely B, Shanahan F, Quigley EM. Efficacy of an encapsulated probiotic Bifidobacterium infantis 35624 in women with irritable bowel syndrome. Am J Gastroenter 2006 Jul;101(7):1581-90.	836

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				Probiotic functionality - critical reviews	Quigley EMM & Flourie B. Probiotics and irritable bowel syndrome: a rationale for their use and an assessment of the evidence to date. Neurogastroenterol Motil (2006) Volume 19, Issue 3, March 2007, Pages 166-172 Quigley EMM. The use of probiotics in functional bowel disease. Gastroenterol Clin N Am 2005. 34:533-545. Picard, C., Fioramonti, J., Francois, A., Robinson, T., Neant, F., and Manuchansky, C. Review article: bifidobacteria as probiotic agents - physiological effects and clinical benefits. Alimentary Pharmacology and Therapeutics, 2005; 22 (6):495-512. Mitsuoka, T. Bifidobacteria and their role in human health. J Ind Microbiol 1990; 6: 263-8. Naidu A.S., W.R. Bidlack, and Clemens, R.A. Probiotic spectra of lactic acid bacteria. In Clydesdale, F.M. Critical Reviews in Food Science and Nutrition, 1999: 13-126. Arunachalam KD. Role of bifidobacteria in Nutrition, Medicine and Technology. Nutrition Research 1999; 19(10)1559-1597. Verdu E., Collins S. Irritable bowel syndrome. Best Practice & Research Clinical Gastroenterology, 2004; 18 (2): 315-321. Mombelli B. and Gismondo, M.R.. The use of probiotics in medical practice. International Journal of Antimicrobial Agents, 2000; 16 (4):531-536. Shanahan F. The host-microbe interface within the gut. Best Pract Res Clin Gastroenterol,	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					2002; 16(6):915-31.	
		Digestive Balance to promote overall Well Being	At least 1 x 107 CFU daily	Randomized Controlled Trials	O'Mahony, L., J. McCarthy, P. Kelly, G. Hurley, F. Luo, K. Chen, G. O'Sullivan, B. Kiely, J.K. Collins, F. Shanahan and E.M.M. Quigley. 2005. Lactobacillus and Bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles. Gastroenterology 2005. 128: 541-551. Whorwell PJ, Altringer L, Morel J, Bond Y, Charbonneau D, O'Mahony L, Kiely B, Shanahan F, Quigley EM. Efficacy of an encapsulated probiotic Bifidobacterium infantis 35624 in women with irritable bowel syndrome. Am J Gastroenter 2006 Jul;101(7):1581-90.	828
				Human Intervention Studies - Physiologic	Chen K, Luo F, Hendrix S, Altringer L, Charbonnneau D, Poehner R, Carryl O, Trowbridge M, O'Mahony L, Shanahan F, Quigley E. Modulation of cytokine profiles in healthy and IBS subjects following supplementation with the unique probiotic strain, Bifidobacterium infantis 35624 Gastroenterology 2005; 128: A-661 (Abstract W1674) Charbonneau DL, Altringer LA, Carryl OR, Chen KS, Kidd KJ, Darcy T, Fawcett DH, Trowbridge MM, Jang C, Luo F, Poehner RD, Meller ST Fecal flora effects following oral supplementation with Bifidobacteria infantis 35624 in healthy and IBS subjects. World Congress of Gastroenterology, Montreal, Canada September 2005.	

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Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium lactis					
		Digestive health	Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 10 million bacteria per	Clinical trial Healthy infants	Weizman Z et al., Pediatrics 2005 Jan; 115(1):5-9	2,284
		Immune support and Immune health	Probiotic (when administered in			2,281

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 10 million bacteria per	Clinical trial Human with Atopic dermatitis Clinical trial Healthy infants Clinical trial Healthy infants	Yim et al., J Microbiol. Biotechnol., 2006; 16(11): 1699-1705 Weizman Z et al., Pediatrics 2005 Jan; 115(1):5-9 Saaveda JM et al., Am J Clin Nut 2004 Feb; 79(2):261-7 Matsumoto M et al., Biosci Biotech Biochem 2006, 70(6):1287-92	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium lactis B420					
		Gut health	10^9 CFU/day	Textbook Review Human clinical study	Textbook: Shils, Shike et al. (2005) Modern nutrition in health and disease. Lippincott, Williams & Wilkins (LWW) Reviews: Naidu, A.S:, Bidlack, W.R. et al. (1999) Probiotic spectra of lactic acid bacteria (LAB) Crit Rev Food Sci Nutr 39(1): 13-126 Roberfroid, M.B. (2000) Prebiotics and probiotics: are they functional foods? Am J Clin Nutr 71 (6 suppl) 1682S-7S; discussion 1688S-90S. Human studies Ouwehand,A.C., Nurminen,P., Mäkivuokko,H., Rautonen,N., 2006. Effect of Bifidobacterium lactis 420 on microbiota and immune function. Ital. J. Food Sci. 18, 1-5. Casiraghi,M.C., Canzi,E., Zanchi,R., Donati,E., Villa,L., 2007. Effects of a synbiotic milk product on human intestinal ecosystem. J Appl. Microbiol. 103, 499-506.	2,517

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium lactis HNO19 (AGAL NM97/09513					
		Gut health	10^9 CFU/day			2,515

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				ndividual study (human intervention) Review article	Reviews: Gill, H. S. 1999. Potential of using dietary lactic acid bacteria for enhancement of immunity. Dialogue 32:6-11 Ouwehand, A. C., and S. Philipp. 2004. Bifidobacterium lactis HN019; the good taste of health. Agrofood Ind. Hi-Tech 15:10-12. Sanders, M. E. 2006. Summary of probiotic activities of Bifidobacterium lactis HN019. J Clin Gastroenterol. 40:776-783 Shu, Q., F. Qu, H. Lin, K. Rutherfurd, J. Zhou, and H. Gill. 1999. Bifidobacterium lactis HN019 enhances host immunity and resistance to gastrointestinal pathogens. In Tuijtelaars, Samson, Rombouts, and Notermans (eds.), Food microbiology and food safety into the next millenium. Foundation Food Micro '99, Wageningen, the Netherlands. p. 858-861 Individual Human Studies Arunachalam, K., H. S. Gill, and R. K. Chandra. 2000. Enhancement of natural immune function by dietary consumption of Bifidobacterium lactis (HN019). Eur. J. Clin. Nutr. 54:263-267. Chiang, B. L., Y. H. Sheih, L. H. Wang, C. K. Liao, H. S. Gill. 2000. Enhancing immunity by dietary consumption of a probiotic lactic acid bacterium (Bifidobacterium lactis HN019): optimisation and definition of cellular immune responses. Eur. J. Clin. Nutr. 54:849-855. Gill, H. S., K. J. Rutherfurd, and M. L. Cross. 2001. Dietary probiotic supplementation enhances natural killer cell activity in the elderly: an investigation of age-related immunological changes. J. Clin. Immunol. 21:264-271. Gill, H. S., K. J. Rutherfurd, , M. L. Cross, and P. K. Gopal. 2001. Enhancement of immunity in the elderly by dietary supplementation with the probiotic Bifidobacterium lactis HN019. Am. J. Clin. Nutr. 74:833-839.	

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					Gopal, P. K., J. Prasad, and H. S. Gill. 2003. Effects of the consumption of Bifidobacterium lactis HN019 (DR10TM) and galacto-oligosaccharides on the microflora of the gastrointestinal tract in human subjects. Nutr. Res. 23:1313-1328. Sazawal, S., U. Dhingra, A. Sarkar, P. Dhingra, S. Deb, D. Marwah, V. P. Menon, J. Kumar, and R.E. Black. 2004. Efficacy of milk fortified with a probiotic Bifidobacterium lactis (DR-10TM) and prebiotic galacto-oligosaccharides in prevention of morbidity and on nutritional status. Asia Pac. J. Clin. Nutr. 13:S28. Sistek, D., R. Kelly, K. Wickens, T. Stanley, P. Fitzharris, and J. Crane. 2006. Is the effect of probiotics on atopic dermatitis confined to food sensitized children? Clin. Exp. Allergy 36:629-633	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Animal and In vitro studies: Gill, H. S., K. J. Rutherfurd, J. Prasad, and P. K. Gopal. 2000. Enhancement of natural and acquired immunity by Lactobacillus rhamnosus (HN001), Lactobacillus acidophilus (HN017) and Bifidobacterium lactis (HN019). Br. J. Nutr. 83:167-176. Gopal, P. K., P. A. Sullivan, and B. J. Smart. 2001. Utilisation of galacto-oligosaccharides as selective substrates for growth by lactic acid bacteria including Bifidobacterium lactis DR10 and Lactobacillus rhamnosus DR20. Int. Dairy Journal 11:19-25 Gopal, P. K., J. Prasad, J. Smart, and H. S. Gill. 2001. In vitro adherence properties of Lactobacillus rhamnosus DR20 and Bifidobacterium lactis DR10 strains and their antagonistic activity against an enterotoxigenic Escherichia coli. Int. J. Food Microbiol. 67:207-216 Prasad, J., H. S. Gill, J. Smart, and P. K. Gopal. 1998. Selection and characterisation of Lactobacillus and Bifidobacterium strains for use as probiotics. Int. Dairy J. 8:993-1002 Shu, Q., J. S. Zhou, K. J. Rutherfurd, M. J. Britles, J. Prasad, P. K. Gopal, and H. S. Gill. 1999. Probiotic lactic acid bacteria (Lactobacillus acidophilus HN017, Lactobacillus rhamnosus HN001 and Bifidobacterium lactis HN019) have no adverse effects on the health of mice. Int. Dairy J. 9:831-836. Shu, Q., L. Hai, K. J. Rutherfurd, S. G. Fenwick, J. Prasad, P. K. Gopal, and H. S. Gill. 2000. Dietary Bifidobacterium lactis (HN019) enhances resistance to oral Salmonella typhimurium infection in mice. Microbiol. Immunol. 44:213-222. Shu, Q. and H. S. Gill. 2001. A dietary probiotic (Bifidobacterium lactis HN019) reduces the severity of Escherichia coli O157:H7 infection in	

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Shu, Q., F. Qu, and H. S. Gill. 2001. Probiotic treatment using Bifidobacterium lactis HN019 reduces weanling diarrhea associated with rotavirus and Escherichia coli infection in a piglet model. J. Ped. Gastroenterol. Nutr. 33:171-177.
Zhou, J. S., Q. Shu, K. J. Rutherfurd, J. Prasad, P. K. Gopal, and H. S. Gill. 2000. Acute oral toxicity and bacterial translocation studies on potentially probiotic srains of lactic acid bacteria. Food Chem. Toxicol. 38:153-161.
Zhou, J. S., Q. Shu, K. J. Rutherfurd, J. Prasad, M. J. Britles, P. K. Gopal, and H. S. Gill. 2000. Safety assessment of potential probiotic lactic acid bacteria strains Lactobacillus rhamnosus HN001, Lb. acidophilus HN017, and Bifidobacterium lactis HN019 in BALB/c mice. Int. J. Food Microbiol. 56:87-96.
Zhou, J. S. and H. S. Gill. 2005. Immunostimulatory probiotic Lactobacillus rhamnosus HN001 and Bifidobacterium lactis HN019 do not induce pathological inflammation in mouse model of experimental autoimmune thyroiditis. Int. J. Food Microbiol. 103:97-104
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Zhou, J. S., C. J. Pillidge, P. K. Gopal, and H. S. Gill. 2005. Antibiotic susceptibility profiles of new probiotic Lactobacillus and Bifidobacterium strains. Int. J. Food Microbiol 98:211-217
Zhou, J. S., K. J. Rutherfurd, and H. S. Gill. 2005. Inability of probiotic bacterial strains Lactobacillus rhamnosus HN001 and

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					Bifidobacterium lactis HN019 to induce human platelet aggregation in vitro. J. Food Protection 68:2459-2464	

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	Bifidobacterium lactis HNO19 AGAL NM97/09513					
		Natural defence/immune system	at least 10[9] cfu/day			248

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual studies (human intervention studies animal studies and in vitro studies) Review articles	Reviews Gill, H. S. 1999. Potential of using dietary lactic acid bacteria for enhancement of immunity. Dialogue 32:6-11. Ouwehand, A. C., and S. Philipp. 2004. Bifidobacterium lactis HN019; the good taste of health. Agrofood Ind. Hi-Tech 15:10-12. Sanders, M. E. 2006. Summary of probiotic activities of Bifidobacterium lactis HN019. J Clin Gastroenterol. 40:776-783. Shu, Q., F. Qu, H. Lin, K. Rutherfurd, J. Zhou, and H. Gill. 1999. Bifidobacterium lactis HN019 enhances host immunity and resistance to gastrointestinal pathogens. In Tuijtelaars, Samson, Rombouts, and Notermans (eds.), Food microbiology and food safety into the next millenium. Foundation Food Micro '99, Wageningen, the Netherlands. p. 858-861. Individual Human Studies Arunachalam, K., H. S. Gill, and R. K. Chandra. 2000. Enhancement of natural immune function by dietary consumption of Bifidobacterium lactis (HN019). Eur. J. Clin. Nutr. 54:263-267. Chiang, B. L., Y. H. Sheih, L. H. Wang, C. K. Liao, H. S. Gill. 2000. Enhancing immunity by dietary consumption of a probiotic lactic acid bacterium (Bifidobacterium lactis HN019): optimisation and definition of cellular immune responses. Eur. J. Clin. Nutr. 54:849-855. Gill, H. S., K. J. Rutherfurd, and M. L. Cross. 2001. Dietary probiotic supplementation enhances natural killer cell activity in the elderly: an investigation of age-related immunological changes. J. Clin. Immunol. 21:264-271. Gill, H. S., K. J. Rutherfurd, , M. L. Cross, and P. K. Gopal. 2001. Enhancement of immunity in the elderly by dietary	

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Animal Studies

Gill, H. S., K. J. Rutherfurd, J. Prasad, and P. K. Gopal. 2000. Enhancement of natural and acquired immunity by Lactobacillus rhamnosus (HN001), Lactobacillus acidophilus (HN017) and Bifidobacterium lactis (HN019). Br. J. Nutr. 83:167-176.

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In Vitro Studies

Gopal, P. K., P. A. Sullivan, and B. J. Smart. 2001. Utilisation of galacto-oligosaccharides as selective substrates for growth by lactic acid bacteria including Bifidobacterium lactis DR10 and

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Prasad, J., H. S. Gill, J. Smart, and P. K. Gopal. 1998. Selection and characterisation of Lactobacillus and Bifidobacterium strains for use as probiotics. Int. Dairy J. 8:993-1002.

Zhou, J. S., P. K. Gopal, and H. S. Gill. 2001. Potential probiotic lactic acid bacteria Lactobacillus rhamnosus (HN001), Lactobacillus acidophilus (HN017) and Bifidobacterium lactis (HN019) do not degrade gastric mucin in vitro. Int. J. Food Microbiol 63:81-90.

Zhou, J. S., C. J. Pillidge, P. K. Gopal, and H. S. Gill. 2005. Antibiotic susceptibility profiles of new probiotic Lactobacillus and Bifidobacterium strains. Int. J. Food Microbiol 98:211-217.

Zhou, J. S., K. J. Rutherfurd, and H. S. Gill. 2005. Inability of probiotic bacterial strains Lactobacillus rhamnosus HN001 and Bifidobacterium lactis HN019 to induce human platelet aggregation in vitro. J. Food Protection 68:2459-2464.

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium longum					
		Beneficial effect on intestinal microflora, gut integrity, digestion	At least 107 cfu / day	Textbooks & peer reviewed journal articles	Elmer, GW. (2001). Probiotics: “living drugs”. Am J Health Syst Pharm. 2001 Jun 15;58(12):1101-9. Benno Y and Mitsuoka T. (1992). Impact of Bifidobacterium longum on human faecal microflora. Microbiol Immunol. 1992;36(7):683-94. Orrhage K, Sjostedt S and Nord CE. (2000). Effects of supplements with lactic acid bacteria and oligofructose on the intestinal microflora during administration of cefpodoxime proxetil. J Antimicrob Chemother. 2000 Oct;46(4):603-12. As listed by A Green	931
		Cholesterol control	Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their	Clinical trial Healthy humans and animals Clinical trial Healthy women	Xiao JZ et al., J Dairy Sci 2003, 86:2452-2461 Kiessling G et al., Eur J Clin Nut 2002 Sept, 56(9);843-9	2,310

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 10 million bacteria per portion/dose			
		Maintenance of healthy Immune system	At least 107 cfu / day			945

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks & peer reviewed journal articles	de Vrese M, Winkler P, Rautenberg P, Harder T, Noah C, Laue C, Ott S, Hampe J, Schreiber S, Heller K and 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. Clin Nutr. 2005 Aug;24(4):481-91. Epub 2005 Apr 21. Takahashi N, Kitazawa H, Iwabuchi N, Xiao JZ, Miyaji K, Iwatsuki K, Saito T. (2006). Oral administration of an immunostimulatory DNA sequence from Bifidobacterium longum improves Th1/Th2 balance in a murine model. Biosci Biotechnol Biochem. 2006 Aug;70(8):2013-7 Bai AP, Ouyang Q, Xiao XR, Li SF. (2006). Probiotics modulate inflammatory cytokine secretion from inflamed mucosa in active ulcerative colitis. Int J Clin Pract. 2006 Mar;60(3):284-8 Furrie E, Macfarlane S, Kennedy A, Cummings JH, Walsh SV, O'neil DA, Macfarlane GT. (2005). Synbiotic therapy (Bifidobacterium longum/Synergy 1) initiates resolution of inflammation in patients with active ulcerative colitis: a randomised controlled pilot trial. Gut. 2005 Feb;54(2):242-9. Silva AM, Barbosa FH, Duarte R, Vieira LQ, Arantes RM, Nicoli JR. (2004). Effect of Bifidobacterium longum ingestion on experimental salmonellosis in mice. J Appl Microbiol. 2004;97(1):29-37 Lee JW, Shin JG, Kim EH, Kang HE, Yim IB, Kim JY, Joo HG, Woo HJ. (2004). Immunomodulatory and antitumor effects in	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					vivo by the cytoplasmic fraction of Lactobacillus casei and Bifidobacterium longum. J Vet Sci. 2004 Mar;5(1):41-8	
		Lactose digestion	Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 10 million bacteria per portion/dose	Clinical trial Lactose malabsorbers	Tianan J et al., J Dairy Sci 1996 May; 79(5):750-7	2,311

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Digestive health,Digestive Balance	Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 10 million bacteria per portion/dose	-Overview of evidence Human trials Overview of evidence Human trials Human Trial IBS patients Clinical trial Healthy humans and animals Overview of evidence Human trials	-Overview of evidence Human trials Overview of evidence Human trials Human Trial IBS patients - Gomes AMP et al., Trends in Food Science & Technology 1999; 10: 139-157 Kailasapathy K et al., Immunology & Cell Biology 2000; 78(1):80-88 Colecchia A et al., Minerva Gastroenterol Dietol 2006; 52:349-58	2,309
		Contains Probiotic that confers a benefit on the host	At least 107 cfu / day			917

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	WHO definition of probiotic FAO/WHO (2001). Guidelines for the Evaluation of Probiotics in Food. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, April 30 and May 1, 2002. Gorbach SL and Goldin BR. (1992). Nutrition and the gastrointestinal microflora. Nutr Rev. 1992 Dec;50(12):378-81 Rolfe, RD. (2000). The role of probiotic cultures in the control of gastrointestinal health. J Nutr. Feb;130(2S Suppl): 396S-402S. Fuller, R and Perdigon, G. (2003). Gut flora, nutrition, immunity and Health. Edited by R Fuller and G Perdigon. Blackwell Publishing.	
		Immune support	Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the	Clinical trial Patients with allergies	Xiao JZ et al., J Investig Allergol Clin Immunol 2006, 16(2).86-93	2,312

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 10 million bacteria per portion/dose			

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Bifidobacterium longum I-3470					
		Immune defenses / support of immunity	at least 1x10[9] cfu/day	Human studies	Individual Human Studies Benno Y, Mitsuoka T. Impact of Bifidobacterium longum on human fecal microflora. Microbiol Immunol. 1992;36(7):683-94. Xiao JZ, Kondo S, Yanagisawa N, Takahashi N, Odamaki T, Iwabuchi N, Iwatsuki K, Kokubo S, Togashi H, Enomoto K, Enomoto T. Effect of probiotic Bifidobacterium longum BB536 [corrected] in relieving clinical symptoms and modulating plasma cytokine levels of Japanese cedar pollinosis during the pollen season. A randomized double-blind, placebo-controlled trial. J Investig Allergol Clin Immunol. 2006;16(2):86-93.	249
		Digestive health	at least 1x10[9] cfu/day	Individual human Study	-Haskey N, Dahl W. Synbiotic therapy: A promissing new adjunctive therapy for ulcerative colitis. Nutrition review 2006, 64(3): 132-138	215
				Additional Human Studies	-Benno Y, Mitsuoka T. Impact of Bifidobacterium longum on human fecal microflora. Microbiol Immunol. 1992;36(7):683-94.	
				Additional Human Studies	-Colecchia A, Vestito A, La Rocca A, Pasqui F, Nikiforaki A, Festi D. Effect of a symbiotic preparation on the clinical manifestations of irritable bowel syndrome, constipation-variant. Results of an open, uncontrolled multicenter study. Minerva Gastroenterol Dietol. 2006 Dec;52(4):349-58.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Additional Human Studies	-Puccio G, Cajozzo C, Meli F, Rochat F, Grathwohl D, Steenhout P. Clinical evaluation of a new starter formula for infants containing live Bifidobacterium longum BL999 and prebiotics. Nutrition. 2007 Jan;23(1):1-8	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus acidophilus					
		Restoration/ maintenance of beneficial gut flora following antibiotic treatment	At least 107 cfu / day	Peer reviewed journal article.	Jernberg, C, Sullivan, A, Edlund, C and Jansson, JK. (2005). Monitoring of Antibiotic-Induced Alterations in the Human Intestinal Microflora and Detection of Probiotic Strains by Use of Terminal Restriction Fragment Length Polymorphism. Applied and Environmental Microbiology, p. 501-506, Vol. 71, No. 1.	949
		Beneficial effect on intestinal microflora, gut integrity, digestion	At least 107 cfu / day			922

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks & peer reviewed journal articles	Gotz, V, Romankiewicz, JA, MossJ and Murrary, HW. (1979). Prophylaxis against ampicillin-associated diarrhea with a Lactobacillus preparation. Am J Hosp Pharm. 36: 754-757. Kirkman, MF and Cedgard, L. (2002) The Digestive Contract. Intestinal Microbiology and Probiotics. Bio Pathica Ltd. Bernet MF, Brassart D, Neeser JR, Servin AL. (1994). Lactobacillus acidophilus binds to cultured human intestinal cell lines and inhibits cell attachment and cell invasion by enterovirulent bacteria; Gut 1994;35:438-489 Sullivan, A., L. Barkholt, and C. E. Nord. (2003). Lactobacillus acidophilus, Bifidobacterium lactis and Lactobacillus F19 prevent antibiotic-associated ecological disturbances of Bacteroides fragilis in the intestine. J. Antimicrob. Chemother. 52:308-311. Sazawal S, Hiremath G, Dhingra U, Malik P, Deb S, Black RE. (2006). Efficacy of probiotics in prevention of acute diarrhoea: a meta-analysis of masked, randomized placebo controlled trials; Lancet Infect Dis 2006 Jun (6): 374-82 Kim HS and Gilland SE (1983). Lactobacillus acidophilus as a dietary adjunct ofr milk to aid lactose digestion in humans; J Dairy Sci 1983 May; 66 (5): 959-66 Plummer SF, Garaiova I, Sarvotham T, Cottrell SL, Le Scouiller S, Weaver MA, Tang J, Dee P, Hunter J. (2005). Effects of probiotics on the composition of the intestinal microbiota	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					following antibiotic therapy; Int J Antimicrob Agents 26 (2005) 69-74	
		Maintenance of healthy Immune system	At least 107 cfu / day	Textbooks & peer reviewed journal articles	PDR (Physician's Desk Reference) For Nutritional Supplements (2001) Sheldon Saul Hendler and David Rorvik (Eds); Montvale NJ; Medical Economics Company. Babinska I, Rotkiewicz T, Otrocka-Domagala I. (2005). The effect of Lactobacillus acidophilus and Bifidobacterium spp. administration on the morphology of the gastrointestinal tract, liver and pancreas in piglets. : Pol J Vet Sci. 2005;8(1):29-35. Lee JW, Shin JG, Kim EH, Kang HE, Yim IB, Kim JY, Joo HG, Woo HJ. (2004). Immunomodulatory and antitumor effects in vivo by the cytoplasmic fraction of Lactobacillus casei and Bifidobacterium longum. J Vet Sci. 2004 Mar;5(1):41-8 As listed by A Green	936
		Digestive health	Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may	Overview of evidence Human trials	Gomes AMP et al., Trends in Food Science & Technology 1999; 10: 139-157	2,317

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 10 million bacteria per portion/dose			
		Contains Probiotic that confers a benefit on the host	At least 107 cfu / day	Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	WHO definition of probiotic FAO/WHO (2001). Guidelines for the Evaluation of Probiotics in Food. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, April 30 and May 1, 2002. Gorbach SL and Goldin BR. (1992). Nutrition and the gastrointestinal microflora. Nutr Rev. 1992 Dec;50(12):378-81 Rolfe, RD. (2000). The role of probiotic cultures in the control of gastrointestinal health. J Nutr. Feb;130(2S Suppl): 396S-402S. Fuller, R and Perdigon, G. (2003). Gut flora, nutrition, immunity and Health. Edited by R Fuller and G Perdigon. Blackwell Publishing.	908

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Cholesterol control	Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 10 million bacteria per portion/dose	Clinical trial Healthy women	Kiessling G et al., Eur J Clin Nut 2002 Sept, 56(9);843-9	2,321
		Hypocholesterolemic action	Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host)	Overview of evidence Animal trials	Gomes AMP et al., Trends in Food Science & Technology 1999; 10: 139-157	2,320

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 10 million bacteria per portion/dose			

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	-Lactobacillus acidophilus					
		Immune support	Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 10 million bacteria per portion/dose	Review article Human studies National Institute of Health Public Access Manuscript Overview of evidence Human trials	Roberfroid MB Am J Clin Nutr 2000;(71 suppl):1682S-7S Brown AC et al., Nutr Clin Care 2004;7(2): 56-68 Gomes AMP et al., Trends in Food Science & Technology 1999; 10: 139-157	2,283

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus acidophilus (ATCC SD5221) & Bifidobacterium lactis ATCC SD5220					
		Natural defence/immune system	minimum of 5x10^9 CFU/day of each strain	Human clinical study review articles	Textbook Shils, Shike et al. (2005) Modern nutrition in health and disease. Lippincott, Williams & Wilkins (LWW) Reviews Naidu, A.S:, Bidlack, W.R. et al. (1999) Probiotic spectra of lactic acid bacteria (LAB) Crit Rev Food Sci Nutr 39(1): 13-126 Roberfroid, M.B. (2000) Prebiotics and probiotics: are they functional foods? Am J Clin Nutr 71 (6 suppl) 1682S-7S; discussion 1688S-90S. Individual Human Study Ouwehand, A.C., Li, S., Mubasher, M. & Leyer, G. Probiotics reduce symptoms of respiratory tract infection (Submitted for publication) Ouwehand, A.C., Carcano, D., Li, S., Leyer, G. (2007) Probiotics reduce incidence and duration of respiratory tract infection symptoms in 3-5 year old children. Cibus 3(2):60	2,516

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus acidophilus CNCM I-1722					
		Digestive health	at least 10[9] cfu/day daily intake	Nutrition Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000.	216
				Nutrition	Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
				Textbook	-Shils, Shike, et al. (2005). Modern Nutrition in Health and Disease. Lippincott Williams & Wilkins (LWW).	
				Reviews	-Naidu, A. S., W. R. Bidlack, et al. (1999). "Probiotic spectra of lactic acid bacteria (LAB)." Crit Rev Food Sci Nutr 39(1): 13-126.	
				Reviews	-Roberfroid, M. B. (2000). "Prebiotics and probiotics: are they functional foods?" Am J Clin Nutr 71(6 Suppl): 1682S-7S; discussion 1688S-90S.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus acidophilus CUL21 NCIMB 30156 Lactobacilus acidophilus CUL 60 NCIMB 30157 Bifibobacterium adolescentis CUL 17 NCIMB 30153 Bifidobacterium lactis (animalis ssp. lactis) CUL 34 NCIMB 30172					
		Gut flora	at least 2.4x10[10] cfu/day	Individual Human Studies	-Can Probiotics play a role in antibiotic resistance? 2nd International Symposium Resistant Gram-Positive Infections 2004, December 10-12, Berlin, Germany. Peer reviewed abstract.	217
				Individual Human Studies	-Madden JAJ, Plummer SF, Tang J, Garaiova I, Plummer NT, Herbison M, Hunter JO, Shimada T, Cheng L, Shirakawa T. Effect of probiotics on preventing disruption of the intestinal microflora following antibiotic therapy: A double blind, placebo controlled pilot study. International Immunopharmacology 2005; 5: 1091-1097	
				Individual Human Studies	-Plummer SF, Garaiova I, Sarvotham T, Cottrell SL, Le Scouiller S, Weaver MA, Tang J, Dee P, Hunter J. Effects of Probiotics on the composition of the intestinal microbiota following antibiotic therapy. International Journal of Antimicrobial Agents 2005; 26: 69-74.	
				Individual Human Studies	-Plummer S, Garaiova I, Cottrell S, Weaver M, Sarvotham T, Tang J, Dee P, Hunter J.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Human Studies	-Plummer S, Cottrell SL, Weaver MA, Garaiova I, Sarvotham T, Tang J, Dee P, Hunter J. The Potential Role of combined Antibiotic and Probiotic Therapy. 44th Interscience Conference on Antimicrobial Agents and Chemotherapy 2004, October 30th- November 2nd, Washington, USA. Peer reviewed abstract.	
		Natural defence and support of the immune system	at least 2.4x10[10] cfu/day	Human studies (double blind placebo controlled randomised studies)	Individual Human Studies Plummer S, Weaver MA, Harris JC, Dee P, Hunter J. Clostridium difficile pilot study: effects of probiotic supplementation on the incidence of C. difficile diarrhoea. International Microbiology 2004;7:59-62. Plummer SF, Garaiova I, Sarvotham T, Cottrell SL, Le Scouiller S, Weaver MA, Tang J, Dee P, Hunter J. Effects of Probiotics on the composition of the intestinal microbiota following antibiotic therapy. International Journal of Antimicrobial Agents 2005; 26: 69-74.	250

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus acidophilus CUL21 NCIMB 30156 Lactobacillus acidophilus CUL60 NCIMB 30157 Bifidobacterium adolescentis (bifidum) CUL 20 NCIMB 30153 Bifidobacterium lactis (animalis ssp. Lactis) CUL34 NCIMB 30172					
		Gut Flora	At least 2.4x10^10cfu/day	Human Studies (Double Blind Placebo Controlled Randomised Studies), in vitro studies	Plummer S, et al. Can probiotics play a role in antibiotic resistance? 2nd International Symposium Resistant Gram-positive infections, December 10-12 Berlin, Germany. Peer reviewed abstract (2004) Madden JAJ et al. Effect of probiotics on preventing disruption of the intestinal microflora following antibiotic therapy: A double blind, placebo controlled pilot study. International Immunopharmacology, 5, 1091-1097 (2005) Plummer S et al. Effects of probiotics on the composition of the intestinal microbiota following antibiotic therapy. International Journal of Antimicrobial Agents, 26, 69-74 (2005) Plummer S et al. The potential role of combined antibiotic and probiotic therapy. 44th Interscience Conference on Antimicrobial Agenst and Chemotherapy, October 30th – November 2nd Washinghton, USA. Peer reviewed abstract (2004).	981
		Natural defence and support of the Immune System	At least 2.4x10^10cfu/day			982

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human Studies (Double Blind Placebo Controlled Randomised Studies), in vitro studies	Plummer S et al. Effects of probiotics on the composition of the intestinal microbiota following antibiotic therapy. International Journal of Antimicrobial Agents, 26, 69-74 (2005) Plummer S et al. Clostridium difficile pilot study: effects of probiotic supplementation on the incidence of C. difficile diarrhoea. International Microbiology, 7, 59-62 (2004).	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus acidophilus LA-5®					
		Vaginal health/flora	at least 10E10 cfu/day			732

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Peer-reviewed scientific papers	Human studies: # 151 Hilton, E., Isenburg, H.D., Alpenstein, P., France, K., Borenstein, M. Ingestion of yogurt containing Lactobacillus acidophilus as prophylaxis for candidal vaginitis. 1992. Annals of Internal Medicine, 116:353-357. Animal studies: In vitro studies: #386: Ouwehand, A.C., Tolkko, S., Kulmala, J., Salminen, S., Salminen, E. Adhesion of inactivated probiotic strains to intestinal mucus. 2000. Letters in Applied Microbiology, 31: 82-86. #414: . C.N. Jacobsen, V Rosenfeldt Nielsen, A.E. Hayford, P.L. Møller, K.F. Michaelsen, A. Pærregaard, B. Sandström, M. Tvede and M. Jakobsen. 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, 1999: 65: 4949-4956.# 432: Jiang T, Savaiano DA. 1997. In vitro lactose fermentation by human bacteria is modified by Lactobacillus acidophilus supplementation. J. Nutri. 127, 1489-1495. #458: Apostolou E, Kirjavainen PV, Saxelin M, Rautelin H, Valtonen V, Salminen S, Ouwehand AC. Good adhesion properties of probiotics: a potential risk for bacteremia? FEMS Immunology and Medical Microbiology 2001. 31; 35-39. #464: Ouwehand, A.C., R. Parhiala, S. Salminen, A. Rantala, Heikki Huhtinen, H. Sarparanta, E. Salminen. 2004. Influence of the endogenous mucosal microbiota on the adhesion of probiotic bacteria in vitro. Microbial Ecology in Health and Disease. 16: 202-204..	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					#486: Ding W, Wang H, Griffiths MW. 2005. Probiotics down-regulate flaA ó28 promotor in Campylobacter jejuni.J. Food Prot. 68 (11): 2295-2300. #493: Schillinger U, Guigas C, Holzapfel WH. 2005. in vitro adherence and other properties of lactobacilli used in probiotic yoghurt-like products. International Dairy Journal 15: 1289-1297.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus acidophilus Lafti L10 (CBS 116.411)					
		Natural defence / immune system	at least 2x10[10] cfu/day	Human studies Animal studies	Individual Human Studies Clancy RL et al. (2005) Reversal of reduced interferon-g secretion on fatigued athletes following consumption of LAFTI L10 (Lactobacillus acidophilus) Br J Sports Med 40: 351-354. Animal Studies Elahi et al. (2005) Enhanced clearance of Candida albicans from the oral cavities of mice following oral administration of Lactobacillus acidophilus Clinical and Experimental Immunology 141:29-36. 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.	251
		Digestive health	at least 5x10[9] cfu/day	Animal Studies	-Elahi et al. (2005) Enhanced clearance of Candida albicans from the oral cavities of mice following oral administration of Lactobacillus acidophilus Clinical and Experimental Immunology 141:29-36	218
				Animal Studies	-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.	
		Intestinal flora	at least 5x10[9] cfu/day	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	219

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus acidophilus NCFM ATCC SD5221					
		Gut health	at least 10[9] cfu/day	Reviews	-Sanders, M. E. and T. R. Klaenhammer. 2001. Invited Review: The scientific basis of Lactobacillus acidophilus NCFM functionality as a probiotic. J. Dairy Sci. 84:319-331.	220
				Individual Human Studies	-Goldin, B. R., L. Swenson, J. Dwyer, M. Sexton, and S. L. Gorbach. 1980. Effect of diet and Lactobacillus acidophilus supplements on human fecal bacterial enzymes. J. Natl. Cancer Instit. 64:255-261.	
				Individual Human Studies	-Goldin, B. R. and S. L. Gorbach. 1984. The effect of milk and lactobacillus feeding on human intestinal bacterial enzyme activity. Amer. J. Clin. Nutr. 39:756-761.	
				Individual Human Studies	-Goldin, B. R. and S. L. Gorbach. 1984. The effect of oral administration of Lactobacillus and antibiotics on intestinal bacterial activity and chemical induction of large bowel tumors. Dev. Indus. Microbiol. 25:139-150.	
				Individual Human Studies	-Kim H. S., and S. E. Gilliland. 1983. Lactobacillus acidophilus as a dietary adjunct for milk to aid lactose digestion in humans. J. Dairy Sci. 66:959-966.	
				Individual Human Studies	-Lin, M-Y. D. Savaiano, and S. Harlander. 1991. Influence of nonfermented dairy products containing bacterial starter cultures on lactose maldigestion in humans. J. Dairy Sci. 74:87-95.	
				Individual Human Studies	-Newcomer, A. D., H. S. Park, P. C. O'Brien, and D. B. McGill. 1983. Response of patients with irritable bowel syndrome and lactase deficiency using unfermented acidophilus milk. Amer. J. Clin. Nutr. 38:257-263.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Human Studies	-Savaiano, D. A., A. AbouElAnouar, D. E. Smith, and M. D. Lewitt. 1984. Lactose malabsorbtion from yoghurt, pasteurized yogurt, sweet acidophilus milk, and cultured milk in lactase-deficient individuals. Amer. J. Clin. Nutr. 40:1219-1223.	
				Individual Human Studies	-Sui, J., Leighton, S., Busta, F., Brady, L. 2002. 16S ribosomal DNA analysis of the faecal lactobacilli composition of human subjects consuming a probiotic strain Lactobacillus acidophilus NCFM. J. Appl. Microb. 93:907-912.	
				Additional Human Studies	-Dunn, S. R., M. L. Simenhoff, K. E. Ahmed, W. J. Gaughan, B. O. Eltayeb, M.-E. D. Fitzpatrick, S. M. Emery, J. W. Ayres, and K. E. Holt. 1998. Effect of oral administration of freeze-dried Lactobacillus acidophilus on small bowel bacterial overgrowth in patients with end stage kidney disease: reducing uremic toxins and improving nutrition. Int. Dairy J. 8:545-553.	
				Additional Human Studies	- Montes, R. G., T. M. Bayless, J. M. Saavedra, and J. A. Perman. 1995. Effect of milks inoculated with Lactobacillus acidophilus or a yogurt starter culture in lactose-maldigesting children. J. Dairy Sci. 78:1657-1664.	
				Additional Human Studies	- Simenhoff, M. L., S. R. Dunn, G. P. Zollner, M.-E. D. Fitzpatrick, S. M. Emery, W. E. Sandine, and J. W. Ayres. 1996. Biomodulation of the toxic and nutritional effects of small bowel bacterial overgrowth in end-stage kidney disease using freeze-dried Lactobacillus acidophilus. Mineral Electrolyte Metab. 22:92-96.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				In vitro Studies	- Daniel, C., S. Poiret, D. Goudencourt, V. Dennin, G. Leyer, and B. Pot. 2006. Selecting lactic acid bacteria for their safety and functionality by use of a mouse colitis model. Appl. Environ. Microbiol. 72 :5799-5805	
				In vitro Studies	- Foligne, B., S. Nutten, C. Grangette, V. Dennin, D. Goudercourt, S. Poiret, J. Dewulf, D. Brassard, A. Mercenier, and B. Pot. Correlation between in vitro and in vivo immunomodulatory properties of lactic acid bacteria. World J. Gastroenterology. 13:236-243	
				In vitro Studies	- Goldin, B. R. and S. L. Gorbach. 1977. Alterations in fecal microflora enzymes related to diet, age, lactobacillus supplements, and dimethylhydrazine. Cancer 40:2421-2426.	
				In vitro Studies	- Goldin, B. R. and S. L. Gorbach. 1980. Effect of Lactobacillus acidophilus dietary supplements on 1,2-dimethylhydrazine dihydrochloride-induced intestinal cancer in rats. J. Nat. Cancer Instit. 64:263-265.	
				In vitro Studies	- Goldin, B. R. and S. L. Gorbach. 1984. Alterations of the intestinal microflora by diet, oral antibiotics, and Lactobacillus: decreased production of free amines from aromatic nitro compounds, azo dyes, and glucuronides. J. Nat. Cancer Instit. 73:689-695.	
				In vitro Studies	- Goldin, B. R. and S. L. Gorbach. 1984. The effect of oral administration of Lactobacillus and antibiotics on intestinal bacterial activity and chemical induction of large bowel tumors. Dev. Indus. Microbiol. 25:139-150.	
				In vitro Studies	- Rao, C. V., M. E. Sanders, C. Indranie, B. Simi, and B. S. Reddy. 1999. Prevention of colonic preneoplastic lesions by the probiotic Lactobacillus acidophilus NCFMTM in F344 rats. Int. J. Oncol. 14:939-944.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				In vitro Studies	- Varcoe, J. J., G. Krejcarek, F. Busta, and L. Brady. 2003. Prophylactic feeding of Lactobacillus acidophilus NCFM to mice attenuates overt colonic hyperplasia. J. Food Prot. 66:457-65.	
		Natural resistance/defence	at least 10[9] cfu/day			252

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual studies (human intervention and animal studies) Review article	Review Sanders, M. E. and T. R. Klaenhammer. 2001. Invited Review: The scientific basis of Lactobacillus acidophilus NCFM functionality as a probiotic. J. Dairy Sci. 84:319-331. Individual Human Studies Goldin, B. R., L. Swenson, J. Dwyer, M. Sexton, and S. L. Gorbach. 1980. Effect of diet and Lactobacillus acidophilus supplements on human fecal bacterial enzymes. J. Natl. Cancer Instit. 64:255-261. Goldin, B. R. and S. L. Gorbach. 1984. The effect of milk and lactobacillus feeding on human intestinal bacterial enzyme activity. Amer. J. Clin. Nutr. 39:756-761. Goldin, B. R. and S. L. Gorbach. 1984. The effect of oral administration of Lactobacillus and antibiotics on intestinal bacterial activity and chemical induction of large bowel tumors. Dev. Indus. Microbiol. 25:139-150. Kim H. S., and S. E. Gilliland. 1983. Lactobacillus acidophilus as a dietary adjunct for milk to aid lactose digestion in humans. J. Dairy Sci. 66:959-966. Lin, M-Y. D. Savaiano, and S. Harlander. 1991. Influence of nonfermented dairy products containing bacterial starter cultures on lactose maldigestion in humans. J. Dairy Sci. 74:87-95. Newcomer, A. D., H. S. Park, P. C. O' Brien, and D. B. McGill. 1983. Response of patients with irritable bowel syndrome and lactase deficiency using unfermented acidophilus milk. Amer. J. Clin. Nutr. 38:257-263. Savaiano, D. A., A. AbouElAnouar, D. E. Smith, and M. D. Lewitt. 1984. Lactose malabsorbtion from yoghurt, pasteurized yogurt, sweet acidophilus milk, and cultured milk in lactase-deficient individuals. Amer. J.	

Clin. Nutr. 40:1219-1223.

Sui, J., Leighton, S., Busta, F., Brady, L. 2002. 16S ribosomal DNA analysis of the faecal lactobacilli composition of human subjects consuming a probiotic strain Lactobacillus acidophilus NCFM. J. Appl. Microb. 93:907-912.

Additional Human Studies

Dunn, S. R., M. L. Simenhoff, K. E. Ahmed, W. J. Gaughan, B. O. Eltayeb, M.-E. D. Fitzpatrick, S. M. Emery, J. W. Ayres, and K. E. Holt. 1998. Effect of oral administration of freeze-dried Lactobacillus acidophilus on small bowel bacterial overgrowth in patients with end stage kidney disease: reducing uremic toxins and improving nutrition. Int. Dairy J. 8:545-553.

Montes, R. G., T. M. Bayless, J. M. Saavedra, and J. A. Perman. 1995. Effect of milks inoculated with Lactobacillus acidophilus or a yogurt starter culture in lactose-maldigesting children. J. Dairy Sci. 78:1657-1664.

Simenhoff, M. L., S. R. Dunn, G. P. Zollner, M.-E. D. Fitzpatrick, S. M. Emery, W. E. Sandine, and J. W. Ayres. 1996. Biomodulation of the toxic and nutritional effects of small bowel bacterial overgrowth in end-stage kidney disease using freeze-dried Lactobacillus acidophilus. Mineral Electrolyte Metab. 22:92-96.

In Vitro Studies

Daniel, C., S. Poiret, D. Goudencourt, V. Dennin, G. Leyer, and B. Pot. 2006. Selecting lactic acid bacteria for their safety and functionality by use of a mouse colitis model. Appl. Environ. Microbiol. 72 :5799-5805

Foligne, B., S. Nutten, C. Grangette, V. Dennin, D. Goudercourt, S. Poiret, J. Dewulf, D. Brassard, A. Mercenier, and B. Pot. Correlation between in vitro and in vivo

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immunomodulatory properties of lactic acid bacteria. World J. Gastroenterology. 13:236-243

Goldin, B. R. and S. L. Gorbach. 1977. Alterations in fecal microflora enzymes related to diet, age, lactobacillus supplements, and dimethylhydrazine. Cancer 40:2421-2426.

Goldin, B. R. and S. L. Gorbach. 1980. Effect of Lactobacillus acidophilus dietary supplements on 1,2-dimethylhydrazine dihydrochloride-induced intestinal cancer in rats. J. Nat. Cancer Instit. 64:263-265.

Goldin, B. R. and S. L. Gorbach. 1984. Alterations of the intestinal microflora by diet, oral antibiotics, and Lactobacillus: decreased production of free amines from aromatic nitro compounds, azo dyes, and glucuronides. J. Nat. Cancer Instit. 73:689-695.

Goldin, B. R. and S. L. Gorbach. 1984. The effect of oral administration of Lactobacillus and antibiotics on intestinal bacterial activity and chemical induction of large bowel tumors. Dev. Indus. Microbiol. 25:139-150.

Rao, C. V., M. E. Sanders, C. Indranie, B. Simi, and B. S. Reddy. 1999. Prevention of colonic preneoplastic lesions by the probiotic Lactobacillus acidophilus NCFMTM in F344 rats. Int. J. Oncol. 14:939-944.

Varcoe, J. J., G. Krejcarek, F. Busta, and L. Brady. 2003. Prophylactic feeding of Lactobacillus acidophilus NCFM to mice attenuates overt colonic hyperplasia. J. Food Prot. 66:457-65.

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus bulgaricus					
		Contains Probiotic that confers a benefit on the host	At least 107 cfu / day	Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	WHO definition of probiotic FAO/WHO (2001). Guidelines for the Evaluation of Probiotics in Food. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, April 30 and May 1, 2002. Gorbach SL and Goldin BR. (1992). Nutrition and the gastrointestinal microflora. Nutr Rev. 1992 Dec;50(12):378-81 Rolfe, RD. (2000). The role of probiotic cultures in the control of gastrointestinal health. J Nutr. Feb;130(2S Suppl): 396S-402S. Fuller, R and Perdigon, G. (2003). Gut flora, nutrition, immunity and Health. Edited by R Fuller and G Perdigon. Blackwell Publishing.	909
		Beneficial effect on intestinal microflora, gut integrity, digestion	At least 107 cfu / day	Textbooks & peer reviewed journal articles	Chaitow, L and Trenev, N. (1990). Probiotics. Thorsons.	923
		Maintenance of healthy Immune system	At least 107 cfu / day			937

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks & peer reviewed journal articles	Bin-Nun, A., Bromiker, R., Wilschanski, M., Kaplan, M., Rudensky, B., Caplan, Borruel, N., Carols, M., Casellas, F., Antolin, M.,de Lara,F., Espin,E., Naval,J., Guarner, F., Malagelada, J.R. (2002) Increased mucosal tumour necrosis factor alpha production in Crohn's disease can be downregulated ex vivo by probiotic bacteria; Gut 2002;51:659-664 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. Infect Immun. 1996 Dec;64(12):5403-5 Pereyra BS, Falcoff R, Falcoff E, Lemonnier D (1991). Interferon induction by Lactobacillus bulgaricus and streptococcus thermophilus in mice; Eur Cytokine Netw. Aug-Sep;2 (4): 299-303 As listed by A Green	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus casei					
		Immune support	Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 10 million bacteria per portion/dose	Review article Human studies National Institute of Health Public Access Manuscript Clinical trial Human with Atopic dermatitis	Roberfroid MB Am J Clin Nutr 2000;(71 suppl):1682S-7S Brown AC et al., Nutr Clin Care 2004;7(2): 56-68 Yim et al., J Microbiol. Biotechnol., 2006; 16(11): 1699-1705	2,327
		Maintenance of	At least 107 cfu / day			934

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		healthy Immune system		Textbooks & peer reviewed journal articles	Barrenetxe J,Aranguren P, Grijalba A, Martinez-Penula JM, Marzo F, Urdaneta E (2006). Modulation of gastrointestinal physiology through probiotic strains of Lactobacillus casei and Bifidobacterium bifidum. An. Sist. Saint Navar. 2006 sep-Dec; 29(3): 337-347. Lee JW, Shin JG, Kim EH, Kang HE, Yim IB, Kim JY, Joo HG, Woo HJ. (2004). Immunomodulatory and antitumor effects in vivo by the cytoplasmic fraction of Lactobacillus casei and Bifidobacterium longum. J Vet Sci. 2004 Mar;5(1):41-8 As listed by A Green	
		Beneficial effect on intestinal microflora, gut integrity, digestion	At least 107 cfu / day			920

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks & peer reviewed journal articles	Gorbach, SL. (2000). Probiotics and gastrointestinal health. Am J Gastroenterol. 2000 Jan;95(1 Suppl):S2-4. Gaon D, Garcia H, Winter L, Rodriguez N, Quintas R, Gonzalez SN and Oliver G. (2003). Effect of Lactobacillus strains and Saccharomyces boulardii on persistent diarrhea in children. Medicina (B Aires). 2003;63(4):293-8. Gaon D, Garmendia C, Murrielo NO, de Cucco Games A, Cerchio A, Quintas R, Gonzalez SN and Oliver G. (2002). Effect of Lactobacillus strains (L. casei and L. acidphilus Strains cereal) on bacterial overgrowth-related chronic diarrhea. Medicina (B Aires). 2002;62(2):159-63. Koebnick C, Wagner I, Leitzmann P, Stern U and Zunft HJ. (2003). Probiotic beverage containing Lactobacillus casei Shirota improves gastrointestinal symptoms in patients with chronic constipation.	
		Contains Probiotic that confers a benefit on the host	At least 107 cfu / day			906

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	WHO definition of probiotic FAO/WHO (2001). Guidelines for the Evaluation of Probiotics in Food. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, April 30 and May 1, 2002. Gorbach SL and Goldin BR. (1992). Nutrition and the gastrointestinal microflora. Nutr Rev. 1992 Dec;50(12):378-81 Rolfe, RD. (2000). The role of probiotic cultures in the control of gastrointestinal health. J Nutr. Feb;130(2S Suppl): 396S-402S. Fuller, R and Perdigon, G. (2003). Gut flora, nutrition, immunity and Health. Edited by R Fuller and G Perdigon. Blackwell Publishing.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus casei CNCM I-1518 / DN-114 001					
		Natural defence	at least 10[10] cfu/day fermented milk product daily consumption all population			254

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative bodies Critical reviews Individual studies	Authoritative/Scientific Body AFSSA (French Food Safety Agency) hearing No 2003-SA-0200. January 23, 2004, Actimel 'helps strengthen the body's natural defenses' Individual Human Studies Agarwal,K.N., Bhasin,S.K., Faridi,M.M., Mathur,M. and Gupta,S. (2001) Lactobacillus casei in the control of acute diarrhea-a pilot study. Indian pediatrics; 38, 905-910. Cobo Sanz, J.M. Mateos J.A. Munoz Conejo A. Effect of Actimel on the incidence of infectious conditions in children. Nutr Hosp. 2006; 21(4): 547-51 Guerin,D.C., Chabanet,C., Pedone,C., Popot,F., Vaissade,P., Bouley,C., Szylit,O. and Andrieux,C. (1998) Milk fermented with yogurt cultures and Lactobacillus casei compared with yogurt and gelled milk: influence on intestinal microflora in healthy infants. Am. J. Clin. Nutr. 67, 111-117. Marcos A, Warnberg J, Nova E, Gomez S, Alvarez A, Alvarez R, Mateos JA, Cobo, JM (2004) 'The effect of milk fermented by yoghurt cultures plus Lactobacillus casei DN 114001 on the immune response of subjects under academic examination stress' Eur. J. Nutr. 43(6) : 381-9 Oozer, R. et al. Survival of L;casei in the human digestive tract after consumption of fermented milk. Applied and environnmental microbiol, aug. 2006, 5615-17 Parra, D., Martinez de Morentin, B., Cobo, J.M., Mateos, A., Martinez, J.A. (2004) 'Daily ingestion of fermented milk containing Lactobacillus casei DN-114 001 improves	

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innate-defense capacity in healthy middle-aged people.' J. Physiol. Biochem ; vol.60, no.2, p.85 -92

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Pedone,C.A., Bernabeu,A.O., Postaire,E.R., Bouley,C.F. and Reinert,P. (1999) The effect of supplementation with milk fermented by Lactobacillus casei (strain DN 114 001) on acute diarrhoea in children attending day care centres. Int. J. Clin. Pract. 53, 179-184.

Pereg D, KimhiO, Tirosh A, Orr N, Kayouf R, Lishner M. The effects of a fermented yogurt on the prevention of diarrhea in a healthy adult population. Am J Infect Control. 2005. Mar; 33(9): 786-90.

Pujol, P., Huguet, J., Drobnic, F., Banquells, M., Ruiz, O., Galilea, P., Segarra, N., Aguilera, S., Burnat, A., Mateos, J. A. and Postaire, E. R. (2000) The effect of fermented milk containing Lactobacillus casei on the immune response to exercise. Sports Med., Training and Rehab. 9[3], 209-223.

Rochet V., Rigottier-Gois L., Sutren M., Krementscki M-N., Andrieux C., Furet J-P., Tailliez P., Levenez F., Mogenet A., Bresson J-L., Meance S., Cayuela C., Leplingard A. and Dore J. Effects of orally administrated Lactobacillus casei DN-114 001 on the

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					composition or activities of the dominant faecal microbiota in healthy humans. British Journal of Nutrition. 2006, 95, 421-29 Rochet,V., Turchet,P.,Laurenzano,M., Auboiron,S., Antoine,J.M. (2003) Effect of fermented milk containing the probiotic Lactobacillus casei DN 114 001 on winter infections in free-living elderly subjects: a randomised, controlled pilot study. J. of Nutr., Health & Aging; 7[2], 75-77 Additional Human Study Sykora,J., Valeckova,K., Amlerova,J., Siala,K., Dedek,P., Watkins,S., Varvarovska,J., Stozicky,F., Pazdiora,P. and Schwartz,J. (2005) Effects of a specially designed fermented milk product containing probiotic Lactobacillus casei DN-114 001 and the eradication of H. pylori in children. A prospective randomized double-blind study. J. Dairy Res. 72, 243-249 Animal Studies Chapat, L., Chemin, K., Bourdet-Sicard, R., Akarid, K., Kaiserlian, D. (2004) 'Lactobacillus casei DN-114 001 reduces CD8+ T cell-mediated skin inflammation'. Eur. J. Immun., vol. 34, no. 9, p. 2520-2528 Llopis M, Antolin M, Guarner A, Malagelada J-R. (2005). Mucosal colonisation with Lactobacillus casei mitigates barrier injury induced by exposure to trinitronbenzene sulphonic acid. Gut. 54; 955-959 Oozeer,R., Goupil,F.N., Alpert,C.A., van de,G.M., Anba,J., Mengaud,J. and Corthier,G. (2002) Lactobacillus casei is able to survive and initiate protein synthesis during its transit in the digestive tract of human flora-associated mice. Applied. and Environmental Microbiology 68, 3570-3574. Djouzi,Z., Andrieux,C., Degivry,M.C., Bouley,C. and Szylit,O. (1997) The association of yogurt starters with Lactobacillus casei DN	

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In Vitro Studies

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Tanabe, H., Shirafuji, Y., Thoreux, K., Freitas, M., Bourdet-Sicard, R., Ouellette, A.J (2004). Lactobacillus casei DN-114 001 induces Paneth cell secretion and is sensitive to enteric a¬defensins. Gastroenterology, 126, 4, S2: A578

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Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus casei I-3429					
		Digestive health	at least 1x10[9] cfu/day	Human study	Individual Human Studies - Oozeer R, Leplingard A, Mater DD, Mogenet A, Michelin R, Seksek I, Marteau P, Dore J, Bresson JL, Corthier G. Survival of Lactobacillus casei in the human digestive tract after consumption of fermented milk. Appl Environ Microbiol. 2006 Aug;72(8):5615-7. - Sykora J, Valeckova K, Amlerova J, Siala K, Dedek P, Watkins S, Varvarovska J, Stozicky F, Pazdiora P, Schwarz J. Effects of a specially designed fermented milk product containing probiotic Lactobacillus casei DN-114 001 and the eradication of H. pylori in children: a prospective randomized double-blind study. J Clin Gastroenterol. 2005 Sep;39(8):692-8. - Tormo Carnicer R, Infante Pina D, Rosello Mayans E, Bartolome Comas R. Intake of fermented milk containing Lactobacillus casei DN-114 001 and its effect on gut flora. An Pediatr (Barc). 2006 Nov;65(5):448-53.	223
	Lactobacillus casei Lafti L26 (CBS 116.412)					
		Intestinal flora	at least 5x10[9] CFU	Animal & in vitro studies	Animal Studies - 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	222

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus casei Shirota (LcS)					
		Digestive system / bowel habit	at least 10[9] cfu/day			225

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative bodies Human study Animal study In vitro study	Review - Nomoto K. Prevention of infection by probiotics. J. bioscience and bioengineering 2005; 100: 583-592 Individual Human Studies - Koebnick C, Wagner I, Leitzmann P et al. Probiotic beverage containing Lactobacillus casei Shirota improves gastrointestinal symptoms in patients with chronic constipation. Can J Gastroenterol 2003;17:655-659. - Matsumoto K, Takada T, Shimizu K et al. The effect of a probiotic milk product containing Lactobacillus casei strain Shirota on de defecation frequency and the intestinal microflora of sub-optimal health state volunteers: a randomized placebo-controlled cross-over study. To be published in Bioscience and Microflora April 2006;25(2). - Spanhaak S, Havenaar R, Schaafsma G. The effect of consumption of milk fermented by Lactobacillus casei strain Shirota on the intestinal microflora and immune parameters in humans. Eur J Clin Nutr 1998;52(12):899-907 Additional Human Studies - Alm L, Humble D, Ryd-Kjellen E, Setterberg G (1983) The effect of acidophilus milk in the treatment of constipation in hospitalised geriatric patients. Symposia of Swedish Nutrition Foundation xv, 131-138. - Numata K (1973) Clinical effect of a high concentrate Lactobacilli preparation on chronic constipation. The Clinical Report 7, 1856-1857 - Ogawa T, Hirai R, Nakakuni H, Sato Y, Wakisaka S, Tachibana M, Tominaga H, Kurata M, Matsubayashi K (1974) Clinical experience with the use of the high-concentration lactic acid bacteria	

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		Natural defence (regulation of cell development)	at least 10[9] cfu/day			258

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
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		Gut health	at least 10[9] cfu/day			224

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative bodies Human study Animal study In vitro study	Reviews - Borriello SP, Hammes WP, Holzapfel W et al. Safety of probiotics that contain lactobacilli or bifidobacteria. Clin Infect Dis 2003;36(6):775-80. - Gibson GR, Rouzaud G, Brostoff J et al. An evaluation of probiotic effects in the human gut: microbial aspects. FSA 2005; ref G01022, 2-22. http://www.food.gov.uk/multimedia/pdfs/probioticreport.pdf - Marteau P, Shanahan F. Basic aspects and pharmacology of probiotics: an overview of pharmacokinetics, mechanisms of action and side-effects. Best Practice & Research Clinical Gastroenterology 2003;17:725-740. - Mitsuoka T. Bifidobacteria and their role in human health. J Ind Microbiol1990;6:263-8. - Nomoto K. Prevention of infection by probiotics. J. bioscience and bioengineering 2005; 100: 583-592. Individual Human Studies - Asahara T, Takahashi M, Nomoto K et al. Assessment of safety of lactobacillus strains based on resistance to host innate defense mechanisms. Clin Diagn Lab Immunol 2003;10:169-73. - Cats A, Kuipers EJ, Bosschaert MAR, Pot RGJ, Vandenbroucke-Grauls CMJE, Kusters JG (2003); Effect of frequent consumption of a Lactobacillus casei-containing milk drink in Helicobacter pylori-colonized subjects". Aliment Pharmacol Ther 17, 429-35. - De Preter V, Geboes K, Verbrugghe K et al. The in vivo use of the stable isotope-labelled biomarkers lactose-[15N]ureide and [2H4]tyrosine to assess the effects of pro- and pre-biotics on the intestinal flora of healthy human volunteers. Br J Nutr 2004;92:439-446.	

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		Natural resistance / defence	at least 10[9] cfu/day	Human study Animal study In vitro study	Reviews Borriello SP, Hammes WP, Holzapfel W et al. Safety of probiotics that contain lactobacilli or bifidobacteria. Clin Infect Dis 2003;36(6):775-80. Gibson GR, Rouzaud G, Brostoff J et al. An evaluation of probiotic effects in the human gut: microbial aspects. FSA 2005; ref G01022, 2-22. http://www.food.gov.uk/multimedia/pdfs/probioticreport.pdf Marteau P, Shanahan F. Basic aspects and pharmacology of probiotics: an overview of pharmacokinetics, mechanisms of action and side-effects. Best Practice & Research Clinical Gastroenterology 2003;17:725-740. Mitsuoka T. Bifidobacteria and their role in human health. J Ind Microbiol1990;6:263-8. Nomoto K. Prevention of infection by probiotics. J. bioscience and bioengineering 2005; 100: 583-592. Individual Human Studies Asahara T, Takahashi M, Nomoto K et al. Assessment of safety of lactobacillus strains based on resistance to host innate defense mechanisms. Clin Diagn Lab Immunol 2003;10:169-73. Cats A, Kuipers EJ, Bosschaert MAR, Pot RGJ, Vandenbroucke-Grauls CMJE, Kusters JG (2003); Effect of frequent consumption of a Lactobacillus casei-containing milk drink in Helicobacter pylori-colonized subjects". Aliment Pharmacol Ther 17, 429-35. De Preter V (2006) Biomarkers to study the in vivo efficacyy of pre- and/or probiotics on the colonic fate of ammonia and p-cresol in healthy volunteers. Doctor thesis at Katholieke Universiteit Leuven. 2006 Apr. Belgium.	256

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		Natural resistance / defence (enhance NK cell activity)	at least 10[9] cfu/day			257

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				Human study Animal study In vitro study	Reviews Nomoto K. Prevention of infection by probiotics. J. bioscience and bioengineering 2005; 100: 583-592. Rowland IR (1996) Gut microflora and cancer. In Gut Flora and Health – Past, Present and Future, pp. 19-25 [A R Leeds & IR Rowland, editors]. London: The Royal Society of Medicine. Individual Human Studies Imai K, Matsuyama S, Miyake S, Suga K, Nakachi K (2000) Natural cytotoxic activity of peripheral-blood lymphocytes and cancer incidence: an 11-year follow-up study of a general population. The Lancet 356, 1795-1799. Morimoto K, Takeshita T, Nanno M, Tokudame S & Nakayama K (2005) Modulation of natural killer cell activity by supplementation of fermented milk containing Lactobacillus casei in habitual smokers. Preventive Medicine 40, 589-594. Nagao F, Nakayama M, Muto T, Okumura K (2000) Effects of a fermented milk drink containing Lactobacillus casei strain Shirota on the immune system in healthy human subjects. Bioscience Biotechnology and Biochemistry 64, 2706-2708. Sawamura et al (1994) The enhancing effect of oral Lactobacillus casei on the immunologic activity of colon cancer patients. Biotherapy 8, 1567-1572. Sugawara G, et al (2006); “Perioperative symbiotic treatment to prevent postoperative infectious complications in biliary cancer surgery-A randomized controlled trial”, Annals of surgery 244 (5), 706-14.	

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Matsuzaki T, Yokokura T (1987) Inhibition of tumor metastasis of Lewis lung carcinoma in C57BL/6 mice by intrapleural administration of Lactobacillus casei. Cancer Immunology Immunotherapy 25, 100-104.

Matsuzaki T, Yokokura T. and Mutai M (1988) Antitumor effect of intrapleural administration of Lactobacillus casei in mice. Cancer Immunology Immunotherapy 26, 209-214.

Takagi A, Matsuzaki T Sato M, Nomoto K, Morotomi M, Yokokura T (1999) Inhibitory effect of oral administration of Lactobacillus casei on 3-methylcholanthrene-induced carcinogenesis in mice. Medical Microbiology and Immunology 188, 111-116.

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Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Microscopy 24, 5-6. Animal Study Rowland IR (1996) Gut microflora and cancer. In Gut Flora and Health – Past, Present and Future, pp. 19-25 [A R Leeds & IR Rowland, editors]. London: The Royal Society of Medicine.	
	Lactobacillus delbruekii					
		Contains Probiotic that confers a benefit on the host	At least 107 cfu / day	Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	WHO definition of probiotic FAO/WHO (2001). Guidelines for the Evaluation of Probiotics in Food. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, April 30 and May 1, 2002. Gorbach SL and Goldin BR. (1992). Nutrition and the gastrointestinal microflora. Nutr Rev. 1992 Dec;50(12):378-81 Rolfe, RD. (2000). The role of probiotic cultures in the control of gastrointestinal health. J Nutr. Feb;130(2S Suppl): 396S-402S. Fuller, R and Perdigon, G. (2003). Gut flora, nutrition, immunity and Health. Edited by R Fuller and G Perdigon. Blackwell Publishing.	913

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus delbruekii (lactis)					
		Maintenance of healthy Immune system	At least 107 cfu / day	Textbooks & peer reviewed journal articles	Cario E. (2005). Bacterial interactions with cells of the intestinal mucosa: Toll-like receptors and NOD2. Gut. 2005 Aug;54(8):1182-93. Epub 2005 Apr 19. Review. Salinas I, Cuesta A, Esteban MA, Meseguer J. (2005). Dietary administration of Lactobacillus delbrueckii and Bacillus subtilis, single or combined, on gilthead seabream cellular innate immune responses. Fish Shellfish Immunol. 2005 Jul;19(1):67-77. Perdigon G, Vintini E, Alvarez S, Medina M, Medici M. (1999). Study of the possible mechanisms involved in the mucosal immune system activation by lactic acid bacteria. J Dairy Sci. 1999 Jun;82(6):1108-14 Castanheira LG, Castro JM, Martins-Filho Ode A, Nicoli JR, Vieira LQ, Afonso LC. (2007). Lactobacillus delbrueckii as a potential skin adjuvant for induction of type 1 immune responses. Front Biosci. 2007 Jan 1;12:1300-7 As listed by A Green	941

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus delbruekii(lactis)					
		Beneficial effect on intestinal microflora, gut integrity, digestion	At least 107 cfu / day	Textbooks & peer reviewed journal articles	Barefoot SF, Nettles CG.(1993). Antibiosis revisited: bacteriocins produced by dairy starter cultures. J Dairy Sci. 1993 Aug;76(8):2366-79. Review. Atassi F, Brassart D, Grob P, Graf F, Servin AL. (2006). In vitro antibacterial activity of Lactobacillus helveticus strain KS300 against diarrhoeagenic, uropathogenic and vaginosis-associated bacteria.J Appl Microbiol. 2006 Sep;101(3):647-54. Hugo AA, De Antoni GL, Perez PF. (2006). Lactobacillus delbrueckii subsp lactis strain CIDCA 133 inhibits nitrate reductase activity of Escherichia coli. Int J Food Microbiol. 2006 Oct 1;111(3):191-6. Epub 2006 Aug 22. Boris S, Jiménez-Díaz R, Caso JL, Barbés C. (2001). Partial characterization of a bacteriocin produced by Lactobacillus delbrueckii subsp. lactis UO004, an intestinal isolate with probiotic potential. J Appl Microbiol. 2001 Aug;91(2):328-33	927

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus fermentum CECT5716					
		Natural defence / immune system	at least 10[9-]10[10] cfu/day powder culture (pills) daily intake period of 3-4 weeks			259

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human and animal trials	Individual Human Studies Martin R., Langa S., Reviriego C., Jimenez E., Marin ML., Xaus J., Fernandez L., Rodriguez JM. Human milk is a source of lactic acid bacteria to the infant gut. J. Pediatrics. 143: 754-758. 2003 Martin R., Langa S., Reviriego C., Jimenez E., Marin ML., Olivares M., Boza J., Jimenez J., Fernandez L., Xaus J., Rodriguez JM. The commensal microflora of human milk: new perspectives for food bacteriotherapy and probiotics. Trends Food Sci Tech. 15: 121-127. 2004. Olivares M., Diaz-Ropero MP., Sierra S., Lara-Villoslada F., Fonolla J., Rodriguez JM., Xaus J. Coadjuvant effect of Lactobacillus fermentum CECT5716 during an influenza vaccination. e-ESPEN 1: 129. 2006 Animal Studies Diaz-Ropero MP, Martin R, Sierra S, Lara-Villoslada F, Rodriguez JM, Xaus J, Olivares M. Two Lactobacillus strains, isolated from breast milk, differently modulate the immune response. J. Appl. Microbiol. In press. 2006. Galvez J, Camuesco D, Peran L, Comalada M, Xaus J, Zarzuelo A. Effects of Lactobacillus fermentum and Lactobacillus reuteri on TNBS-induced colitis in rats. Falk Symposium 153: Inmunoregulation in IBD, current understanding and innovation. Berlin (Germany) 2006. Galvez J, Peran L, Sierra S, Comalada M, Lara-Villoslada F, Bailon E, Nieto A, Concha A, Olivares M, Zarzuelo A, Xaus J. A comparative study of the preventative effects exerted by two probiotics, Lactobacillus reuteri and Lactobacillus fermentum, in the	

trinitrobenzensulphonic acid model of rat colitis. Br. J. Nutr. In Press. 2006.

Loren V, Mane J, Pedrosa E, Ojanguren I, Bartoli R, Cabre E, Xaus J, Gassull MA. La administracion de Lactyobacillus fermentum (LF) despues de la induccion de colitis por TNBS en ratones Blab/c mejora la evolucion de la lesion colonica (The administration of L. fermentum (LF) after the induction of a TNBS colitis improves the evolution of the colonic lessions). Gastroenterol Hepatol. 29: 189. 2006.

Loren V, Mane J, Pedrosa E, Ojanguren I, Bartoli R, Cabre E, Xaus J, Gassull MA. Pretreatment with L. fermentum (LF) decreases the short-term severity of experimental colitis in balb/c mice. e-ESPEN 1: 138-139. 2006

Mane J, Loren V, Pedroisa E, Ojanguren I, Cabre E, Bartoli R, Xaus J, Gassull MA. La administracion de Lactyobacillus fermentum (LF) previa a la induccion de colitis por TNBS reduce la lesion intestinal en ratones Blab/c (The administration of L. fermentum (LF) before the induction of a TNBS colitis reduces the intestinal lessions in Balb/c mice.). Gastroenterol Hepatol. 29: 188. 2006

Mane J, Loren V, Pedroisa E, Ojanguren I, Cabre E, Bartoli R, Xaus J, Gassull MA. Treatment with Lactobacillus fermentum (LF) alter the induction of experimental colitis accelerates the healing of colonia damage in Balb/c mice. e-ESPEN 1: 140. 2006

Olivares M., Diaz-Ropero MP., Martin R., Rodriguez JM., Xaus J. Antimicrobial potential of four lactobacillus strains isolated from breast milk. J. Appl. Microbiol. 101: 72-79. 2006.

Peran L., Camuesco D., Comalada M., Nieto A., Concha A., Adrio JL., Olivares M., Xaus J.,

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Zarzuelo A., Galvez J. Lactobacillus fermentum, a probiotic capable to release glutathione, prevents colonic inflammation in the TNBS model of rat colitis. Int. J. Colorectal. Dis. On line Jul 29. 2005 In Vitro Studies Diaz-Ropero MP, Martin R, Sierra S, Lara-Villoslada F, Rodriguez JM, Xaus J, Olivares M. Two Lactobacillus strains, isolated from breast milk, differently modulate the immune response. J. Appl. Microbiol. In press. 2006.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus gasseri CECT5714 and Lactobacilus coryniformis CECT5711					
		Natural defence / immune system	at least 10[8] cfu/day dairy fermented product period of 3-4 weeks daily consumption			260

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human trials: adults and children	Individual Human Studies Martin R., Langa S., Reviriego C., Jimenez E., Marin ML., Xaus J., Fernandez L., Rodriguez JM. Human milk is a source of lactic acid bacteria to the infant gut. J. Pediatrics. 143: 754-758. 2003 Olivares M., Diaz-Ropero MP., Gomez N., Lara-Villoslada F., Sierra S., Maldonado JA., Martin R., Lopez-Huertas E., Rodriguez JM., Xaus J. Oral administration of two probiotic strains, Lactobacillus gasseri CECT5714 and Lactobacillus coryniformis CECT5711, enhances the intestinal function of healthy adults. Int. J. Food Microbiol. 107: 104-111.. 2006. Olivares M., Diaz-Ropero MP., Gomez N., Sierra S., Lara-Villoslada., Martin R., Rodriguez JM., Xaus J. The deprivation of fermented foods in diet causes a fall in innate immune response. Lactic acid bacteria can counteract the immunological effect of this deprivation. J. Dairy Res. 21: 1-7. 2006. Olivares M., Diaz-Ropero MP., Gomez N., Sierra S., Lara-Villoslada F., Maldonado JA., Martin R., Rodriguez JM., Xaus J. The consumption of two probiotic strains, Lactobacillus gasseri CECT5714 and Lactobacillus coryniformis CECT5711, boost the immune system of healthy adults. Int. Microbiol .9: 47-52. 2006 Animal Studies Olivares M., Diaz-Ropero MP., Lara-Villoslada., Rodriguez JM., Xaus J. Probiotic effectiveness in allergy: Child game or adult affair?. Nutrafoods. 4: 59-64. 2005 Olivares M., Diaz-Ropero MP., Martin R., Rodriguez JM., Xaus J. Antimicrobial potential of four lactobacillus strains isolated from breast	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					milk. J. Appl. Microbiol. 101: 72-79. 2006. In Vitro Studies Martin R., Langa S., Reviriego C., Jimenez E., Marin ML., Olivares M., Boza J., Jimenez J., Fernandez L., Xaus J., Rodriguez JM. The commensal microflora of human milk: new perspectives for food bacteriotherapy and probiotics. Trends Food Sci Tech. 15: 121-127. 2004 Olivares M., Diaz-Ropero MP., Martin R., Rodriguez JM., Xaus J. Antimicrobial potential of four lactobacillus strains isolated from breast milk. J. Appl. Microbiol. 101: 72-79. 2006.	
		Intestinal flora and intestinal transit	at least 10[8] cfu/day dairy fermented product periods of 3-4 weeks daily consumption			227

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual human studies: adults and children	Individual Human Studies - Martin R., Langa S., Reviriego C., Jimenez E., Marin ML., Xaus J., Fernandez L., Rodriguez JM. Human milk is a source of lactic acid bacteria to the infant gut. J. Pediatrics. 143: 754-758. 2003 - Olivares M., Diaz-Ropero MP., Lara-Villoslada., Rodriguez JM., Xaus J. Probiotic effectiveness in allergy: Child game or adult affair?. Nutrafoods. 4: 59-64. 2005. - Olivares M., Diaz-Ropero MP., Gomez N., Lara-Villoslada F., Sierra S., Maldonado JA., Martin R., Lopez-Huertas E., Rodriguez JM., Xaus J. Oral administration of two probiotic strains, Lactobacillus gasseri CECT5714 and Lactobacillus coryniformis CECT5711, enhances the intestinal function of healthy adults. Int. J. Food Microbiol. 107: 104-111.. 2006. - Olivares M., Diaz-Ropero MP., Gomez N., Sierra S., Lara-Villoslada., Martin R., Rodriguez JM., Xaus J. The deprivation of fermented foods in diet causes a fall in innate immune response. Lactic acid bacteria can counteract the immunological effect of this deprivation. J. Dairy Res. 21: 1-7. 2006. - Olivares M., Diaz-Ropero MP., Gomez N., Sierra S., Lara-Villoslada F., Maldonado JA., Martin R., Rodriguez JM., Xaus J. The consumption of two probiotic strains, Lactobacillus gasseri CECT5714 and Lactobacillus coryniformis CECT5711, boost the immune system of healthy adults. Int. Microbiol .9: 47-52. 2006 Animal Studies - Lara-Villoslada F, Sierra S, martin R, delgado S, Rodriguez JM, Olivares M, Xaus J. Safety assesment of two probiotic strains,	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Lactobacillus coryniformis CECT5711 and Lactobacillus gasseri CECT5714. J. Appl. Microbiol. In Press. 2006 - Olivares M., Diaz-Ropero MP., Lara-Villoslada., Rodriguez JM., Xaus J. Probiotic effectiveness in allergy: Child game or adult affair?. Nutrafoods. 4: 59-64. 2005. - Olivares M., Diaz-Ropero MP., Martin R., Rodriguez JM., Xaus J. Antimicrobial potential of four lactobacillus strains isolated from breast milk. J. Appl. Microbiol. 101: 72-79. 2006. In Vitro Studies - Martin R., Olivares M., Marin ML., Fernandez L., Xaus J., Rodriguez JM. Probiotic potential of three lactobacilli strains isolated from human breast milk. J. Hum. Lactation. 21: 8-17. 2005. - Martin R., Olivares M., Marin ML., Xaus J., Fernandez L., Rodriguez JM. Characterization of a reuterin-producing Lactobacillus coryniformis strain isolated from an artisan goat's milk cheese. J. Food. Microbiol. 104: 267-277. 2005. - Olivares M., Diaz-Ropero MP., Martin R., Rodriguez JM., Xaus J. Antimicrobial potential of four lactobacillus strains isolated from breast milk. J. Appl. Microbiol. 101: 72-79. 2006.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus gasseri PA 16/8 and Bifidobacterium bifidum MF 20/5					
		Intestinal flora / digestive health / digestive system	at least 10[8] cfu/day at least 10[7] cfu/day	Individual human studies Animal studies In-vitro study	Individual Human Studies - Honma N. On effect of lactic acid bacteria, Clinical effects. Part II. New Medicines and Clinics 36 (1): 75 (1987) Animal Studies - Isa Y, Ohgushi H, Yamashita M, Ishihara Y, Sakutani W, Shimakawa M, Arai T, Ohno H., Effects of Bifidobacterium Bifidum MF 20/5 on experimental constipation models. Medicine and Pharmaceuticals 49 (5): 745-51 (2003) - Kitada Y, Shimakawa M, Isa Y, Hosokawa Y, Mizuguchi Y, Ohno H, Yamamura H., Effects of Bifidobacterium Bifidum MF 20/5 on experimental constipation model and diarrhea model. J New Rem & Clin. 52 (6): 761-9 (2203) - Yamashita, M. et al., Ecological study of effects of administration of three kinds of lactic acid bacteria on suppression of intestinal decomposed substance. Clinics and Microorganisms 13 (b): 87 (1987) - Yoneda, K., Biological study on live bacteria products in the market. Medicine and Pharmacology 17 (6): 1529-1534 (1987) In vitro Study - Yamamoto, T., Effect of lactic acid bacteria on intestinal putrefactive substance producing bacteria of human source. Basics and Clinics 20 (14): 20 (1986)	226

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual human studies Animal study	DeVrese M. et al (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. Clin Nutr 24 : 481-491 Winkler, P. et al (2005). Effect of a dietary supplement containing probiotic bacteria plus vitamins and minerals on common cold infections and cellular immune parameters. Int J Clin Pharmacol Ther 43 : 318-326 DeVrese, M. et al (2006). Probiotic bacteria reduced duration and severity but not the incidence of common cold episodes in a double blind, randomized controlled trial. Vaccine 24 : 6670-6674 Honma, N. (1974). Intestinal bacteria flora of infants and infection protection. Pediatric Clinics 27 : 20 Honma N. (1986). On effect of lactic acid bacteria. Part I: Biological significance. New Medicines and Clinics 35 : 2687-2695	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus gasseri PA 16/8, Bifidobacterium bifidum MF 20/5 and Bifidobacterium longum SP 07/3					
		Natural defence / immune system	at least 10[7] cfu/day Applicable to adults and children			261

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human studies Animal studies	Individual Human Studies de Vrese, M. et al., Effect of Lactobacillus gasseri PA 16/8, Bifidobacterium longum SP 07/3, Bifidobacterium bifidum MF 20/5 on common cold episodes: A double blind, randomized, controlled trial. Clinical Nutrition 24: 481-491 (2005) de Vrese M. et al., Probiotic bacteria reduced duration and severity but not the incidence of common cold episodes in a double blind, randomized, controlled trial. Vaccine 24: 6670-6674 (2006) Winkler P., de Vrese M., Laue CH., Schrezenmeir J., Effect of a dietary supplement containing probiotic bacteria plus vitamins and minerals on common cold infections and cellular immune parameters. Int. Journal of Clinical Pharmacology and Therapeutics 43 (7): 318-326 (2005) Additional Human Study Honma N. On effect of lactic acid bacteria, Clinical effects. Part II. New Medicines and Clinics 36 (1): 75 (1987) Animal Study Honma, N., Intestinal bacteria flora of infants and infection protection. Pediatrics Clinics, 27 (11): 20 (1974) Honma, N., On effect of lactic acid bacteria. Part 1-Biological significance. New Medicines and Clinics 35 (12): 2687-95 (1986) Ohno, H. et al., Oral administration of Bifidobacterium bifidum MF 20/5 suppresses total and antigen specific immunoglobulin E production in mice. Biol. Pharm. Bull. 28 (8): 1462-6 (2005	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual human studies Animal study In vitro study	Kitada Y. et al (2003). Effects of Bifidobacterium bifidum G9-1 on experimental constipation model and diarrhea model. J New Rem Clin 52 : 761-769 Isa, Y. et al (2003). Effects of Bifidobacterium bifidum G9-1 on experimental constipation models. Medicine and Pharmaceuticals 49 : 745-751 Yoneda K. (1987). Biological study on live bacteria products in the market. Medicine and Pharmacology 17 1529-1534 Honma N. et al (1987). On effect of lactic acid bacteria. Part II : Clinical Effects. New Medicines and Clinics 36 : 75 Yamashita, M. et al (1987). Ecological study of effects of administration of three kinds of lactic acid bacteria on suppression of intestinal decomposed substance. Clinics and Microorganisms 13(b) : 87 Yamamoto, T. (1986). Effect of lactic acid bacteria on intestinal putrefactive substance producing bacteria of human source. Basics and Clinics 20 : 20	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus gasseri PA 16/8, Bifidobacterium bifidum MF 20/5, Bifidobacterium longum SP 07/3					
		Intestinal flora/gut health	At least 10 [7] cfu/day Applicable to adults and children			560

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human/Clinical study animal study In vitro study	DeVrese M. et al (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. Clin Nutr 24 : 481-491 Winkler, P. et al (2005). Effect of a dietary supplement containing probiotic bacteria plus vitamins and minerals on common cold infections and cellular immune parameters. Int J Clin Pharmacol Ther 43 : 318-326 DeVrese, M. et al (2006). Probiotic bacteria reduced duration and severity but not the incidence of common cold episodes in a double blind, randomized controlled trial. Vaccine 24 : 6670-6674 Honma, N. (1974). Intestinal bacteria flora of infants and infection protection. Pediatric Clinics 27 : 20 Honma N. (1986). On effect of lactic acid bacteria. Part I: Biological significance. New Medicines and Clinics 35 : 2687-2695 Kitada Y. et al (2003). Effects of Bifidobacterium bifidum G9-1 on experimental constipation model and diarrhea model. J New Rem Clin 52 : 761-769 Isa, Y. et al (2003). Effects of Bifidobacterium bifidum G9-1 on experimental constipation models. Medicine and Pharmaceuticals 49 : 745-751 Yoneda K. (1987). Biological study on live bacteria products in the market. Medicine and Pharmacology 17 1529-1534	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Honma N. et al (1987). On effect of lactic acid bacteria. Part II : Clinical Effects. New Medicines and Clinics 36 : 75 Yamashita, M. et al (1987). Ecological study of effects of administration of three kinds of lactic acid bacteria on suppression of intestinal decomposed substance. Clinics and Microorganisms 13(b) : 87 Yamamoto, T. (1986). Effect of lactic acid bacteria on intestinal putrefactive substance producing bacteria of human source. Basics and Clinics 20 : 20	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus helveticus					
		Contains Probiotic that confers a benefit on the host	At least 107 cfu / day	Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	WHO definition of probiotic FAO/WHO (2001). Guidelines for the Evaluation of Probiotics in Food. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, April 30 and May 1, 2002. Gorbach SL and Goldin BR. (1992). Nutrition and the gastrointestinal microflora. Nutr Rev. 1992 Dec;50(12):378-81 Rolfe, RD. (2000). The role of probiotic cultures in the control of gastrointestinal health. J Nutr. Feb;130(2S Suppl): 396S-402S. Fuller, R and Perdigon, G. (2003). Gut flora, nutrition, immunity and Health. Edited by R Fuller and G Perdigon. Blackwell Publishing.	911
		Maintenance of healthy Immune system	At least 107 cfu / day			939

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks & peer reviewed journal articles	Cario E. (2005). Bacterial interactions with cells of the intestinal mucosa: Toll-like receptors and NOD2. Gut. 2005 Aug;54(8):1182-93. Epub 2005 Apr 19. Review. Rachid M, Matar C, Duarte J, Perdigon G. (2006). Effect of milk fermented with a Lactobacillus helveticus R389(+) proteolytic strain on the immune system and on the growth of 4T1 breast cancer cells in mice. FEMS Immunol Med Microbiol. 2006 Jul;47(2):242-53. Vinderola G, Matar C, Perdigon G. (2005). Role of intestinal epithelial cells in immune effects mediated by gram-positive probiotic bacteria: involvement of toll-like receptors. Clin Diagn Lab Immunol. 2005 Sep;12(9):1075-84. O'Riordan M, Yi CH, Gonzales R, Lee KD, Portnoy DA. (2002). Innate recognition of bacteria by a macrophage cytosolic surveillance pathway. Proc Natl Acad Sci U S A. 2002 Oct 15;99(21):13861-6. Epub 2002 Oct 1. Abrahams VM, Bole-Aldo P, Kim YM, Straszewski-Chavez SL, Chaiworapongsa T, Romero R, Mor G. (2004). Divergent trophoblast responses to bacterial products mediated by TLRs. J Immunol. 2004 Oct 1;173(7):4286-96. As listed by A Green	
		Beneficial effect on intestinal microflora, gut integrity, digestion	At least 107 cfu / day			925

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks & peer reviewed journal articles	Barefoot SF, Nettles CG.(1993). Antibiosis revisited: bacteriocins produced by dairy starter cultures. J Dairy Sci. 1993 Aug;76(8):2366-79. Review. Atassi F, Brassart D, Grob P, Graf F, Servin AL. (2006). In vitro antibacterial activity of Lactobacillus helveticus strain KS300 against diarrhoeagenic, uropathogenic and vaginosis-associated bacteria.J Appl Microbiol. 2006 Sep;101(3):647-54. Hugo AA, De Antoni GL, Perez PF. (2006). Lactobacillus delbrueckii subsp lactis strain CIDCA 133 inhibits nitrate reductase activity of Escherichia coli. Int J Food Microbiol. 2006 Oct 1;111(3):191-6. Epub 2006 Aug 22. Johnson-Henry KC, Hagen KE, Gordonpour M, Tompkins TA, Sherman PM. (2006). Surface-layer protein extracts from Lactobacillus helveticus inhibit enterohaemorrhagic Escherichia coli O157:H7 adhesion to epithelial cells.Cell Microbiol. 2006 Aug 22; [Epub ahead of print]	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus helveticus CNCM I-1722 and Bifidobacterium longum CNCM I-3470					
		Digestive system	at least 3x10[9] cfu/ day	Individual human studies Animal and in vitro studies (supporting)	Review - Haskey, N. and Dahl, W. Synbiotic therapy: A promising new adjunctive therapy for ulcerative colitis. Nutrition review 2006, Vol 64 (3): 132-138. Individual Human Study - Diop L, Guillou S, Durand H et al. Evaluation of the probiotic food supplement on stress-induced symptoms in volunteers: a double-blind, placebo-controlled randomized trial. 2006, submitted to Nutrition Research. In Vitro Study - Johnson-Henry, K C, Hagen, K E, Gordonpour, M, Tompkins T and P M Sherman. Surface-layer protein extracts from Lactobacillus helveticus inhibit enterohaemorrhagic Escherichia coli O157:H7 adhesion to epithelial cells. Cellular Microbiology 2006 Vol 9 (2): 356-357.	228

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus helveticus CNCM I-1722 and Lactobacilus rhamnosus					
		Digestive system	at least 3x10[9] cfu/ day	Individual human studies Animal and in vitro studies (supporting)	Individual Human Studies - Benes Z, Krtek V and T Tompkins. A probiotic combination for IBS- A pilot Clinical Study, Nutrafoods 2006 5(1) 20-27. Additional Human Study - Tlaskal, P, Michkova, E, Klayarova, H, Jerabkova, L, Nevoral, J, Balackova, J, Tejnecka, Valtrova, V, Simandlova, M and L Kejvalova. Lactobacillus acidophilus in the treatment of children with gastrointestinal tract illness. Cesko-Slovenska Pediatrie 1995, vol 51: 615-619. In Vitro Study - Johnson-Henry, K C, Hagen, K E, Gordonpour, M, Tompkins T and P M Sherman. Surface-layer protein extracts from Lactobacillus helveticus inhibit enterohaemorrhagic Escherichia coli O157:H7 adhesion to epithelial cells. Cellular Microbiology 2006 Vol 9 (2): 356-357.	229

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus helveticus l-1722					
		Immune defenses / support of immunity	at least 1x10[9] cfu/day	Human studies Review articles Animal studies	Reviews Bruzzese E, Canani RB, De Marco G, Guarino A. Microflora in inflammatory bowel diseases: a pediatric perspective. J Clin Gastroenterol. 2004 Jul;38(6 Suppl):S91-3. Kullen MJ, Bettler J. The delivery of probiotics and prebiotics to infants. Curr Pharm Des. 2005;11(1):55-74. Individual Human Studies Donnet-Hugues A, Rochat F, Serrant P, Aeschlimann JM, Schiffrin EJ. Modulation of non specific mechanism of defenses by lactic acid bacteria: effective dose. J Dairy Sci. 1999 May;82(5):863-9. Hatakka K, Savilahti E, Ponka A, Meurman JH, Poussa T, Nase L, Saxelin M, Korpela R. Effect of long term consumption of probiotic milk on infections in children attending day care centres: double blind, randomised trial. BMJ. 2001 Jun 2;322(7298):1327 Kalliomaki M, Salminen S, Arvilommi H, Kero P, Koskinen P, Isolauri E. Probiotics in primary prevention of atopic disease: a randomised placebo-controlled trial. Lancet. 2001 Apr 7;357(9262):1076-9. Weston S, Halbert A, Richmond P, Prescott SL. Effects of probiotics on atopic dermatitis: a randomised controlled trial. Arch Dis Child. 2005 Sep;90(9):892-7. Epub 2005 Apr 29. Animal Study - Perdigon G, Maldonado Galdeano C, Valdez JC, Medici M. Interaction of lactic acid bacteria with the gut immune system. Eur J Clin Nutr. 2002 Dec;56 Suppl 4:S21-6.	253

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Digestive health	at least 10[9] cfu/day	Human studies Review articles	Individual Human Studies - Easo JG, Measham JD, Munroe J. and Green-Johnson JM. 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 2002, 14: 73-83 - Johnson-Henry KC, Nadjafi M, Avitzur Y, Mictchell DJ, Ngan B-Y, Galindo-Mata E, Jones NL, Sherman PM. Amelioration of the effects of Citrobacter rodentium infection in mice by pretreatment with probiotics. Journal of Infectious Disease 2005, 191: 2106-2117 - Tlaskal P, Michkova E, Klayarova H, Jerabkova L, Nevoral J, Balackova J, Tejnecka, Valtrova V, Simandlova M, Kejvalova L. Lactobacillus acidophilus in the treatment of children with gastrointestinal tract illness. Cesko-Slovenska Pediatrie 1995, 51: 615-619 - Wallace TD, Bradley S, Buckley ND, Green-Johnson JM. Interactions of Lactic acid bacteria with human intestinal epithelial cells: effects on cytokine production. Journal of Food Protection 2003, 66(3): 466-472 Review - Bruzzese E, Canani RB, De Marco G, Guarino A. Microflora in inflammatory bowel diseases: a pediatric perspective. J Clin Gastroenterol. 2004 Jul;38(6 Suppl):S91-3 Additionnal Individual Human Studies - Bausserman M, Michail S. The use of Lactobacillus GG in irritable bowel syndrome in children: a double-blind randomized control trial. J Pediatr. 2005 Aug;147(2):197-201. - Donnet-Hugues A, Rochat F, Serrant P, Aeschlimann JM, Schiffrin EJ. Modulation of non specific mechanism of defenses by lactic	221

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					acid bacteria: effective dose. J Dairy Sci. 1999 May;82(5):863-9. - Hatakka K, Savilahti E, Ponka A, Meurman JH, Poussa T, Nase L, Saxelin M, Korpela R. Effect of long term consumption of probiotic milk on infections in children attending day care centres: double blind, randomised trial. BMJ. 2001 Jun 2;322(7298):1327	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus jjohnsoni La-19/CLbA5 and Bifidobacterium animalis ssp. lactis Bf-6/Bif-6/CB111 (Biogarde®/Bioghurt®/Bigarde®/Bighurt®-Cultures)					
		Natural / immune defences	at least 10[8] cfu/day			262

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Scientific/authoritative bodies Text book Reviews Human studies Animal and in vitro studies	Authoritative/Scientific Bodies Textbooks Brock, TD et al. (1994). Biology of Microorganisms, Prentices-Hall International. 403-405. Reviews Buttriss, J (1997). Nutritional properties of fermented milk products. International Journal of Dairy Technology 50 (1), 21-27. Cummings, JH et al. (2004). Passclaim - Gut Health and Immunity. Eur. J. Nutr. 43 (2). 119-122, 131-132 Fooks, LJ, Fuller, R, Gibson, GR (1999). Prebiotics, Probiotics and Human Gut Microbiology. International Dairy Journal 9, 53-61. Kneifel, W, Bonaparte, C (1998). Novel trends related to health-relevant foods: 1. Probiotics. Nutrition 22 (9), 357-363. Mitsuoka, T (1990). Bifidobacteria and their Role in Human Health. Journal of Industrial Microbiology and Biotechnology 6 (4), 263-267. Rasic, JL, Kurmann, JA (1983). Bifidobacteria and their Role. Microbiological, Nutritional-Physiological, Medical and Technological Aspects and Bibliography. Experientia Suppl. 39, 1-295. Individual Human Studies Kullen, MJ et al. (1996). Differentiation of ingested and endogenous Bifidobacteria by DNA fingerprinting demonstrates the survival of an unmodified strain in the gastrointestinal tract of humans. The Journal of Nutrition 127 (1). 89-94. Animal Study Tejada-Simon, MW et al. (1999). Ingestion	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					of yogurt containing L. acidophilus and Bifidobacterium to potentiate IgA responses to cholera toxin in mice. J. Dairy Science 82. 649-660 In Vitro Studies Shin, HS et al. (2000). Growth and viability of commercial Bifidobacterium ssp. in skim milk containing Oligosacchaides and Inulin. J. Food Science 65 (5), 884-887.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus jjohnsoni NCC 533 (La1) (Pasteur culture colection CNCM I 1225)					
		Natural defence / immune system	at least 109 cfu/day Fermented milk and spray-dried			263

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual human studies	Individual Human Studies Donnet-Hughes, A., Rochat, F., Serrant, P., Aeschlimann, J.M., Schiffrin, E.J. 1999. Modulation of nonspecific mechanisms of defense by lactic acid bacteria: effective dose. J Dairy Sci 82:863-869. Guarner, F., Malagelada, J.R. 2003. Gut flora in health and disease. Lancet 361:512-519. Link-Amster, H., Rochat, F., Saudan, K.Y., Mignot, O., Aeschlimann, J.M. 1994. Modulation of a specific humoral immune response and changes in intestinal flora mediated through fermented milk intake. FEMS Immunol Med Microbiol 10:55-63. Marteau, P., Vaerman, J.P., Dehennin, J.P., Bord, S., Brassart, D., Pochart, P., Desjeux, J.F., Rambaud, J.C. 1997. Effects of intrajejunal perfusion and chronic ingestion of Lactobacillus johnsonii strain La1 on serum concentrations and jejunal secretions of immunoglobulins and serum proteins in healthy humans. Gastroenterol Clin Biol 21:293-298. Schiffrin, E.J., Brassart, D., Servin, A.L., Rochat, F., Donnet-Hughes, A. 1997. Immune modulation of blood leukocytes in humans by lactic acid bacteria: criteria for strain selection. Am J Clin Nutr 66:515S-520S. Schiffrin, E.J., Rochat, F., Link-Amster, H., Aeschlimann, J.M., Donnet-Hughes, A. 1995. Immunomodulation of human blood cells following the ingestion of lactic acid bacteria. J Dairy Sci 78:491-497.. Animal Studies Blum, S., Schiffrin, E.J. (2003). Intestinal microflora and homeostasis of the mucosal immune response: implications for probiotic bacteria? Curr Issues Intest Microbiol 4:53-60.	

Gueniche, A., Benyacoub, J., Buetler, T. M., Smola, H. and Blum, S., Supplementation with oral probiotic bacteria maintains cutaneous immune homeostasis after UV exposure, Eur. J. Dermatol., 16: 511-7, 2006.

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Link, H., Rochat, F., Saudan, K.Y., Schiffrin, E. 1995. Immunomodulation of the gnotobiotic mouse through colonization with lactic acid bacteria. Adv Exp Med Biol 371A:465-467.

Prioult, G., Fliss, I. and Pecquet, S. (2003). Effect of probiotic bacteria on induction and maintenance of oral tolerance to beta-lactoglobulin in gnotobiotic mice. Clin Diagn Lab Immunol 10:787-792.

In Vitro Studies

Haller, D., Blum, S., Bode, C., Hammes, W.P., Schiffrin, E.J. 2000. Activation of human peripheral blood mononuclear cells by nonpathogenic bacteria in vitro: evidence of NK cells as primary targets. Infect Immun 68:752-759.

Haller, D., Bode, C., Hammes, W.P. 1999. Cytokine secretion by stimulated monocytes depends on the growth phase and heat treatment of bacteria: a comparative study

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					between lactic acid bacteria and invasive pathogens. Microbiol Immunol 43:925-935. Haller, D., Bode, C., Hammes, W.P., Pfeifer, A.M., Schiffrin, E.J., Blum, S. 2000. Non-pathogenic bacteria elicit a differential cytokine response by intestinal epithelial cell/leucocyte co-cultures. Gut 47:79-87. Haller, D., Serrant, P., Granato, D., Schiffrin, E. J., Blum, S. (2002). Activation of human NK cells by Staphylococci and Lactobacilli requires cell contact-dependent costimulation by autologous monocytes. Clinical and Diagnostic Laboratory Immunology, 9:649–657. Vidal, K., Donnet-Hughes, A., Granato, D. 2002. Lipoteichoic acids from Lactobacillus johnsonii strain La1 and Lactobacillus acidophilus strain La10 antagonize the responsiveness of human intestinal epithelial HT29 cells to lipopolysaccharide and gram-negative bacteria. Infect Immun 70:2057-2064.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus jjohnsoni NCC 533 (La1) (Pasteur culture colection CNCM I 1225)					
		Gut health	at least 10[8] cfu/day Fermented milk			231

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual human studies	Individual Human Studies - Felley, C.P., Corthesy-Theulaz, I., Rivero, J.L., Sipponen, P., Kaufmann, M., Bauerfeind, P., Wiesel, P.H., Brassart, D., Pfeifer, A., Blum, A.L., Michetti, P. 2001. Favourable effect of an acidified milk (LC-1) on Helicobacter pylori gastritis in man. Eur J Gastroenterol Hepatol 13:25-29. - Fukushima, Y., Yamano, T., Kusano, A., Takada, M., Amano, M., Iino, H. 2004. Effect of fermented milk containing Lactobacillus johnsonii La1 on defecation in healthy Japanese adults - a double blind placebo controlled study -. Bioscience Microflora. 23: 139-147. - Garrido, D., Suau, A., Pochart, P., Cruchet, S., Gotteland, M. 2005. Modulation of the fecal microbiota by the intake of a Lactobacillus johnsonii La1-containing product in human volunteers. FEMS Microbiology Letters 248:249–256. - Michetti, P., Dorta, G., Wiesel, P.H., Brassart, D., Verdu, E., Herranz, M., Felley, C., Porta, N., Rouvet, M., Blum, A.L., Corthesy-Theulaz, I. 1999. Effect of whey-based culture supernatant of Lactobacillus acidophilus (johnsonii) La1 on Helicobacter pylori infection in humans. Digestion 60:203-209. - Pantoflickova, D., Corthesy-Theulaz, I., Dorta, G., Stolte, M., Isler, P., Rochat, F., Enslen, M., Blum, A.L. 2003. Favourable effect of regular intake of fermented milk containing Lactobacillus johnsonii on Helicobacter pylori associated gastritis. Aliment Pharmacol Ther 18:805-813. - Yamano T, Iino H, Takada M, Blum S, Rochat F, Fukushima Y (2006) Improvement of the human intestinal flora by ingestion of the	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

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- Ibnou-Zekri, N., Blum, S., Schiffrin, E.J., von der Weid, T. 2003. Divergent patterns of colonization and immune response elicited from two intestinal Lactobacillus strains that display similar properties in vitro. Infect Immun 71:428-436.
- Link, H., Rochat, F., Saudan, K.Y., Schiffrin, E. 1995. Immunomodulation of the gnotobiotic mouse through colonization with lactic acid bacteria. Adv Exp Med Biol 371A:465-467.
- Prioult, G., Fliss, I. and Pecquet, S. (2003). Effect of probiotic bacteria on induction and maintenance of oral tolerance to beta-lactoglobulin in gnotobiotic mice. Clin Diagn Lab Immunol 10:787-792.
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Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

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- Bernet-Camard, M.F., Lievin, V., Brassart, D., Neeser, J.R., Servin, A.L., Hudault S. 1997. The human Lactobacillus acidophilus strain LA1 secretes a nonbacteriocin antibacterial substance(s) active in vitro and in vivo. Appl Environ Microbiol 63:2747-2753.
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Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Knabenhans, C., Brassart, D., De Antoni, G.L., Schiffrin, E.J. (2001). Inhibition of Giardia intestinalis by extracellular factors from Lactobacilli: an in vitro study. Appl Environ Microbiol 67:5037-5042.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus johnsonii La-19/CLbA5 and Bifidobacterium animalis ssp. lactis Bf-6/Bif-6/CB111 (Biogarde®/Bioghurt®/Bigarde®/Bighurt®-Cultures)					
		Intestinal flora / digestive health	at least 10[8] cfu/day			230

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Scientific/authoritative bodies Text book Reviews Human studies Animal and In vitro studies	Authoritative/Scientific Bodies Textbooks - Brock, TD et al. (1994). Biology of Microorganisms, Prentices-Hall International. 403-405. Reviews - Buttriss, J (1997). Nutritional properties of fermented milk products. International Journal of Dairy Technology 50 (1), 21-27. - Cummings, JH et al. (2004). Passclaim - Gut Health and Immunity. Eur. J. Nutr. 43 (2). 119-122, 131-132 - Fooks, LJ, Fuller, R, Gibson, GR (1999). Prebiotics, Probiotics and Human Gut Microbiology. International Dairy Journal 9, 53-61. - Kneifel, W, Bonaparte, C (1998). Novel trends related to health-relevant foods: 1. Probiotics. Nutrition 22 (9), 357-363. - Mitsuoka, T (1990). Bifidobacteria and their Role in Human Health. Journal of Industrial Microbiology and Biotechnology 6 (4), 263-267. - Rasic, JL, Kurmann, JA (1983). Bifidobacteria and their Role. Microbiological, Nutritional-Physiological, Medical and Technological Aspects and Bibliography. Experientia Suppl. 39, 1-295. Individual Human Studies - Heidt, PJ (1989). Gnotobiotics and bone marrow transplantation. Publication of the Radiobiological Institute Rijswijk, Netherlands. S. 96-97 - Kullen, MJ et al. (1996). Differentiation of ingested and endogenous Bifidobacteria by DNA fingerprinting demonstrates the survival of an unmodified strain in the gastrointestinal tract of humans. The Journal of Nutrition 127 (1). 89	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					-94. Animal Study - Tejada-Simon, MW et al. (1999). Ingestion of yogurt containing L. acidophilus and Bifidobacterium to potentiate IgA responses to cholera toxin in mice. J. Dairy Science 82. 649-660 In Vitro Studies - Shin, HS et al. (2000). Growth and viability of commercial Bifidobacterium ssp. in skim milk containing Oligosacchaides and Inulin. J. Food Science 65 (5), 884-887.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus paracasei NCC 2461 (ST11) (Pasteur culture colection CNCM I 2116)					
		Natural defence / immune system				264

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual human studies	Individual Human Studies Bunout D., Barrera G., Hirsch S., Gattas V., de la Maza MP., Haschke F., Steenhout P., Klassen P., Hager C., Avendano M., Petermann M. and Munoz C. Effects of a Nutritional Supplement on the Immune Response and Cytokine Production in Free-Living Chilean Elderly. J. Parental Enteral Nutrition 2004, 28(5):348-354 Additional Supportive Data Von der Weid T., Ibnou-Zekri N., Pfeifer A. (2002). Novel probiotics for the management of allergic inflammation. Digest. Liv. Dis. ;34(suppl.2):S25-S28. Animal Studies Ibnou-Zekri N., Blum S., Schiffrin J., von der Weild T. Divergent patterns of colonization and immune response elicited from two Intestinal Lactobacillus strains that display similar properties in vitro. Infection and Immunity 2003; 1 (73): 428-436. Prioult G, Fliss I, Pecquet S. (2003) Effect of probiotic bacteria on induction and maintenance of oral: Tolerance to Lactoglobulin in Gnotobiotic mice. Clinical Lab Immunol. 787–92 Prioult G., Pecquet S., Fliss I. (2004). Stimulation of interleukin-10 production by acidic _-Lactoglobulin-derived peptides hydrolyzed with Lactobacillus paracasei NCC2461 peptidases. Clin. Diagn. Lab. Immunol. ;11(2):266-271. Von der Weid T., Ibnou-Zekri N., Pfeifer A. Induction by lactic acid bacterium of a population of CD4+ T cells with low proliferative capacity that produce transforming growth factor beta and interleukin-10. Clinical and Diagnostic laboratory immunology 2001; 4 (8):	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					695-701.	
	Lactobacillus paracasei NCC 2461 (ST11) (Pasteurculture colection CNCM I 2116)					
		Gut health	at least 10[9] cfu/day Fermented milk	Individual human studies	Sarker SA, Sultana S, Fuchs GJ, Alam NH, Azim T, Brussow H, Hammarstr6m L, Lactobacillus paracasei strain ST11 has no effect on rotavirus but ameliorates the outcome of non rotavirus diarrhea in children from Bangladesh, Pediatrics, 2005:116: e221-e228 Animal Studies Ibnou-Zekri N., Blum S., Schiffrin EJ., von der Weid T., Divergent Patterns of Colonization and Immune Response Elicited from Two Intestinal Lactobacillus Strains That Display Similar Properties In Vitro. Infection and Immunity, 2003, p. 428-436. Verdu E. F., P. Bercik, G. Bergonzelli, X-X. Huang, P. Blennerhasset, F. Rochat, M. Fiaux, R. Mansourian, I. Corthesy-Theulaz, S. M. Collins. Lactobacillus paracasei normalizes muscle hypercontractility in a murine model of post-infective gut dysfunction. Gastroenterology 2004 127 (3): 826-837. Verdu E.F., P Bercik, M Verma-Gandhu, X-X Huang, P Blennerhassett, W Jackson, Y Mao, L Wang, F Rochat and S M Collins. Specific probiotic therapy attenuates antibiotic induced visceral hypersensitivity in mice. 2006, Gut;55;182-190. Conway P. L., Gorbach S. L., Goldin B. R., Survival of lactic acid bacteria in the human stomach and adhesion to intestinal cells, J Dairy Sci 1987; 70: 1-12	232

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus paracasei ssp. paracasei CRL-431 (=L. casei 431)					
		Natural defence / immune system	at least 10[10] cfu/day			265

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human study Animal sutdy In vitro study	Individual Human Studies Christensen HR, Larsen CN, Kæstel P, Rosholm LB, Sternberg C, Michaelsen KF, Frøkiær H. 2006. Immunomodulatory potential of supplementation with probiotics: a dose-response study in healthy young adults. FEMS Immunology & Medical Microbiology 47(3): p. 380-390. de Vrese M, Rautenberg P, Laue C, Koopmans M, Herremans T, Schrezenmeir J. Probiotic bacteria stimulate virus-specific neutralizing antibodies following a booster polio vaccination. Eur J Nutr 2004, 394 Gaon, D., Garmendia, C., Murrielo, N.O., de Cucco Games, A., Cerchio, A., Quintas, R., Gonzalez, S.N., Oliver, G. Effect of Lactobacillus strains (L. casei and L. acidophilus Cerela) on bacterial overgrowth-related chronic diarrhea. 2002. Medicina, 62: 159-163. Gaon, D., Doweck, Y., Zavaglia, A., Holgado, A., Oliver, G. Lactose digestion by milk fermented with human strains of Lactobacillus acidophilus and Lactobacillus casei. 1995. Medicina (Buenos Aires), 55: 237-242 Gaon D, Garcia H, Winter L, Rodriguez N, Quintas R, Gonzalez SN, Oliver G. Effect of Lactobacillus strains and Saccharomyces boulardii on persistent diarrhea in children. Medicina, 63: 293-298 Gonzalez, S., Albarracin, G., Locascio de Ruiz Pesce, M., Male, M., Apella, M.C., Pesce de Ruiz Holgado, A., Oliver, G. Prevention of infantile diarrhea by fermented milk. 1990. Microbiologie-Aliments-Nutrition, 8:349-354 Gonzalez, S., Cardozo, R., Apella, M., Oliver, G. Biotherapeutic role of fermented milk. 1995. Biotherapy, 8: 129-134.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

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Cano, P.G., Aguero, G., Perdigon, G. Adjuvant effects of Lactobacillus casei added to a renutrition diet in a malnourished mouse model. 2002. Biocell, 26(1):35-48.

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Nader de Macias, M.E., Romero, C., Apella, M.C., Gonzalez, S.N., Oliver, G. Prevention of infection produced by Escherichia coli and Listeria monocytogenes by feeding milk fermented with Lactobacilli. 1993. Journal of Food Protection, 56 (5): 401-405.

Perdigon, G., Alvarez, S., Nader de Macias, M., Roux, M., Pesce de Ruiz Holgado, A. The oral administration of lactic acid bacteria increase the mucosal intestinal immunity in response to enteropathogens. 1990. Journal of Food Protection, 53 (5): 404-410.

Perdigon, G., Nader de Macia, M., Alvarez, S., Oliver, G., Pesce de Ruiz Holgado, A. Prevention of gastrointestinal infection using immunobiological methods with milk fermented with Lactobacillus casei and Lactobacillus acidophilus. 1990. Journal of Dairy Research, 57: 255-264.

Perdigon, G., Alvarez, S., Medici, M.,

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Pesce de Ruiz Holgado, A. Influence of the use of Lactobacillus casei as an oral adjuvant on the levels of secretory IgA during an infection with Salmonella typhimurium. 1993. Food & Agricultural Immunology, 5: 27-37. Perdigon, G., Nader de Macias, M.E., Alvarez, S., Oliver, G., Pesce de Ruiz Holgado, A. Systemic augmentation of the immune response in mice by feeding fermented milk with Lactobacillus casei and Lactobacillus acidophilus. 1988. Immunology, 63: 17-23. Perdigon, G., Alvarez, S., Nader de Macias, M.E., Margini, R.A., Oliver, G., de Ruiz Holgado, A.P. Lactobacilli administered orally induce release of enzymes from peritoneal macrophages in mice. 1986. Milchwissenschaft, 41(6): 344-348. Perdigon, G., Alvarez, S., Gobbato, N., de Budeguer, M.V., de Ruiz Holgado, A.A.P. Comparative effect of the adjuvant capacity of Lactobacillus casei and lipopolysaccharide on the intestinal secretory antibody response and resistance to Salmonella infection in mice. 1995. Food & Agricultural Immunology, 7: 283-294. Perdigon, G., Medici, M., Bibas Bonet de Jorrat, M.E., Valverde de Budeguer, M., Pesce de Ruiz Holgado, A. Immunomodulating effects of lactic acid bacteria on mucosal and tumoral immunity. 1993. Int. J. Immunotherapy, IX (1): 29-52. Perdigon, G., Alvarez, S., Pesce de Ruiz Holgado, A. Immunoadjuvant activity of oral Lactobacillus casei: influence of dose on the secretory immune response and protective capacity in intestinal infections. 1991. Journal of Dairy Research, 58: 485-496. Perdigon, G., Nader de Macias, M.E., Alvarez, S., Oliver, G., Pesce de Ruiz Holgado,	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

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Perdigon, G.,Nader de Macias, M.E., Alvarez, S., Medici, M., Oliver, G., Pesce de Ruiz Holgado, A. Effect of a mixture of Lactobacillus casei and Lactobacillus acidophilus administered orally on the immune system in mice. 1986. Journal of Food Protection, 49 (12): 986-989

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Petrino, S., Jorrat, M., Perdigon, G. Effect of different lactic acid bcteria on immune response in corticoid-immunosuppressed mice. 1996. Microbiologie - Aliments - Nutrition, 14: 227-236.

Petrino, S., Eugenia, M., de Jorrat, B., de Budeguer, M., Perdigon, G. Influence of the oral administration of different latic acid bacteria on intestinal microflora and IgA-secreting cells in mice treated with ampicillin. 1997. Food and Agricultural

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Immunology, 9: 265-275. Villena, J., Racedo S., Aguero G., Bru E., Medina M., Alvarez S. 2005. Lactobacillus casei improves resistance to pneumococcal respiratory infection in malnourished mice. J. Nutr. 135: 1462-1469 Vitini, E., Alvarez, S., Medina, M., Medici, M., de Buduguer, M.V., Perdigon, G. Gut mucosal immunostimulation by lactic acid bacteria. 2000. Biocell, 24(3): 223-232. In Vitro Studies Ambrosini, V., Gonzalez, S., Holgado, A., Oliver, G. Study of the morphology of the cell walls of some strains of lactic acid bacteria and related species. 1998. Journal of Food Protection, 61 (5): 557-562. Ambrosini, V., Gonzalez, S., Holgado, A., Oliver, G. Cell wall sugars from strains used as starters for dairy products. 1994. Microbiologie - Aliments - Nutrition, 12: 17-21 Ambrosini, V., Gonzalez, S., Perdigon, G., Holgado, A., Oliver, G. Chemical composition of the cell wall of lactic acid bacteria and related species. 1996. C.P. Bulletin, 44 (12): 2263-2267 Apella, M.C., Gonzalez, S.N., Nader de Macias, M.E., Romero, N., Oliver, G. In vitro studies on the inhibition of the growth of Shigella sonnei by Lactobacillus casei and Lactobacillus acidophilus. 1992. Journal of Applied Bacteriology, 73: 480-483. Gonzalez, S., Apella, M., Romero, N., Macias, M., Oliver, G. Inhibition of enteropathogens by lactobacilli strains used in fermented milk. 1993. Journal of Food Protection, 56 (9): 773-776. Vinderola G, Matar C, Perdigon G. 2005. Role of intestinal epithelial cells in immune effects mediated by gram-positive probiotic bacteria: Involvement of toll-like receptors.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Clinical and Diagnostic Laboratory Immunology (12)9: 1075-1084	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus paracasei ssp. paracasei CRL-431 (=L. casei 431) and Lactobacillus acidophilus					
		Intestinal flora Digestive system	10E8-10E9 cfu/day			730

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Peer-reviewed scientific papers	Human studies: #407 Gaon, D., Garmendia, C., Murrielo, N.O., de Cucco Games, A., Cerchio, A., Quintas, R., Gonzalez, S.N., Oliver, G. Effect of Lactobacillus strains (L. casei and L. acidophilus Cerela) on bacterial overgrowth-related chronic diarrhea. 2002. Medicina, 62: 159-163. #333 Gonzalez, S., Cardozo, R., Apella, M., Oliver, G. Biotherapeutic role of fermented milk. 1995. Biotherapy, 8: 129-134. #419 Gaon D, Garcia H, Winter L, Rodriguez N, Quintas R, Gonzalez SN, Oliver G. Effect of Lactobacillus strains and Saccharomyces boulardii on persistent diarrhea in children. Medicina, 63: 293-298 Other human studies: #115 Lin. M.-Y., Savaiano, D., Harlander, S. Influence of nonfermented dairy products containing bacterial starter cultures on lactose maldigestion in humans. 1991. J. Dairy Sci,. 74: 87-95 Animal studies: #222 Perdigon, G., Alvarez, S., Nader de Macias, M., Roux, M., Pesce de Ruiz Holgado, A. The oral administration of lactic acid bacteria increase the mucosal intestinal immunity in response to enteropathogens. 1990. Journal of Food Protection, 53 (5): 404-410. #244 Perdigon, G., Nader de Macia, M., Alvarez, S., Oliver, G., Pesce de Ruiz Holgado, A. Prevention of gastrointestinal infection using immunobiological methods with milk fermented with Lactobacillus casei and Lactobacillus acidophilus. 1990. Journal of Dairy Research, 57: 255-264. #245 Perdigon, G., Alvarez, S., Medici, M., Pesce de Ruiz Holgado, A. Influence of the use of Lactobacillus casei as an oral adjuvant on	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

the levels of secretory IgA during an infection with Salmonella typhimurium. 1993. Food & Agricultural Immunology, 5: 27-37.

#293 Perdigon, G., Nader de Macias, M.E., Alvarez, S., Oliver, G., Pesce de Ruiz Holgado, A. Systemic augmentation of the immune response in mice by feeding fermented milk with Lactobacillus casei and Lactobacillus acidophilus. 1988. Immunology, 63: 17-23.

298 Nader de Macias, M.E., Romero, C., Apella, M.C., Gonzalez, S.N., Oliver, G. Prevention of infection produced by Escherichia coli and Listeria monocytogenes by feeding milk fermented with Lactobacilli. 1993. Journal of Food Protection, 56 (5): 401-405.

#299 Perdigon, G., Alvarez, S., Gobbato, N., de Budeguer, M.V., de Ruiz Holgado, A.A.P. Comparative effect of the adjuvant capacity of Lactobacillus casei and lipopolysaccharide on the intestinal secretory antibody response and resistance to Salmonella infection in mice. 1995. Food & Agricultural Immunology, 7: 283-294.

#301 Perdigon, G., Alvarez, S., Pesce de Ruiz Holgado, A. Immunoadjuvant activity of oral Lactobacillus casei: influence of dose on the secretory immune response and protective capacity in intestinal infections. 1991. Journal of Dairy Research, 58: 485-496.

#302 Perdigon, G., Nader de Macias, M.E., Alvarez, S., Oliver, G., Pesce de Ruiz Holgado, A. Effect of perorally administered lactobacilli on macrophage activation in mice. 1986. Infection and Immunity, 53 (2): 404-410

#336 Macias, M., Apella, M., Romero, N., Gonzalez, S., Oliver, G. Inhibition of Shigella sonnei by Lactobacillus casei and Lactobacillus acidophilus. 1992. Journal of Applied

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Bacteriology, 73: 407-411 #340 de Petrino, S., Eugenia, M., de Jorrat, B., de Budeguer, M., Perdigon, G. Influence of the oral administration of different latic acid bacteria on intestinal microflora and IgA-secreting cells in mice treated with ampicillin. 1997. Food and Agricultural Immunology, 9: 265-275. #454 Maldonado Galdeano C and Perdigon G. 2004. Role of viability of probiotic strains in their persistence in the gut and in mucosal immune stimulation. J. Appl. Microbiol. 7, 673-681 In vitro studies: #297 Apella, M.C., Gonzalez, S.N., Nader de Macias, M.E., Romero, N., Oliver, G. In vitro studies on the inhibition of the growth of Shigella sonnei by Lactobacillus casei and Lactobacillus acidophilus. 1992. Journal of Applied Bacteriology, 73: 480-483. #328 Gonzalez, S., Apella, M., Romero, N., Macias, M., Oliver, G. Inhibition of enteropathogens by lactobacilli strains used in fermented milk. 1993. Journal of Food Protection, 56 (9): 773-776. # 335 Ambrosini, V., Gonzalez, S., Perdigon, G., Holgado, A., Oliver, G. Chemical composition of the cell wall of lactic acid bacteria and related species. 1996. C.P. Bulletin, 44 (12): 2263-2267. #338 Ambrosini, V., Gonzalez, S., Holgado, A., Oliver, G. Study of the morphology of the cell walls of some strains of lactic acid bacteria and related species. 1998. Journal of Food Protection, 61 (5): 557-562. #486 Ding W, Wang H, Griffiths MW. 2005. Probiotics down-regulate flaA ó28 promotor in Campylobacter jejuni.J. Food Prot. 68 (11): 2295-2300.	

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	Lactobacillus paracaseii CUL08 NCIMB 30154 Lactobacillus salivarius CUL 61 Bifidobacterium adolescentis (bifidum) CUL20 NCIMB 30153 Bifidobacterium lactis CUL34 NCIMB 30172					
		Gut Flora/ Immune System	3x10^9cfu/day 3x10^19cfu/day	Human Studies (Double Blind Placebo Controlled Randomised Studies), in vitro studies	Plummer S et al. Effects of probiotics on the composition of the intestinal microbiota following antibiotic therapy. International Journal of Antimicrobial Agents, 26, 69-74 (2005) Niers et al, Selection Probiotic Bacteria For Prevention Of Allergic Diseases: Immunomodulation Of Neonatal Dendritic Cells. Clinical and Experimental Immunology. 149 344-352 (2007) Daniel C et al., Selecting Lactic Acid Bacteria for Their Safety and Functionality by Use of a Mouse Colitis Model. Applied and Environmental Microbiology. 17 (9) 5799-5805 (2006) Gareth Morgan, Probiotics of in the prevention of atopy in infants and children. ISRCTN Register No 26287422 (2005)	983

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus plantarum					
		Contains Probiotic that confers a benefit on the host	At least 107 cfu / day	Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	WHO definition of probiotic FAO/WHO (2001). Guidelines for the Evaluation of Probiotics in Food. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, April 30 and May 1, 2002. Gorbach SL and Goldin BR. (1992). Nutrition and the gastrointestinal microflora. Nutr Rev. 1992 Dec;50(12):378-81 Rolfe, RD. (2000). The role of probiotic cultures in the control of gastrointestinal health. J Nutr. Feb;130(2S Suppl): 396S-402S. Fuller, R and Perdigon, G. (2003). Gut flora, nutrition, immunity and Health. Edited by R Fuller and G Perdigon. Blackwell Publishing.	910
		Digestive Balance	Strains must be: Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable	National Institute of Health Public Access Manuscript	Brown AC et al., Nutr Clin Care 2004;7(2): 56-68	2,276

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 100 million bacteria per portion/dose			
		Maintenance of healthy Immune system	At least 107 cfu / day			938

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks & peer reviewed journal articles	Cario E. (2005). Bacterial interactions with cells of the intestinal mucosa: Toll-like receptors and NOD2. Gut. 2005 Aug;54(8):1182-93. Epub 2005 Apr 19. Review. Bujalance C, Moreno E, Jimenez-Valera M, Ruiz-Bravo A. (2007). A probiotic strain of Lactobacillus plantarum stimulates lymphocyte responses in immunologically intact and immunocompromised mice. Int J Food Microbiol. 2007 Jan 1;113(1):28-34. Epub 2006 Oct 5. Perdigon G, Vintini E, Alvarez S, Medina M, Medici M. (1999). Study of the possible mechanisms involved in the mucosal immune system activation by lactic acid bacteria. J Dairy Sci. 1999 Jun;82(6):1108-14. Hirose Y, Murosaki S, Yamamoto Y, Yoshikai Y, Tsuru T. (2006). Daily intake of heat-killed Lactobacillus plantarum L-137 augments acquired immunity in healthy adults. J Nutr. 2006 Dec;136(12):3069-73.	
		Beneficial effect on intestinal microflora, gut integrity, digestion	At least 107 cfu / day			924

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks & peer reviewed journal articles	Barefoot SF, Nettles CG.(1993). Antibiosis revisited: bacteriocins produced by dairy starter cultures. J Dairy Sci. 1993 Aug;76(8):2366-79. Review. Atassi F, Brassart D, Grob P, Graf F, Servin AL. (2006). In vitro antibacterial activity of Lactobacillus helveticus strain KS300 against diarrhoeagenic, uropathogenic and vaginosis-associated bacteria.J Appl Microbiol. 2006 Sep;101(3):647-54. Hugo AA, De Antoni GL, Perez PF. (2006). Lactobacillus delbrueckii subsp lactis strain CIDCA 133 inhibits nitrate reductase activity of Escherichia coli. Int J Food Microbiol. 2006 Oct 1;111(3):191-6. Epub 2006 Aug 22.	
		Immune support	Strains must be: Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in	Clinical trial Human with Atopic dermatitis	Yim et al., J Microbiol. Biotechnol., 2006; 16(11): 1699-1705	2,277

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 100 million bacteria per portion/dose			

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus plantarum 299v					
		Digestive system	at least 20x10[9] cfu/ day			234

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative body Individual human studies Animal and in vitro studies (supporting)	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. Individual Human Studies Johansson, ML, Nobaek S, Berggren A. Survival of Lactobacillus plantarum DSM 9843 (299v) and effect on the short-chain fatty acid content of faeces after ingestion of a rose-hip drink with fermented oats. Int J Food Microbiol 1998, Vol 42, 29-38. Niedzielin, K., Kordecki, H. and B. Birkenfeld. A controlled, double-blind, randomized study on the efficacy of Lactobacillus plantarum 299v in patients with irritable bowel syndrome. European Journal of Gastroenterology & Hepatology, 2001, Vol 13 (10): 1143-1147. Nobaek, S., Johansson, M-L., Molin, G., Ahrne, S., and B. Jeppsson. Alteration of Intestinal Microflora is associated with reduction in abdominal bloating and pain in patients with Irritable Bowel Syndrome. The American Journal of Gastroentorology, 2000, Vol 95 (5): 1231-1238. Additional Human Studies Cunningham Rundles, S, Ahrne, S, Bengmark, S, Hohann-Liang, R, Marshall, F, Metakis, L, Califano, C, Dunn, A-M, Grassey, C, Hinds, G and J Cervia. Probiotics and Immune Response. The American Journal of Gastroenterology 2000, Vol 95 (1) Suppl: S22 -S25. Goossens, D, Jonkers, D, Russel, M, Stobberingh, E, Van Den Bogaard and R StockbrUgger. The effect of Lactobacillus plantarum 299v on the bacterial composition	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

and metabolic activity in faeces of healthy volunteers: a placebo-controlled study on the onset and duration of effects. Aliment Pharmacol Ther, 2003, Vol 18 (5): 495-505.

Goossens, D, Jonkers DM, Russel MG, Stobberingh EE, and RW StockbrUgger. The effect of a probiotic drink with Lactobacillus plantarum 299v on the bacterial composition in faeces and mucosal biopsies of rectum and ascending colon. Aliment Pharmacol Ther, 2006, Vol 23 (2): 255-263.

Johansson, M-L, Molin, G, Jeppsson, B, Nobaek, S, Ahrnd, S and S Bengmark. Administration of
different Lactobacillus strains in fermented oatmeal soup: in vivo colonization of human intestinal
mucosa and effect on indigenous flora. Applied and Environmental Microbiology 1993, Vol 59 (1):
15-20.

Klarin B, Johansson M-L, Molin G, Larsoon A and B Jeppsson. Adhesion of the probiotic bacterium Lactobacillus plantarum 299v onto the gut mucosa in critically ill patients: a randomized open trial. Critical Care 2005, Vol 9 (3): R285-R293.

Onning, G, Berggren, A, Drevelius, M, Jeppsson, B, Lindberg, A M and M-L Johansson. Influence of a drink containing different antioxidants and Lactobacillus plantarum 299v on plasma total antioxidant capacity, selenium status and faecal microbial flora. Int J Sci Nutr 2003, Vol 54 (4): 281-289.

Wullt, M, Johansson, M-L and I Odenholt. Lactobacillus plantarum 299v for the treatment of Recurrent Clostridium difficile-associated Diarrhoea: A double-blind, placebo controlled trial. Scand J Infect Dis 2003, Vol 35: 365-367.

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					Animal Study Mangell P, Lennernas, P, Wang, M, Olsson, C, Arhne, S, Molin, G, Thorlacius, H and B Jeppsson. Adhesive capability of Lactobacillus plantarum 299v is important for preventing bacterial translocation in endotoxemic rats. APMIS 2006, Vol 114 (9): 611-618. In Vitro Studies Hutt, P, Shchepetova, J, Loivukene, K, Kullisaar, T and M Mikelsaar. Antagonistic activity of probiotic Lactobacilli and Bifidobacteria against entero and uropathogens. J Appl Microbiol 2006, Vol 100 (6): 1324-1332. Mangell P, Jacobsen, C N, Rosenfeldt, N, Hayford, A E, Moller, P L, Michaelsen, K F, Paerregaard, A, Sandstrom, B, Tvece, M and M Jakobsen. 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 human. Applied and Env Microbiology 1999, Vol 65 (11): 4949-4956. Michail S. and F Abernathy. Lactobacillus plantarum reduces the in vitro secretory response of intestinal epithelial cells to enteropathogenic Escherichia coli infection. J Pediatr Gastroenterol Nutr Sept 2002, 35 (3):350-355.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus plantarum Rosel-1012					
		Digestive health	at least 1x10[9] cfu/day	Human studies In vitro study	Individual Human Studies Anderson AD, McNaught CE, Jain PK, MacFie J. Randomised clinical trial of synbiotic therapy in elective surgical patients. Gut. 2004 Feb;53(2):241-5. Goossens DA, Jonkers DM, Russel MG, Stobberingh EE, Stockbrugger RW. The effect of a probiotic drink with Lactobacillus plantarum 299v on the bacterial composition in faeces and mucosal biopsies of rectum and ascending colon. Aliment Pharmacol Ther. 2006 Jan 15;23(2):255-63. Koll-Klais P, Mandar R, Leibur E, Marcotte H, Hammarstrom L, Mikelsaar M. Oral lactobacilli in chronic periodontitis and periodontal health: species composition and antimicrobial activity. Oral Microbiol Immunol. 2005 Dec;20(6):354-61 In Vitro Study Brink M, Todorov SD, Martin JH, Senekal M, Dicks LM. The effect of prebiotics on production of antimicrobial compounds, resistance to growth at low pH and in the presence of bile, and adhesion of probiotic cells to intestinal mucus. J Appl Microbiol. 2006 Apr;100(4):813-20.	233

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus plantarum Rosell-1012					
		Immune defenses / support of immunity	at least 1x10[9] cfu/day	Human study In vitro study	Individual Human Study - Koll-Klais P, Mandar R, Leibur E, Marcotte H, Hammarstrom L, Mikelsaar M. Oral lactobacilli in chronic periodontitis and periodontal health: species composition and antimicrobial activity. Oral Microbiol Immunol. 2005 Dec;20(6):354-61. In Vitro Study Brink M, Todorov SD, Martin JH, Senekal M, Dicks LM. The effect of prebiotics on production of antimicrobial compounds, resistance to growth at low pH and in the presence of bile, and adhesion of probiotic cells to intestinal mucus. J Appl Microbiol. 2006 Apr;100(4):813-20.	266

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus reuteri ATCC 55730					
		Natural defence	at least 10[8] cfu/day daily consumption			267

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual human studies	Reviews Casas IA, Dobrogosz WJ. Validation of the probiotic concept: Lactobacillus reuteri confers broad-spectrum protection against disease in humans and animals. Microbial Ecology in Health and Disease 2006; 12:247-285. Connolly E. Lactobacillus reuteri ATCC 55730 – A clinically proven probiotic. Nutrafoods 2004; 3:15-22. Dobrogosz WJ. Enhancement of human health with Lactobacillus reuteri. A probiotic, immunobiotic and immunoprobiotic. Nutrafoods 2005;4:15-28. Individual Human Studies Caglar,E.; Cildir,S.K.; Ergeneli,S.; Sandalli,N.; Twetman,S. Salivary mutans streptococci and lactobacilli levels after ingestion of the probiotic bacterium Lactobacillus reuteri ATCC 55730 by straws or tablets. Acta Odontol. Scan.2006; 64:314-318 Nikawa H, Makihira S, Fukushima H et al. Lactobacillus reuteri in bovine milk fermented decreases the oral carriage of mutans streptococci. Int.J.Food Microbiol. 2004;95:219-23. Tubelius P, Stan V, Zachrisson A. Increasing work-place healthiness with the probiotic Lactobacillus reuteri: A randomised, double-blind placebo-controlled study. Environ.Health 2005;4:25. Valeur N, Engel P, Carbajal N, Connolly E, Ladefoged K. Colonization and immunomodulation by Lactobacillus reuteri ATCC 55730 in the human gastrointestinal tract. Appl.Environ.Microbiol. 2004;70:1176-81. Additional Human Studies Imase K, Tanaka A, Tokunaga K, Sugano H, Takahashi S. Lactobacillus reuteri tablets	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

can suppress Helicobacter pylori infection: a double-blind, randomised, placebo-controlled cross-over clinical study. Am J Gastroenterol 2005; 100(S9): abstract No. 98.

Krasse P, Carlsson B, Dahl C, Paulsson A, Nilsson A, Sinkiewicz G.Decreased gum bleeding and reduced gingivitis by the probiotic Lactobacillus reuteri. Swed Dent J 2006; 30:55-60

Niv E., Naftali T., Hallak R. and 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. Clin.Nutr 24, 925-931.

Saggioro A, Caroli M, Pasini M, Bortoluzzi F, Girardi L, Pilone G. Helicobacter pylori eradication with Lactobacillus reuteri. A double blind placebo-controlled study. Dig Liver Dis 37(suppl 1) 2005; S88, abstr. PO1.49

Shornikova AV, Casas IA, Isolauri E, Mykkanen H, Vesikari T. Lactobacillus reuteri as a therapeutic agent in acute diarrhea in young children. J Pediatr.Gastroenterol.Nutr. 1997;24:399-404.

Shornikova AV, Casas IA, Mykkanen H, Salo E, Vesikari T. Bacteriotherapy with Lactobacillus reuteri in rotavirus gastroenteritis. Pediatr Infect Dis J 1997;16:1103-7.

Weizman Z, Asli G, Alsheikh A. Effect of a probiotic infant formula on infections in child care centers: comparison of two probiotic agents. Pediatrics 2005;115:5-9.

Wolf B.W., Galeb K.A., Ataya D.G. and Casas I.A. (1995) Safety and tolerance of lactobacillus reuteri in healthy adult subjects. Microbial Ecol Health Dis 8, 41-50.

Wolf B.W., Wheeler K.B., Ataya D.G. and Garleb K.A. (1998) Safety and tolerance of

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Lactobacillus reuteri supplementation to a population infected with the human immunodeficiency virus. Food Chem.Toxicol. 36, 1085-1094.	
		Intestinal flora	at least 1x10[8] cfu/day daily consumption			235

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual human studies	Reviews Casas IA, Dobrogosz WJ. Validation of the probiotic concept: Lactobacillus reuteri confers broadspectrum protection against disease in humans and animals. Microbial Ecology in Health and Disease 2006; 12:247-285. Connolly E. Lactobacillus reuteri ATCC 55730 – A clinically proven probiotic. Nutrafoods 2004; 3:15-22. Dobrogosz WJ. Enhancement of human health with Lactobacillus reuteri. A probiotic, immunobiotic and immunoprobiotic. Nutrafoods 2005;4:15-28. Gibson GR, Rouzaud G, Brostoff J, Rayment N. An evaluation of probiotic effects in the human gut: microbial aspects. Final Technical report for Food Standards Agency (FSA) 2005 project ref G01022. http://www.food.gov.uk/multimedia/pdfs/probioticreport.pdf Individual Human Studies Valeur N, Engel P, Carbajal N, Connolly E, Ladefoged K. Colonization and immunomodulation by Lactobacillus reuteri ATCC 55730 in the human gastrointestinal tract. Appl.Environ.Microbiol. 2004;70:1176-81. Wolf B.W., Galeb K.A., Ataya D.G. and Casas I.A. (1995) Safety and tolerance of lactobacillus reuteri in healthy adult subjects. Microbial Ecol Health Dis 8, 41-50. Additional Human Studies Caglar E., Cildir S.K., Ergeneli S., Sandalli N., Twetman S. Salivary mutans streptococci and lactobacilli levels after ingestion of the probiotic bacterium Lactobacillus reuteri ATCC 55730 by straws or tablets. Acta Odontol. Scan.2006; 64:314-318 Imase K, Tanaka A, Tokunaga K, Sugano	

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H, Takahashi S. Lactobacillus reuteri tablets can suppress Helicobacter pylori infection: a double-blind, randomised, placebo-controlled cross-over clinical study. Am J Gastroenterol 2005; 100(S9): abstract No. 98.

Krasse P, Carlsson B, Dahl C, Paulsson A, Nilsson A, Sinkiewicz G.Decreased gum bleeding and reduced gingivitis by the probiotic Lactobacillus reuteri. Swed Dent J 2006; 30:55-60

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Shornikova AV, Casas IA, Mykkanen H, Salo E, Vesikari T. Bacteriotherapy with Lactobacillus reuteri in rotavirus gastroenteritis. Pediatr Infect Dis J 1997;16:1103-7.

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					Weizman Z, Asli G, Alsheikh A. Effect of a probiotic infant formula on infections in child care centers: comparison of two probiotic agents. Pediatrics 2005;115:5-9. Wolf B.W., Wheeler K.B., Ataya D.G. and Garleb K.A. (1998) Safety and tolerance of Lactobacillus reuteri supplementation to a population infected with the human immunodeficiency virus. Food Chem.Toxicol. 36, 1085-1094.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus rhamnosus					
		Beneficial effect on intestinal microflora, gut integrity, digestion	At least 107 cfu / day	Textbooks & peer reviewed journal articles	Gill, H.S. (2003).. Probiotics to enhance anti-infective defences in the gastrointestinal tract. Best Practice & Research Clinical Gastroenterology. 17(5): 755-773.	921
		Maintenance of healthy Immune system	At least 107 cfu / day	Textbooks & peer reviewed journal articles	Hessle, C., Hanson, Å., Wold, AE., (1999). Lactobacilli from human gastrointestinal mucosa are strong stimulators of IL-12 production. Clinical and Experimental Immunology. 116: 276-282 Gill, H.S. (2003).. Probiotics to enhance anti-infective defences in the gastrointestinal tract. Best Practice & Research Clinical Gastroenterology. 17(5): 755-773.	935
		Immune support	Strains must be: Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their	Clinical study Healthy humans DBPC National Institute of Health Public Access Manuscript Clinical trial Humans with Atopic dermatitis	Ying H et al., J Am College Nut, 2001; 20(2): 149-156 Brown AC et al., Nutr Clin Care 2004;7(2): 56-68 Yim et al., J Microbiol. Biotechnol., 2006; 16(11): 1699-1705	2,269

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 100 million bacteria per portion/dose			
		Contains Probiotic that confers a benefit on the host	At least 107 cfu / day	Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	WHO definition of probiotic FAO/WHO (2001). Guidelines for the Evaluation of Probiotics in Food. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, April 30 and May 1, 2002. Gorbach SL and Goldin BR. (1992). Nutrition and the gastrointestinal microflora. Nutr Rev. 1992 Dec;50(12):378-81 Rolfe, RD. (2000). The role of probiotic cultures in the control of gastrointestinal health. J Nutr. Feb;130(2S Suppl): 396S-402S. Fuller, R and Perdigon, G. (2003). Gut flora, nutrition, immunity and Health. Edited by R Fuller and G Perdigon. Blackwell Publishing.	907
		Restoration/ maintenance of beneficial gut flora following antibiotic	At least 107 cfu / day			948

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		treatment		Peer reviewed journal article.	Tannock, GW, Munro, K, Harmsen, HJM, Welling, GW, Smart, J and Gopal, PK. Analysis of the Fecal Microflora of Human Subjects Consuming a Probiotic Product Containing Lactobacillus rhamnosus DR20. Applied and Environmental Microbiology, June 2000, p. 2578-2588, Vol. 66, No. 6	
		Digestive Balance	Strains must be: Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the	National Institute of Health Public Access Manuscript	Brown AC et al., Nutr Clin Care 2004;7(2): 56-68	2,268

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			food matrix of application 100 million bacteria per portion/dose			

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus rhamnosus ATCC53103 (LGG®)					
		Gastro-intestinal health	Food matrix: at least 108 cfu/day Capsules, tablets etc: at least 109 cfu/da			236

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative bodies Meta-analyses Critical review articles Individual human studies Animal studies In vitro studies	Authoritative/Scientific Bodies The Netherlands Nutrition Centre, Assessment report Vifit 14-8-2006 Reviews Doron S, Snydman DR, Gorbach SL. 2005. Lactobacillus GG : Bacteriology and clinical applications. Gastroenterol Clin N Am 34: 483-498. Saxelin M, Korpela R, Mayra-Makinen A. 2003. Classifying functional dairy products. In eds. Mattila-Sandholm T and Saarela M. Functional Dairy Products. Woodhead Publishing Ltd. pp. 1-16. Servin AL. 2004. Antagonistic activities of lactobacilli and bifidobacteria against micorbial pathogens. FEMS Microbiol Rev. 28(4): 405-40. Meta-Analyses and Systematic Reviews D'Souza AL, Rajkumar C, Cooke J, Bulpitt CJ. Probiotics in prevention of antibiotic-associated diarrhoea: meta-analysis. 2002. BMJ 324(7350):1361 Hawrelak JA, Whitten DL, Myers SP. 2005. Is Lactobacillus rhamnosus GG effective in preventing the onset of antibiotic-associated diarrhoea: a systematic review. Digestion 72(1):51-56. Huang JS, Bousvaros A, Lee JW et al. 2002. Efficacy of probiotic use in acute diarrhea in children: a meta-analyses. Dig Dis Sci 47(11): 2625-34. Mc Farland LV. 2006. Meta-analyses of probiotics for the prevention of antibiotic associated diarrhoea and the treatment of Clostridium difficile disease. Am J Gastroenterol 101(4): 812-22. Sazawal S, Hiremath G, Dhingra U, Malik P, Deb S, Black RE. 2006. Efficacy of probiotics in prevention of acute diarrhoea: a	

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		Natural defence, immune response	Food matrix: at least 10[8] cfu/day, Capsules, tablets: at least 10[9] cfu/day			268

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Critical reviews Individual studies Animal and in vitro studies	Review Vaarala O. 2003. Immunological effects of probiotics with special reference to lactobacilli. Clin Exp Allergy 33:1634–1640. Individual Human Studies de Vrese M, Rautenberg P, Laue C, Koopmans M, Herremans T, and Schrezenmeir J. 2005. Probiotic bacteria stimulate virus-specific neutralizing antibodies following a booster polio vaccination. Eur J Nutr 44(7):406-413. Di Caro S, Tao H, Grillo A, Elia C, Gasbarrini G, Sepulveda AR, Gasbarrini A. 2005. Effects of Lactobacillus GG on genes expression pattern in small bowel mucosa. Dig Liver Dis 37(5):320-9. He F, Tuomola E, Arvilommi H, and Salminen S. 2000. Modulation of humoral immune response through probiotic intake. FEMS Immunol Med Microbiol 29: 47-52. Schultz M, Linde H-L, Lehn N, Zimmermann K, Grossmann J, Falk W, and Scholmerich J. 2003. Immunomodularoty consequences of oral administration of Lactobacillus rhamnosus GG in healthy volunteers. J Dairy Res 70: 165-73. Pelto L, Isolauri E, Lilius E-M, Nuutila J, and Salminen S. 1998. Probiotic bacteria down-regulate the milk-induced inflammatory response in milk-hypersensitive subjects but have an immunostimulatory effect in healthy subjects. Clin Experiment Allergy 28: 1474-1479. Additional Human Studies Hatakka K, Savilahti E, P6nk5 A, Meurman JH, Poussa T, Nase L, Saxelin M, and Korpela R. 2001. Effect of long term consumption of probiotic milk on infections in children attending	

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		Vaginal health/flora	at least 10[9] cfu/day			272

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					antagonistic activity against an enterotoxigenic Escherichia coli. Int. J. Food Microbiol. 67:207-216 Prasad, J., H. S. Gill, J. Smart, and P. K. Gopal. 1998. Selection and characterisation of Lactobacillus and Bifidobacterium strains for use as probiotics. Int. Dairy J. 8:993-1002 Shu, Q., J. S. Zhou, K. J. Rutherfurd, M. J. Britles, J. Prasad, P. K. Gopal, and H. S. Gill. 1999. Probiotic lactic acid bacteria (Lactobacillus acidophilus HN017, Lactobacillus rhamnosus HN001 and Bifidobacterium lactis HN019) have no adverse effects on the health of mice. Int. Dairy J. 9:831-836. Shu, Q. and H. S. Gill. 2002. Immune protection mediated by the probiotic Lactobacillus rhamnosus HN001 (DR20TM) against Escherichia coli O157:H7 infection in mice. FEMS Immunol. Med. Microbiol. 34: 59-64. Zhou, J. S., Q. Shu, K. J. Rutherfurd, J. Prasad, P. K. Gopal, and H. S. Gill. 2000. Acute oral toxicity and bacterial translocation studies on potentially probiotic srains of lactic acid bacteria. Food Chem. Toxicol. 38:153-161. Zhou, J. S., Q. Shu, K. J. Rutherfurd, J. Prasad, M. J. Britles, P. K. Gopal, and H. S. Gill. 2000. Safety assessment of potential probiotic lactic acid bacteria strains Lactobacillus rhamnosus HN001, Lb. acidophilus HN017, and Bifidobacterium lactis HN019 in BALB/c mice. Int. J. Food Microbiol. 56:87-96. Zhou, J. S. and H. S. Gill. 2005. Immunostimulatory probiotic Lactobacillus rhamnosus HN001 and Bifidobacterium lactis HN019 do not induce pathological inflammation in mouse model of experimental autoimmune thyroiditis. Int. J. Food Microbiol. 103:97-104 Zhou, J. S., P. K. Gopal, and H. S. Gill. 2001.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Potential probiotic lactic acid bacteria Lactobacillus rhamnosus (HN001), Lactobacillus acidophilus (HN017) and Bifidobacterium lactis (HN019) do not degrade gastric mucin in vitro. Int. J. Food Microbiol 63:81-90 Zhou, J. S., C. J. Pillidge, P. K. Gopal, and H. S. Gill. 2005. Antibiotic susceptibility profiles of new probiotic Lactobacillus and Bifidobacterium strains. Int. J. Food Microbiol 98:211-217 Zhou, J. S., K. J. Rutherfurd, and H. S. Gill. 2005. Inability of probiotic bacterial strains Lactobacillus rhamnosus HN001 and Bifidobacterium lactis HN019 to induce human platelet aggregation in vitro. J. Food Protection 68:2459-2464	
		Natural defence/immune system	at least 10[9] cfu/day			269

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual studies (human intervention, animal studies and in vitro studies)	Reviews Gill, H. S. 1998. Stimulation of the immune system by lactic cultures. Int. Dairy J. 8: 535-544. Gill, H. S. 1999. Potential of using dietary lactic acid bacteria for enhancement of immunity. Dialogue 32:6-11. Individual Human Studies Gill, H. S., K. J. Rutherfurd, and M. L. Cross. 2001. Dietary probiotic supplementation enhances natural killer cell activity in the elderly: an investigation of age-related immunological changes. J. Clin. Immunol. 21:264-271. Gill, H. S., M. L. Cross, K. J. Rutherfurd, and P. K. Gopal. 2001. Dietary probiotic supplementation to enhance cellular immunity in the elderly. Br. J. Biomed. Sci. 58: 94-96. Gill, H. S. and K. J. Rutherfurd. 2001. Probiotic supplementation to enhance natural immunity in the elderly: effects of a newly characterized immunostimulatory strain Lactobacillus rhamnosus HN001 (DR20TM) on leucocyte phagocytosis. Nutr. Res. 21: 183-189. Sheih, Y.-H., B.-L. Chiang, L.-H. Wang, C. -K. Liao, H. S. Gill. 2001. Systemic immunity-enhancing effects in healthy subjects following dietary consumption of the lactic acid bacterium Lactobacillus rhamnosus HN001. J. Am. Coll. Nutr. 20:149-156 Sistek, D., R. Kelly, K. Wickens, T. Stanley, P. Fitzharris, and J. Crane. 2006. Is the effect of probiotics on atopic dermatitis confined to food sensitized children? Clin. Exp. Allergy 36:629-633 Tannock, G. W., K. Munro, H. J. M. Harmsen, G. W. Welling, J. Smart, and P. K. Gopal. 2000. Analysis of the fecal microflora of	

human subjects consuming a probiotic product containing Lactobacillus rhamnosus DR20. Appl. Environ. Microbiol. 66: 2578-2588.

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Gill, H. S., Q. Shu, H. Lin, K. J. Rutherfurd, and M. L. Cross. 2001 Protection against translocating Salmonella typhimurium infection in mice by feeding the immuno-enhancing probiotic Lactobacillus rhamnosus strain HN001. Med. Microbiol. Immunol. 190: 97-104.

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Gill, H. S. and K. J. Rutherfurd. 2001. Immune enhancement conferred by oral delivery of Lactobacillus rhamnosus HN001 in different milk-based substrates. Dairy Res. 68: 611-616.

Shu, Q., J. S. Zhou, K. J. Rutherfurd, M. J. Britles, J. Prasad, P. K. Gopal, and H. S. Gill. 1999. Probiotic lactic acid bacteria (Lactobacillus acidophilus HN017, Lactobacillus rhamnosus HN001 and Bifidobacterium lactis HN019) have no adverse effects on the health

of mice. Int. Dairy J. 9:831-836.

Shu, Q. and H. S. Gill. 2002. Immune protection mediated by the probiotic Lactobacillus rhamnosus HN001 (DR20TM) against Escherichia coli O157:H7 infection in mice. FEMS Immunol. Med. Microbiol. 34: 59-64.

Zhou, J. S., Q. Shu, K. J. Rutherfurd, J. Prasad, P. K. Gopal, and H. S. Gill. 2000. Acute oral toxicity and bacterial translocation studies on potentially probiotic srains of lactic acid bacteria. Food Chem. Toxicol. 38:153-161.

Zhou, J. S., Q. Shu, K. J. Rutherfurd, J. Prasad, M. J. Britles, P. K. Gopal, and H. S. Gill. 2000. Safety assessment of potential probiotic lactic acid bacteria strains Lactobacillus rhamnosus HN001, Lb. acidophilus HN017, and Bifidobacterium lactis HN019 in BALB/c mice. Int. J. Food Microbiol. 56:87-96.

Zhou, J. S. and H. S. Gill. 2005. Immunostimulatory probiotic Lactobacillus rhamnosus HN001 and Bifidobacterium lactis HN019 do not induce pathological inflammation in mouse model of experimental autoimmune thyroiditis. Int. J. Food Microbiol. 103:97-104

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Gopal, P. K., P. A. Sullivan, and B. J. Smart. 2001. Utilisation of galacto-oligosaccharides as selective substrates for growth by lactic acid bacteria including Bifidobacterium lactis DR10 and Lactobacillus rhamnosus DR20. Int. Dairy Journal 11:19-25

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Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Escherichia coli. Int. J. Food Microbiol. 67:207-216 Prasad, J., H. S. Gill, J. Smart, and P. K. Gopal. 1998. Selection and characterisation of Lactobacillus and Bifidobacterium strains for use as probiotics. Int. Dairy J. 8:993-1002 Zhou, J. S., P. K. Gopal, and H. S. Gill. 2001. Potential probiotic lactic acid bacteria Lactobacillus rhamnosus (HN001), Lactobacillus acidophilus (HN017) and Bifidobacterium lactis (HN019) do not degrade gastric mucin in vitro. Int. J. Food Microbiol 63:81-90 Zhou, J. S., C. J. Pillidge, P. K. Gopal, and H. S. Gill. 2005. Antibiotic susceptibility profiles of new probiotic Lactobacillus and Bifidobacterium strains. Int. J. Food Microbiol 98:211-217 Zhou, J. S., K. J. Rutherfurd, and H. S. Gill. 2005. Inability of probiotic bacterial strains Lactobacillus rhamnosus HN001 and Bifidobacterium lactis HN019 to induce human platelet aggregation in vitro. J. Food Protection 68:2459-2464	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus rhamnosus I-1720					
		Digestive health	at least 1x10[9] cfu/day	Human studies Review article	Review Reid G, Sanders ME, Gaskins HR, Gibson GR, Mercenier A, Rastall R, Roberfroid M, Rowland I, Cherbut C, Klaenhammer TR. New scientific paradigms for probiotics and prebiotics. J Clin Gastroenterol. 2003 Aug;37(2):105-18 Individual Human Studies Guandalini S, Pensabene L, Zikri MA, Dias JA, Casali LG, Hoekstra H, Kolacek S, Massar K, Micetic-Turk D, Papadopoulou A, de Sousa JS, Sandhu B, Szajewska H, Weizman Z. Lactobacillus GG administered in oral rehydration solution to children with acute diarrhea: a multicenter European trial. J Pediatr Gastroenterol Nutr. 2000 Jan;30(1):54-60. Majamaa H, Isolauri E, Saxelin M, Vesikari T. Lactic acid bacteria in the treatment of acute rotavirus gastroenteritis. J Pediatr Gastroenterol Nutr. 1995 Apr;20(3):333-8.	237
		Immune defenses / support of immunity	at least 1x10[9] cfu/day			270

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human studies	Individual Human Studies Guandalini S, Pensabene L, Zikri MA, Dias JA, Casali LG, Hoekstra H, Kolacek S, Massar K, Micetic-Turk D, Papadopoulou A, de Sousa JS, Sandhu B, Szajewska H, Weizman Z. Lactobacillus GG administered in oral rehydration solution to children with acute diarrhea: a multicenter European trial. J Pediatr Gastroenterol Nutr. 2000 Jan;30(1):54-60. Majamaa H, Isolauri E. Probiotics: a novel approach in the management of food allergy. J Allergy Clin Immunol. 1997 Feb;99(2):179-85. Rosenfeldt V, Benfeldt E, Nielsen SD, Michaelsen KF, Jeppesen DL, Valerius NH, Paerregaard A. Effect of probiotic Lactobacillus strains in children with atopic dermatitis. J Allergy Clin Immunol. 2003 Feb;111(2):389-95.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacillus salivarius					
		Maintenance of healthy Immune system	At least 107 cfu / day	Textbooks & peer reviewed journal articles	Cario E. (2005). Bacterial interactions with cells of the intestinal mucosa: Toll-like receptors and NOD2. Gut. 2005 Aug;54(8):1182-93. Epub 2005 Apr 19. Review. O'Hara AM, O'Regan P, Fanning A, O'Mahony C, Macsharry J, Lyons A, Bienenstock J, O'Mahony L, Shanahan F. (2006). Functional modulation of human intestinal epithelial cell responses by Bifidobacterium infantis and Lactobacillus salivarius. Immunology. 2006 Jun;118(2):202-15. As listed by A Green	940
		Contains Probiotic that confers a benefit on the host	At least 107 cfu / day	Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	WHO definition of probiotic FAO/WHO (2001). Guidelines for the Evaluation of Probiotics in Food. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, April 30 and May 1, 2002. Gorbach SL and Goldin BR. (1992). Nutrition and the gastrointestinal microflora. Nutr Rev. 1992 Dec;50(12):378-81 Rolfe, RD. (2000). The role of probiotic cultures in the control of gastrointestinal health. J Nutr. Feb;130(2S Suppl): 396S-402S. Fuller, R and Perdigon, G. (2003). Gut flora, nutrition, immunity and Health. Edited by R Fuller and G Perdigon. Blackwell Publishing.	912
		Beneficial effect on	At least 107 cfu / day			926

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		intestinal microflora, gut integrity, digestion		Textbooks & peer reviewed journal articles	Barefoot SF, Nettles CG.(1993). Antibiosis revisited: bacteriocins produced by dairy starter cultures. J Dairy Sci. 1993 Aug;76(8):2366-79. Review. Atassi F, Brassart D, Grob P, Graf F, Servin AL. (2006). In vitro antibacterial activity of Lactobacillus helveticus strain KS300 against diarrhoeagenic, uropathogenic and vaginosis-associated bacteria.J Appl Microbiol. 2006 Sep;101(3):647-54. Hugo AA, De Antoni GL, Perez PF. (2006). Lactobacillus delbrueckii subsp lactis strain CIDCA 133 inhibits nitrate reductase activity of Escherichia coli. Int J Food Microbiol. 2006 Oct 1;111(3):191-6. Epub 2006 Aug 22.	
	Lactobacilus acidophilus CUL60 Lactobacillus casei LC11 Bifidobacterium lactis CUL34					
		Gut Flora	1x10^9cfu/day		Madden JAJ et al. Effect of probiotics on preventing disruption of the intestinal microflora following antibiotic therapy: A double blind, placebo controlled pilot study. International Immunopharmacology, 5, 1091-1097 (2005)	984

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lactobacilus jjohnsoni NCC 533 (La1) (Pasteur culture colection CNCM I 1225)					
		Skin health	at least 5x10[9] cfu/day Powder	Individual human studies	Animal Studies Gueniche, A., Benyacoub, J., Buetler, T. M., Smola, H. and Blum, S., Supplementation with oral probiotic bacteria maintains cutaneous immune homeostasis after UV exposure, Eur. J. Dermatol., 16: 511-7, 2006. Inoue R., Nishio, A., Fukushima Y., and Ushida K. Oral treatment with probiotic Lactobacillus johnsonii NCC533 (La1) for a specific part of the weaning period prevents the development of atopic dermatitis induced after maturation in model mice, NC/Nga, Br. J. Dermatol., 156:499-509, 2007	275

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	OptiBac					
		Maintains optimal digestive health and natural immune defenses promoting digestive regularity and overall natural balance and well being	Daily dose must provide at least 2.5 billion Colony Forming Units of probiotics. To present a safety statement: It is not recommended to give Probiotics to severely immunosuppressed patients, post cardiac surgery patients, patients with pancreatic dysfunction or patients with blood in the stool unless under a doctor's care.	European Journal of Nutrition – PASSCLAIM Report British Journal of Nutrition – Review Article Journal of Food Protection – Expert Analysis The Journal of Applied Bacteriology – Expert analysis	Cummings, J.H. et al (2004) PASSCLAIM – Gut Health & Immunity. European Journal of Nutrition [Suppl 2], 43: 11/118- 11/173 (http://europe.ilsi.org/activities/ecprojects/PASSCLAIM/passpubs.htm) Saavedra, J. & Tschernia, A. (2002) Human studies with probiotics and prebiotics: clinical implications. British Journal of Nutrition, Volume 87, Supplement s2, 1 May 2002, pp. 241-246(6) (http://www.ingentaconnect.com/content/cabi/bjn/2002/00000087/900000s2/art00015) Wallace TD, Bradley S, Buckley ND, and Green-Johnson JM (2003) Interactions of lactic acid bacteria with human intestinal epithelial cells: effects on cytokine production. Journal of Food Protection, 66, 3; 446-472. (http://apt.allenpress.com/perlserv/?request=get-abstract&issn=0362-028X&volume=066&issue=03&page=0466&ct=1) Gibson, G.R. & Wang, X. (1994) Regulatory Effects of Bifidobacteria on the growth of other colonic bacteria. The Journal of Applied Bacteriology. Oct;77(4):412-20. (http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=7989269&dopt=Citation)	876

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Journal of Gastroenterology Nutrition Research – Placebo controlled study The Lancet – Professional Research Report Die Pharmazie – Review Article Alternative Medicine Review – Review Article European Journal of Cancer Prevention – Expert Analysis	Gibson, G. R. et al (1995) Selective stimulation of bifidobacteria in the human colon by oligofructose and inulin. Gastroenterology. Apr;108(4):975-82. (http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=7698613&dopt=Citation) Rao, V. (2001) The prebiotic properties of oligofructose at low intake levels. Nutrition Research. Volume 21, Issue 6, June 2001, Pages 843-848 (http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6TB1-435KTC1-5&_user=10&_coverDate=06%2F30%2F2001&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=aefca133e8d045201b21d0c4bf7e42a6) Guarner, F. & Malagelada, J. R. (2003) Gut flora in health and disease. Lancet; Vol. 8 pp. 512 – 9 (http://www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed&cmd=Retrieve&dopt=AbstractPlus&list_uids=12583961&query_hl=18&itool=pubmed_docsum) Kumar et al. (2005) Beneficial effects of probiotics and prebiotics on human health; Pharmazie Vol. 60 (3) pp.163 – 71 (http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=15801666&dopt=AbstractPlus) Drisko, J. A., Giles C. K. & Bischoff B. J. (2003) Probiotics in health maintenance and disease prevention. Alternative Medicine Review; Vol. 8 (2) pp.143 - 55. (http://www.dtecta.co.uk/casestudies/Drisko,_G	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					iles_&_Bischoff_(2003)_Probiotics_in_Health_Maintenance_and_disease_prevention_DTECTA_Probiotics_www.dtecta.co.uk.pdf?cmd=Retrieve&db=PubMed&list_uids=12777160&dopt=Abstract) Hill, M. J. (1997) Intestinal flora and endogenous vitamin synthesis. European Journal of Cancer Prevention; Vol. 6 Suppl. 1 pp. S43 – 5 (http://www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed&cmd=Retrieve&dopt=AbstractPlus&list_uids=9167138&query_hl=16&itool=pubmed_docsum)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Optibiotics containing Bacillus mesentericus TO-A, Clostridium butyricum TO-A and Streptococcus faecalis T-110					
		Beneficial effect on intestinal flora	Bacillus mesentericus TO-A: 3 x 5^6 cfu per day, Clostridium butyricum TO-A: 3 x 5^6 cfu per day, and Streptococcus faecalis T-110: 3 x 15^7 cfu per day			1,123

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human studies; Animal studies; In vitro studies; modelling studies	Rolfe RD. The role of probiotic cultures in the control of gastrointestinal health. J Nutr. 2000 Feb;130(2S Suppl): 396S-402S. Horie, H., M. Zeisig, et al. (2003). "Probiotic mixture decreases DNA adduct formation in colonic epithelium induced by the food mutagen 2-amino-9H-pyrido[2,3-b]indole in a human-flora associated mouse model." Eur J Cancer Prev 12(2): 101-7. Urao, M., T. Fujimoto, et al. (1999). "Does probiotics administration decrease serum endotoxin levels in infants?" J Pediatr Surg 34(2): 273-6. Seo G, Akimoto Y, Hamashima H, Masuda K, Shiojima K, Sakuma C, Sasatsu M, Arai T. A new factor from Bacillus mesentericus which promotes the growth of Bifidobacterium. Microbios Lett 2000; 101(399): 105-14. Iino H, Fukaya K, Hirasawa Y, Seo G. The effects of a division promoting-factor for Bifidobacteriym produced by Bacillus mesentericus on bacterial flora in the rat caecum Microbios 1994, 80: 49-53. Kanuchi O, Matsumoto Y, Matsumura M, Fukuoka M, Bamba T. The beneficial effects of microflora, especially obligate anaerobes and their products on the colonic environment in inflammatory bowel disease. Current Pharmaceutical Design, 2005, 11: 1047-01053, Shimbo I, Yamaguchi T, Odaka T, Nakajima K,	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Koide A, Koyama H, Saisho H. Effect of Clostridium butyricum on fecal flora in Helicobacter pylori eradication therapy. World J Gastroenterol. 2005, 11: 7520-7524. Song ZF, Wu TX, Cai LS, Zhang LJ, Zheng XD. Effects of dietary supplementation with clostridium butyricum on the growth performance and humoral immune response in Miichthys miiuy. J Zhejiang Univ Sci B. 2006 Jul;7(7):596-602. Fukuda, M., O. Kanauchi, et al. (2002). "Prebiotic treatment of experimental colitis with germinated barley foodstuff: a comparison with probiotic or antibiotic treatment." Int J Mol Med 9(1): 65-70. Kong, Q., G. Q. He, et al. (2006). "Studies on a kinetic model for butyric acid bioproduction by Clostridium butyricum." Lett Appl Microbiol 43(1): 71-7. Takahashi, M., H. Taguchi, et al. (2004). "The effect of probiotic treatment with Clostridium butyricum on enterohemorrhagic Escherichia coli O157:H7 infection in mice." FEMS Immunol Med Microbiol 41(3): 219-26. Araki, Y., Y. Fujiyama, et al. (2000). "The dietary combination of germinated barley foodstuff plus Clostridium butyricum suppresses the dextran sulfate sodium-induced experimental colitis in rats." Scand J Gastroenterol 35(10): 1060-7. Araki, Y., A. Andoh, et al. (2004). "Clostridium butyricum, a probiotic derivative, suppresses dextran sulfate sodium-induced experimental colitis in rats." Int J Mol Med 13(4): 577-80.	

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Ichikawa, H., T. Kuroiwa, et al. (1999). "Probiotic bacteria stimulate gut epithelial cell proliferation in rat." Dig Dis Sci 44(10): 2119-23.

Nakanishi, S., T. Kuwahara, et al. (2005). "Rapid species identification and partial strain differentiation of Clostridium butyricum by PCR using 16S-23S rDNA intergenic spacer regions." Microbiol Immunol 49(7): 613-21.

Sato, R. and M. Tanaka (1997). "Intestinal distribution and intraluminal localization of orally administered Clostridium butyricum in rats." Microbiol Immunol 41(9): 665-71.

Seki, H., M. Shiohara, et al. (2003). "Prevention of antibiotic-associated diarrhea in children by Clostridium butyricum MIYAIRI." Pediatr Int 45(1): 86-90.

Takahashi, M., H. Taguchi, et al. (2000). "Studies of the effect of Clostridium butyricum on Helicobacter pylori in several test models including gnotobiotic mice." J Med Microbiol 49(7): 635-42.

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Probiotic ingredient Lactobacillus casei F19 (LMG P-17806)					
		Digestive health Intestinal flora and gut function	Daily intake 1x10E10 cfu	Scientific investigations Scientific reviews	Crittenden, R., Saarela, M., Mättö, J., Ouwehand, A.C., Salminen, S., Pelto, L., Vaughan, E.E., de Vos, W.M., von Wright, A., Fondén, R., Mattila-Sandholm, T. 2002. Lactobacillus paracasei subsp. paracasei F19: survival, ecology and safety in the human intestinal tract - a survey of feeding studies within the PROBDEMO project. Microbial Ecology in Health and Disease Suppl. (Lactobacillus F19 – Closing the broken circle) 3:22-26. Sullivan, Å., Palmgren, A.C., Nordh, C.E. 2001. Effect of Lactobacillus paracasei on intestinal colonisation of Lactobacilli, Bifidobacteria and Clostridium difficile in elderly persons. Anerobe 07: 67-70. Sullivan, Å., Bennet, R., Viitanen, M., Palmgren, A.C., Nord, C.E. 2002. Influence of Lactobacillus F19 on intestinal microflora in children and elderly persons and impact on Helicobacter pylori infections. Microbial Ecology in Health and Disease Suppl. (Lactobacillus F19 – Closing the broken circle) 3:17-21. Sullivan A, Barkholt L, Nord CE. 2003 Lactobacillus acidophilus, Bifidobacterium lactis and Lactobacillus F19 prevent antibiotic-associated ecological disturbances of Bacteroides fragilis in the intestine. J Antimicrob Chemother. 52:308-11.	776

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Probiotic ingredient. Lactobacillus casei F19 (LMG P-17806)					
		Digestive health. Balanced gut flora	Daily intake 1x10E10 cfu			775

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Scientific investigations Scientific reviews	Black F, Einarsson K, Lidbeck A, Orrhage K, Nord CE 1991 Effect of lactic acid producing bacteria on the human intestinal microflora during ampicillin treatment SWcand J Infect Dis 23:247-254 Jernberg C, Sullivan A, Edlund C, Jansson JK. 2005 Monitoring of antibiotic-induced alterations in the human intestinal microflora and detection of probiotic strains by use of terminal restriction fragment length polymorphism. Appl Environ Microbiol. 71:501-6. Lidbeck A, Edlund C, Gustafsson JA, Kager L, Nord CE. 1988 Impact of Lactobacillus acidophilus on the normal intestinal microflora after administration of two antimicrobial agents. Infection. 16:329-36. Nord CE, Lidbeck A, Orrhage K, Sjostedt S. 1997 Oral supplementation with lactic acid-producing bacteria during intake of clindamycin. Clin Microbiol Infect. 3:124-132. Orrhage K, Brismar B, Nord CE 1994 Effets of supplements with Bifidobacterium longum and Lactobacillus acidophilus on the intestinal microbiota during administration of clindamycin. Microb Ecol Health Dis 7:17-25. Sullivan A, Barkholt L, Nord CE. 2003 Lactobacillus acidophilus, Bifidobacterium lactis and Lactobacillus F19 prevent antibiotic-associated ecological disturbances of Bacteroides fragilis in the intestine. J Antimicrob Chemother. 52:308-11.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Probiotics					
		Normal immune function				547

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Published Review	Nochi T, Kiyono H (2006) Innate immunity in the mucosal immune system. Curr Pharm Des; 12(32): 4203-4213. Parvez S, Malik KA, Ah S et al (2006) Probiotics and their fermented food products are beneficial for health. J Appl Microbiol; 100(6): 1171-185. Tlaskalova H, Stepankova R, Hudcovic T et al (2004) Commensal bacteria (normal microflora), mucosal immunity and chronic inflammatory and autoimmune diseases. Immunol Lett; 93(2): 97-108. Marteau P, Seksik P, Lepage P et al (2004) Cellular and physiological effects of probiotics and prebiotics. Mini Rev Med Chem; 4(8): 889-896. Shi HN, Walker A (2004) Bacterial colonization and the development of intestinal defences. Can J Gastroenterol; 18(8): 493-500. Acheson DW, Luccioli S (2004) Microbial-gut interactions in health and disease. Mucosal immune responses. Best Pract Res Clin Gastroenterol; 18(2): 387-404. Guarner F, Malagelada JR (2003) Gut flora in health and disease. Lancet; 361(9356): 512-519. Heller F, Duchmann R (2003) Intestinal flora and mucosal immune response. Int J Med Microbiol; 293(1): 77-86. Marteau P, Shanahan F (2003) Basic aspects and pharmacology of probiotics: an overview of	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

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Fioramonti J, Theodorou V, Bueno L (2003) Probiotics: what are they, what are their effects on gut physiology? Best Pract Res Clin Gastroenterol; 17(5): 711-724.

Drisko JA, Giles CK, Bischoff BJ (2003) Probiotics in health maintenance and disease prevention. Altern Med Rev; 8(2): 143-155.

Goossens D, Jonkers D, Stobberingh E et al (2003) Probiotics in gastroenterology: indications and future perspectives. Scand J Gastroenterol Suppl; 239: 15-23.

Gill HS (2003) Probiotics to enhance anti-infective defences in the gastrointestinal tract. Best Pract Res Clin Gastroenterol; 17(5): 755-773.

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Macfarlane GT, Cummings JH (2002) Probiotics, infection and immunity. Curr Opin Infect Dis; 15(5): 501-506.

Kaur IP, Chopra K, Saini A (2002) Probiotics: potential pharmaceutical applications. Eur J Pharm Sci; 15(1): 1-9.

Tlaskalova H, Tuckova L, Lodinova R et al (2002) Mucosal immunity: its role in defense and allergy. Int Arch Allergy Immunol; 128(2): 77-89.

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Elson CO, Cong Y, Iqbal N et al (2001) Immuno-bacterial homeostasis in the gut: new insights into an old enigma. Semin Immunol; 13(3): 187-194. Perdigon G, Fuller R, Raya R (2001) Lactic acid bacteria and their effect on the immune system. Curr Issues Intest Microbiol; 2(1): 27-42. Naidu AS, Bidlack WR, Clemens RA (1999) Probiotic spectra of lactic acid bacteria. Crit Rev Food Sci Nutr; 39(1): 13-126.	
		Normal gastrointestinal tract function				546

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Published Review	Parvez S, Malik KA, Ah S et al (2006) Probiotics and their fermented food products are beneficial for health. J Appl Microbiol; 100(6): 1171-185. Marteau P, Seksik P, Lepage P et al (2004) Cellular and physiological effects of probiotics and prebiotics. Mini Rev Med Chem; 4(8): 889-896. Goosens D, Jonkers D, Stobberingh E et al (2003) Probiotics in gastroenterology: indications and future perspectives. Scand J Gastroenterol Suppl; 239: 15-23. Marteau P, Shanahan F (2003) Basic aspects and pharmacology of probiotics: an overview of oharmacokinetics, mechanismds of action and side-effects. Best Pract Res Clin Gastroenterol; 17(5): 725-740. Guarner F, Malagelada JR (2003) Gut flora in health and disease. Lancet; 361(9356): 512-519. Kaur IP, Chopra K, Saini A (2002) Probiotics: potential pharmaceutical applications. Eur J Pharm Sci; 15(1): 1-9.	
		Digestive health, balanced gut flora	Basic criteria: The product shall contain an adequate number of live probiotic bacteria compared to the human studies performed. The same daily dose as in the studies should be achievable.			772

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual studies Review Animal studies In vitro studies	Cremoni F et al. 2002. Meta-analysis: the effect of probiotic adminstration on antibiotic-associated diarrhoea. Aliment Pharmacol Ther 16:1461-1467. D'Souza AL. et al. Probiotics in prevention of antibiotic-associated diarrhoea: Meta-analysis. BMJ 324 (17359):1361 (2002). Hawrelak JA. At al. Is L. rahmnosus GG eefective in prevention the onset of antibiotic-associated diarrhoea: A systematic review. Digestion 72:51-56 (2005). Kramer S. and Bischoff SC. Theraputic possibilities of probiotics in antibiotic-related diarrhea. MMW Fortschr. Med. 31:148 (35-36): 28-30 (2006). Lewis, S.J., Freedman, A.R. Review: The use of biotherapeutic agents in the prevention and treatment of gastrointestinal disease. 1998. Aliment Pharmacol Ther, 12: 807-822. McFarland LV. 2006 Meta-analysis of probiotics for the prevention of antibiotic associated diarrhea and the treatment of Clostridium difficile disease. Am J Gastroenterol. 101:812-22. Naaber P, Mikelsaar M. 2004 Interactions between Lactobacilli and antibiotic-associated diarrhea. Adv Appl Microbiol. 54:231-60. Plummer SF, Garaiova I, Sarvotham T, Cottrell SL, Le Scouiller S, Weaver MA, Tang J, Dee P, Hunter J. 2005 Effects of probiotics on the composition of the intestinal microbiota following antibiotic therapy. Int J Antimicrob	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Agents. 26:69-74. Reid G. et al. New scientific paradigms for probiotics and prebiotics. J. Clin Gastroenterol. 37:105-118 (2003). Sazawal S, Hiremath G, Dhingra U, Malik P, Deb S, Black RE. 2006 Efficacy of probiotics in prevention of acute diarrhoea: a meta-analysis of masked, randomised, placebo-controlled trials. Lancet Infect Dis. 6:374-82. Sullivan A, Edlund C, Nord CE. 2001 Effect of antimicrobial agents on the ecological balance of human microflora. Lancet Infect Dis.1:101-14. Szajewska H, Ruszczynski M, Radzikowski A. 2006 Probiotics in the prevention of antibiotic-associated diarrhea in children: a meta-analysis of randomized controlled trials. J Pediatr. 149:367-372.	
		Digestive health, intestinal flora and bowel function	Basic criteria: The product shall contain an adequate number of live probiotic bacteria compared to the human studies performed. The same daily dose as in the studies should be achievable.			771

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual studies Review Animal studies In vitro studies	Buttriss, J (1997). Nutritional properties of fermented milk products. International Journal of Dairy Technology 50 (1), 21-27. Cummings, JH et al. (2004). Passclaim - Gut Health and Immunity. Eur. J. Nutr. Jun;43 Suppl 2:II118-II173. Review Cummings JH, Macfarlane GT. Role of intestinal bacteria in nutrient metabolism. Clinical Nutrition 1997; 16: 3-11. De Roos NM, Katan MB. Effects of probiotic bacteria on diarrhea, lipid metabolism, and carcinogenesis: review Am J Clin Nutr 2000;71(2):405-11. Fooks, LJ, Fuller, R, Gibson, GR (1999). Prebiotics, Probiotics and Human Gut Microbiology. International Dairy Journal 9, 53-61. Gibson GR, Rouzaud G, Brostoff J, Rayment N. An evaluation of probiotic effects in the human gut: microbial aspects. Final Technical report for FSA 2005 project ref G01022. http://www.food.gov.uk/multimedia/pdfs/probioticreport.pdf Goldin BR. Health benefits of probiotics. Br J Nutr 1998;80(4):S203-7. Kneifel, W, Bonaparte, C (1998). Novel trends related to health-relevant foods: 1. Probiotics. Nutrition 22 (9), 357-363. Lewis, S.J., Freedman, A.R. Review: The use of biotherapeutic agents in the prevention and treatment of gastrointestinal disease. 1998. Aliment Pharmacol Ther, 12: 807-822.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

Locke GR, Pemberton JH, Phillips SF. American Gastroenterological Association Technical review on constipation. Gastroent. 2000;119(6):1766-78.

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Picard C. Review article : bifidobacteria as probiotic agents – physiological effects and clinical benefits. Aliment Pharmacol Therm 2005;22: 495-512

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Tanaka, R. Clinical applications of Bifidobacterium in humans. Research of Bifidobacteria, T. Mitsuoka (editor), 221-228 (1994)

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Probiotics & Prebiotics as contained in the probiotic formula ProbioStart: Bifidobacterium infantis (CNCM I-3424), Bifidobacterium bifidum (CNCM I-3426), Lactobacillus acidophilus (CNCM I-1722), Fructooligosaccharides.					
		Supports digestive health, natural immune defences and overall well being for children and pregnant women.	Daily dose must provide at least 1 billion colony forming units of both lactobacilli and bifidobacterium probiotic strains.	Peer reviewed scientific journal.	Reid G, Anukam K, James VI, van der Mei HC, Heineman C, Busscher HJ, Bruce AW (2005). Oral probiotics for maternal and newborn health. J Clin Gastroenterol. May-Jun;39(5):353-4	891
			To present a safety statement: Food supplements should not be given to infants under 6 months of age without the advice of a doctor.	Peer reviewed scientific journal.	Nishijima K, Shukunami K, Kotsuji F.J Clin Gastroenterol (2004).. Probiotics affects vaginal flora in pregnant women, suggesting the possibility of preventing preterm labor. 2004 Jul;38(6 Suppl):S94-101	
				Human Study	Gregor Reid, Dee Beuerman, Christine Heinemann, Andrew W Bruce (2001). Probiotic Lactobacillus dose required to restore and maintain a normal vaginal flora. FEMS Immunology & Medical Microbiology 32 (1), 37–41.	
			To present a safety statement: It is not recommended to give Probiotics to severely immunosuppressed patients, post cardiac surgery patients, patients with pancreatic dysfunction or patients with blood in the stool unless under a doctor's care.	Expert review of human studies	Falagas ME, Betsi GI, Tokas T, Athanasiou S. Alfa Institute of Biomedical Sciences (AIBS), Athens, Greece (2006). Probiotics for prevention of recurrent urinary tract infections in women: a review of the evidence from microbiological and clinical studies. Drugs. 2006;66(9):1253-61.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				The American Journal of Clinical Nutrition – Expert Analysis	H Beerens, C Romond and C Neut (1980) Influence of breast-feeding on the bifid flora of the newborn intestine. American Journal of Clinical Nutrition, Vol 33, 2434-2439. http://www.ajcn.org/cgi/reprint/33/11/2434	
				Journal of Nutrition Research Reviews – Review Article	Heining MJ, Dewey KG (1996): Health advantage of breast feeding for infants: a critical review. Nutr Research Rev, 9: 89-110. http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=593960&fulltextType=RA&fileId=S095442249600008X	
				Journal of Pediatric Gastroenterology & Nutrition – Randomised, double-blind placebo-controlled study	Knol J, Scholtens P, Kafka C, Steenbakkers J, Gro S, Helm K, Klarczyk M, Schöpfer H, Böckler HM, Wells J. Numico Research B.V., Wageningen, The Netherlands (2005) Colon microflora in infants fed formula with galacto- and fructo-oligosaccharides: more like breast-fed infants J Pediatr Gastroenterol Nutr. 2005 Jan;40(1):36-42. (http://www.jpgn.org/pt/re/jpgn/abstract.00005176-200501000-00007.htm;jsessionid=GyYV9CRLG8L32YRhDPB5whc6mfXGpCWtLTYbQh28gMDl99QxCbKn!29071008!181195628!8091!-1)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Journal of Pediatric Gastroenterology & Nutrition – Review of published randomised, double-blind placebo controlled trials Pediatrics – Meta-Analysis of 9 randomised controlled trials The Lancet – Double blind placebo-controlled Trial	Zajewska H, Mrukowicz JZ. Probiotics in the treatment and prevention of acute infectious diarrhea in infants and children: a systematic review of published randomized, double-blind, placebo-controlled trials. J Pediatr Gastroenterol Nutr. 2001;33(suppl 2) :S17 – S25 (http://www.jpgn.org/pt/re/jpgn/abstract.00005176-200110002-00004.htm;jsessionid=GyZDNBJw4gNnpm3Lp24DJznT0qqYV2YX2CnV1TKyLvc1NBXKs7hD!29071008!181195628!8091!-1) Van Niel CW, Feudtner C, Garrison MM, Christakis DA. Lactobacillus therapy for acute infectious diarrhea in children: a meta-analysis. Pediatrics. 2002;109 :678 –684 (http://pediatrics.aappublications.org/cgi/content/abstract/109/4/678) Saavedra, J.M. et al. (1994) Feeding of Bifidobacterium bifidum and Streptococcus thermophilus to infants in hospital for prevention of diarrhoea and shedding of rotavirus. The Lancet. Oct 15;344(8929):1046-9. (http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=7934445&dopt=Citation)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				International Journal of Food Microbiology Journal of pediatric gastroenterology and nutrition – Double-blind randomised controlled study Journal of the American College of Nutrition – Randomised placebo-controlled trial	Fukushima, Y. et al (1998) Effect of a probiotic formula on intestinal immunoglobulin A production in healthy children. International Journal of Food Microbiology. Volume 42, Issues 1-2, 30 June 1998, Pages 39-44 (http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T7K-3T2PC8Y-4&_user=10&_coverDate=06%2F30%2F1998&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=981114963087353bd529bc6b40366fe1) Langhendries, J.P. et al. Effect of fermented infant formula containing viable bifidobacteria on the fecal flora composition and pH of healthy full-term infants: J Pediatr Gastroenterol Nutr, 21, 2, 177081, 1995. (http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=7472904&dopt=Citation) Zvi Weizman, MD, FACN and Ahmed Alsheikh, MD Pediatric Gastroenterology and Nutrition Unit, Soroka Medical Center, Faculty of Health Sciences, Ben-Gurion University, Beer-Sheva, ISRAEL (2006) Safety and Tolerance of a Probiotic Formula in Early Infancy Comparing Two Probiotic Agents: A Pilot Study. Journal of the American College of Nutrition, Vol. 25, No. 5, 415-419 http://www.jacn.org/cgi/content/abstract/25/5/415	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				American Journal of Clinical Nutrition – Double blind randomised placebo controlled study	Saavedra JM, Abi-Hanna A, Moore N, Yolken RH. Long-term consumption of infant formulas containing live probiotic bacteria: tolerance and safety. Am J Clin Nutr. 2004;79 :261 – 267 (http://www.ajcn.org/cgi/content/abstract/79/2/261)	
				The Pediatric Infectious Disease Journal – Randomised placebo controlled trial	Rosenfeldt V, Michaelsen KF, Jakobsen M, et al. Effect of probiotic Lactobacillus strains in young children hospitalized with acute diarrhea. Pediatr Infect Dis J. 2002;21 :411 –416 (http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=retrieve&db=pubmed&list_uids=12150178&dopt=AbstractPlus)	
				The Pediatric Infectious Disease Journal – Randomised placebo-controlled trial	Rosenfeldt V, Michaelsen KF, Jakobsen M, et al. Effect of probiotic Lactobacillus strains on acute diarrhea in a cohort of nonhospitalized children attending day-care centers. Pediatr Infect Dis J. 2002;21 :417 –419 (http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=retrieve&db=pubmed&list_uids=12150179&dopt=AbstractPlus)	
				Journal of Pediatric Health Care – Review article	Young RJ, Huffman S. Probiotic use in children. J Pediatr Health Care. 2003;17 :277 –283 (http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=retrieve&db=pubmed&list_uids=14610440&dopt=AbstractPlus)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Probiotics (Saccharomyces boulardii) as contained in the probiotic formula DiarSafe: - Saccharomyces boulardii					
		Supports bowel health, comfort and function promoting intestinal well- being and normalizing the balance of intestinal flora.	Daily dose must provide at least 5 billion colony forming units of Saccharomyces boulardii. To present a safety statement: It is not recommended to give Probiotics to severely immunosuppressed patients, post cardiac surgery patients, patients with pancreatic dysfunction or patients with blood in the stool unless under a doctor's care.	Alimentary Pharmacology & Therapeutics – Randomised placebo-controlled double blind study Journal of Tropical Pediatrics British Medical Journal – Meta-Analysis of clinical trials	1. Antibiotic Associated Diarrhoea M. Kotowska, P. Albrecht, H. Szajewska (2005) Saccharomyces boulardii in the prevention of antibiotic-associated diarrhoea in children: a randomized double-blind placebo-controlled trial. Alimentary Pharmacology & Therapeutics 21 (5), 583–590 (http://www.blackwell-synergy.com/doi/abs/10.1111/j.1365-2036.2005.02356.x?cookieSet=1) Erdeve, O. et al (2004) 'The probiotic effect of S.boulardii in a pediatric age group' Journal of Trop Pediatr. Aug;50(4) pp.234-6 (http://www.ingentaconnect.com/content/oup/tropej/2004/00000050/00000004/art00234;jsessionid=xd1mslb6sqtw.alice?format=print) D'Souza, A. et al (2002) Probiotics in prevention of antibiotic associated diarrhoea: meta-analysis. Care of the Elderly Section, Faculty of Medicine, Imperial College School of Medicine, Hammersmith Hospital, London. BMJ 2002;324:1361 (8 June) http://www.bmj.com/cgi/content/full/324/7350/1361	877

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Alimentary Pharmacology & Therapeutics – Meta-Analysis of five randomised controlled trials The American Journal of Gastroenterology – Double-blind, placebo-controlled parallel-group study Microbial Ecology in Health and Disease	Szajewska H. & Mrukowicz J. (2005) 'Meta-analysis: non-pathogenic yeast Saccharomyces boulardii in the prevention of antibiotic-associated diarrhoea' Aliment Pharmacol Ther. Sep 1;22(5):365-72. (http://pt.wkhealth.com/pt/re/alpt/abstract.00001716-200509050-00001.htm;jsessionid=GyBQdWtHSn1DjDcWQ9MQbjclly3SNGy4yhLXtDYWVcxLBp44R6FD!29071008!181195628!8091!-1) McFarland LV, Surawics CM, Greenberg RN, Elmer GW, Moyer KA, Melcher SA, Bowen KE, Cox JL. Am J Gastroenterol 1995 Mar; 90 (3): 439-48 (http://www.florastor.com/client_images/gd2005113122591.pdf) 2. Acute & Chronic Diarrhoea McFarland, L.V. & Bernasconi, P. (1993) Saccharomyces boulardii: A Review of an Innovative Biotherapeutic Agent. Microbial Ecology in Health and Disease; Vol. 6 pp. 157-171. (http://www.dtecta.co.uk/casestudies/McFarland_&_Bernasconi_(1993)_Saccharomyces_boulardii_A_Review_of_an_Innovative_Biotherapeutic_Agent_DiarSafe_DTECTA_Probiotics_www.dtecta.co.uk.pdf)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Munchener Medizinische Wochenschrift Annales de Pediatrie Acta Paediatrica Journal of Travel Medicine and Infectious Disease Fortschr Med	Hochter, W. et al (1990) Saccharomyces boulardii in acute adult diarrhea. Efficacy and tolerance of treatment. Munchener Medizinische Wochenschrift; Vol. 132 (12) pp. 188-192. (http://www.dtecta.co.uk/casestudies/Hochter_%281990%29_Saccharomyces_boulardii_in_acute_adult_diarrhoea_Efficacy_and_tolerance_of_treatment_DiarSafe_DTECTA_Probiotics_www.dtecta.co.uk.pdf) Cetina-Sauri, G. & Basto, S. (1994) Therapeutic evaluation of Saccharomyces boulardii in children with acute diarrhea. Annales de Pediatrie; Vol. 41 (6) pp. 397-400. (http://www.dtecta.co.uk/casestudies/Cetina_Sauri_&_Basto_%281994%29_Therapeutic_Evaluation_of_Saccharomyces_boulardii_in_children_with_acute_diarrhoea_DiarSafe_DTECTA_Probiotics_www.dtecta.co.uk.pdf) Kurugol, Z. & Koturoglu, G. (2005) Effects of Saccharomyces boulardii in children with acute diarrhea. Acta Paediatrica; Vol. 94 pp. 44-47. (http://www.dtecta.co.uk/casestudies/Kurugol_&_Koturoglu_%282005%29_Effects_of_saccharomyces_boulardii_in_children_with_acute_diarrhoea_DiarSafe_DTECTA_Probiotics_www.dtecta.co.uk.pdf?cmd=Retrieve&db=PubMed&list_uids=15858959&dopt=Abstract 3. Traveller's Diarrhoea McFarland, L. V. (2007) Meta-analysis of probiotics for the prevention of traveller's diarrhoea. Travel Medicine and Infectious Disease. Vol. 5, Issue 2, pp. 97 – 105 (http://www.dtecta.co.uk/casestudies/McFarland_L._V._(2005)_Meta_analysis_of_probiotics_f	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					or_the_prevention_of_travellers_diarrhoea_Travla_DTECTA_Probiotics_www.dtecta.co.uk.pdf?cmd=Retrieve&db=PubMed&list_uids=8682428&dopt=Abstract) Kollaritsch, H.H. et al (1993) Prevention of traveller's diarrhoea: Comparison of different non-antibiotic preparations. Results of a placebo-controlled double-blind study; Fortschr Med; Vol. 111 pp. 152-156 (http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=8486328&dopt=Citation) Kirchhelle, A., Fruhwein, N. & Toburen, D. (1996) Treatment of persistent diarrhoea with Saccharomyces Boulardii in returning travellers. Results of a prospective study; Fortschr Med; Vol. 114 (11) pp. 136-140 (http://www.dtecta.co.uk/casestudies/Kirchelle_et_al_(1996)_Treatment_of_persistent_diarrhoea_with_saccharomyces_boulardii_in_returning_travellers_DTECTA_Probiotics_www.dtecta.co.uk.pdf?cmd=Retrieve&db=PubMed&list_uids=8682428&dopt=Abstract)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				The Journal of the American Medical Association – randomised placebo controlled trial Journal of Clinical Infectious Diseases Journal of Pediatric Gastroenterology and Nutrition The American Journal of Gastroenterology	4. Clostridium Difficile Disease McFarland, L.V. et al (1994) A randomised placebo-controlled trial of saccharomyces boulardii in combination with standard antibiotics for clostridium difficile disease. The Journal of the American Medical Association. Vol. 271. pp. 1913 – 1918 (http://www.dtecta.co.uk/casestudies/McFarland_et_al_(1994)_Randomised_placebo-controlled_trial_of_s.boulardii_with_antibiotics_for_clostridium_difficile_disease_DiarSafe_DTECTA_Probiotic_www.dtecta.co.uk.pdf) Surawicz, C.M. et al (2000) The Search for a Better Treatment for Recurrent Clostridium difficile Disease: Use of High-Dose Vancomycin Combined with Saccharomyces boulardii. Clinical Infectious Diseases. Vol. 31 pp. 1012 – 1017 (http://www.dtecta.co.uk/casestudies/Surawicz_et_al_(2000)_Search_for_better_treatment_for_recurrent_clostridium_difficile_use_of_high_dosage_vancomycin_with_s_boulardii_DiarSafe_DTECTA_Probiotics_www.dt.pdf) Buts, J., Corthier, G. & Delmee, M. (1993) Saccharomyces boulardii for Clostridium difficile-Associated Enteropathies in Infants. Journal of Pediatric Gastroenterology and Nutrition. Vol. 16 pp. 419 – 425 (http://www.dtecta.co.uk/casestudies/Buts_et_al_%281993%29_Saccharomyces_boulardii_for_Clostriduim_difficile-Associated_Enteropathies_in_Infants_DiarSafe_DTECTA_Probiotics_www.dtecta.co.uk.pdf) Surawicz, C.M. et al (1989) Treatment of Recurrent Clostridium difficile Colitis with Vancomycin and Saccharomyces boulardii. The American Journal of Gastroenterology.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Vol. 85 (10) (http://www.dtecta.co.uk/casestudies/Surawicz_et_al_%281989%29_Treatment_of_Recurrent_Clostridium_difficile_Colitis_with_Vancomycin_and_Saccharomyces_boulardii_DiarSafe_DTECTA_Probiotics_www.dtecta.co.uk.pdf)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Best Practice & Research Clinical Gastroenterology European Journal of Gastroenterology & Hepatology Medecine Chirurgie Digestives	Surawicz, C.M. (2003) Probiotics, antibiotic-associated diarrhoea and Clostridium difficile diarrhoea in humans. Best Practice & Research Clinical Gastroenterology. Vol. 17 (5) pp. 775 – 783 (http://www.dtecta.co.uk/casestudies/Surawicz_C._%20M.,_%282003%29_Probiotics,_antibiotic-associated_diarrhoea_and_clostridium_difficile_in_humans_DiarSafe_DTECTA_Probiotics_www.dtecta.co.uk.pdf) 5. Other Guslandi, M., Giollo, P. & Testoni, P.A. (2003) A pilot trial of Saccharomyces boulardii in ulcerative colitis. European Journal of Gastroenterology & Hepatology. Vol. 15 pp. 697 – 698. (http://www.dtecta.co.uk/casestudies/Guslandi_et_al_%282003%29_A_pilot_trial_of_Saccharomyces_boulardii_in_ulcerative_colitis_DiarSafe_DTECTA_Probiotics_www.dtecta.co.uk.pdf?cmd=Retrieve&db=PubMed&list_uids=15858959&dopt=Abstract) Maupas, J.L., Champemont, P. & Delforge, M. (1983) Treatment of Irritable Bowel Syndrome (IBS) Double Blind Trial of Saccharomyces Boulardii. Medecine Chirurgie Digestives. Vol. 12 (1) pp. 77 – 79. (http://www.dtecta.co.uk/casestudies/Maupas_et_al_%281983%29_Treatment_of_Irritable_Bowel_Syndrome_Double_Blind_Trial_of_Saccharomyces_Boulardii_DiarSafe_DTECTA_Probiotics_www.dtecta.co.uk.pdf?cmd=Retrieve&db=PubMed&list_uids=15858959&dopt=Abstract)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Probiotics and Prebiotics as contained in the formula AntiBloat: Bifidobacterium bifidum (CNCM I-3426), Lactobacillus casei (CNCM MA 64U), Lactobacillus acidophilus (CNCM I-1722), Lactococcus lactis (CNCM MA67/4J), Fructooligosaccharides (FOS)					
		AntiBloat Probiotic & Prebiotic rebalances the gut with good bacteria to support healthy digestion and good intestinal passage and transit for a comfortably flatter stomach.	Daily dose must provide at least 5 billion Colony Forming Units of probiotic bacteria to guarantee an intensive daily course. To be taken: 7 day course once a month To present a safety statement: It is not recommended to give Probiotics to severely immunosuppressed patients, post cardiac surgery patients, patients with pancreatic dysfunction or patients with blood in the stool unless under a doctor's care.			873

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				American Society for Clinical Nutrition Supplements – Review article Journal of Applied microbiology and biotechnology – Expert Analysis Journal of Food Protection – Expert Analysis	Saavedra JM. Clinical applications of probiotic agents. Am Soc Clin Nutr. 2001: 73(6); 1147S-1151S (http://www.ajcn.org/cgi/content/abstract/73/6/1147S) Tzortzis G, Goulas AK. Synthesis of prebiotic galactooligosaccharides using whole cells of a novel strain, bifidobacterium bifidum NCIMB 41171. Appl Microbiol Biotechnol. 2005; 68: 412-416. (http://www.springerlink.com/content/2vrvdpngrj323dvk/) Wallace TD, Bradley S, Buckley ND, and Green-Johnson JM (2003) Interactions of lactic acid bacteria with human intestinal epithelial cells: effects on cytokine production. Journal of Food Protection, 66, 3; 446-472. (http://apt.allenpress.com/perlserv/?request=get-abstract&issn=0362-028X&volume=066&issue=03&page=0466&ct=1) Houghton, L. A. & Whorwell, P. J. (2005) Towards a better understanding of abdominal bloating and distension in functional gastrointestinal disorders. Neurogastroenterology & Motility. Vol. 17 pp. 500 – 511	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Journal of Alimentary Pharmacology and Therapeutics – Review Article	Zar, S., Benson, M. J. & Kumar, D. (2002) Review Article: bloating in functional bowel disorders. Alimentary Pharmacology and Therapeutics. Vol. 16 pp. 1867 – 1876	
				British Journal of Nutrition – Review Article	Marteau, P. & Boutron-Ruault, M. C. (2002) Nutritional Advantages of Probiotics and Prebiotics. British Journal of Nutrition. Vol. 87 Suppl. 2 pp. S153 – S157	
				Die Pharmazie – Review Article	Kumar et al. (2005) Beneficial effects of probiotics and prebiotics on human health; Pharmazie Vol. 60 (3) pp.163 - 171	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Probiotics as contained in the probiotic formula Travla: Saccharomyces boulardii, Lactobacillus acidophilus (CNCM I-1722), Lactobacillus rhamnosus (CNCM I-1720), Bifidobacterium longum (CNCM I-3470)					
		Supports healthy digestion and immunity during travel abroad	Daily dose must provide at least 4 billion colony forming units of the Lactobacillus cultures, and at least 1 billion Colony Forming Units of Saccharomyces boulardii. To present directions statement: Take two capsules daily one week before departure and continuing during travel abroad or as professionally directed. To present a safety statement: It is not recommended to give Probiotics to severely immunosuppressed patients, post cardiac surgery patients, patients with pancreatic dysfunction or patients with blood in the stool unless under a doctor's care.	Department of Specific Prophylaxis and Tropical Medicine, University of Vienna – Meta Analysis Travel Medicine and Infectious Disease - Placebo controlled double-blind study. Bavarian society for immunity, tropical medicine and inoculation - Expert Study Journal of Food Protection – Expert Analysis	McFarland, L. V. (2007) Meta-analysis of probiotics for the prevention of traveller's diarrhoea. Travel Medicine and Infectious Disease. Vol. 5, Issue 2, pp. 97 – 105 Kollaritsch, H.H. et al (1993) Prevention of traveller's diarrhoea: Comparison of different non-antibiotic preparations. Results of a placebo-controlled double-blind study; Fortschr Med; Vol. 111 pp. 152-156 http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=8486328&dopt=Citation Kirchhelle, A., Fruhwein, N. & Toburen, D. (1996) Treatment of persistent diarrhoea with Saccharomyces Boulardii in returning travellers. Results of a prospective study; Fortschr Med; Vol. 114 (11) pp. 136-140 Wallace TD, Bradley S, Buckley ND, and Green-Johnson JM (2003) Interactions of lactic acid bacteria with human intestinal epithelial cells: effects on cytokine production. Journal of Food Protection, 66, 3; 446-472. http://apt.allenpress.com/perlserv/?request=get-abstract&issn=0362-028X&volume=066&issue=03&page=0466&ct=1	890

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Journal of Travel Medecine – Expert Report The Pediatric Infectious Disease Journal – Expert Review	Eileen Hilton, Pat Kolakowski, Carol Singer, Miriam Smith (1997) Efficacy of Lactobacillus rhamnosus (GG) as a Diarrheal Preventive in Travelers. Journal of Travel Medicine 4 (1), 41–43 http://www.blackwell-synergy.com/action/showPdf?submitPDF=Full+Text+PDF+%28274+KB%29&doi=10.1111%2Fj.1708-8305.1997.tb00772.x Jonathan E. Teitelbaum. (2005) Probiotics and the Treatment of Infectious Diarrhea. The Pediatric Infectious Disease Journal 24:3, 267 http://www.medscape.com/viewarticle/501960	
	Propionibacterium freudenreichi SI 41 and Propionibacterium freudenreichi i SI 26 Propio Fidus®					
		Intestinal flora	at least 10[10] cfu/day daily consumption	Individual human studies	Individual Human Studies Bougle D, Roland N, Lebeurrier F, Arhan P (1999). Effect of propionibacteria supplementation on fecal bifidobacteria and segmental colonic transit time in healthy human subjects. Scand J Gastroenterol 34, 144-148. Herve C, Fondrevez M, Cheron A, Barloy-Hubler F, Jan G (dec 2006). Transcarboxylase mRNA: a marker which evidences P. freudenreichii survival and metabolic activity during its transit in the human gut. Int. J Food Microbiol, in publication. Jan G, Leverrier P, Proudy I, Roland N (2002). Survival and beneficial effects of propionibacteria in the human gut: in vivo and in vitro investigations. Lait 82, 131-144.	238

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Saccharomyces boulardi (trade name PXN68)					
		Digestive health	at least 2x109 cfu/day	Human studies Meta-analysis	Meta-Analysis McFarland LV. Meta-analysis of probiotics for the prevention of traveler's diarrhea. Travel Med Infect Dis. 2007 Mar;5(2):97-105. Epub 2005 Dec 5. Individual Human Studies Kirchhelle A, Fruhwein N, Toburen D. Treatment of persistent diarrhea with S. boulardii in returning travelers. Results of a prospective study. Fortschr Med. 1996 Apr 20;114(11):136-40. Kollaritsch H, Holst H, Grobara P, Wiedermann G. Prevention of traveler's diarrhea with Saccharomyces boulardii. Results of a placebo controlled double-blind study. Fortschr Med. 1993 Mar 30;111(9):152-6. Villarruel G, Rubio DM, Lopez F, Cintioni J, Gurevech R, Romero G, Vandenplas Y. Saccharomyces boulardii in acute childhood diarrhoea: a randomized, placebo-controlled study. Acta Paediatr. 2007 Feb 13; [Epub ahead of print]	239

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Sacharomyces cerevisiae var boulardi					
		Digestive system	at least 4x10[9] cfu/ day	Meta-analysis In vitro studies (supporting)	Meta-Analysis D'Souza et al, Probiotics in prevention of Antibiotic associated diarrhea: meta-analysis, British Medical Journal 2002 June, 324: 1-6 H Szajewska and J.Mrukowicz, Meta-Analysis: non pathogenic yeast Saccharomyces boulardii in the prevention of Antibiotic-Associated Diarrhea, Alimentary Pharmacology & Therapeutics, 2005 Sept, 22(5): 365-371 Mc Farland, L.V. Meta-Analysis of Probiotics for the Prevention of Antibiotic Associated Diarrhea and the Treatment of clostridium difficile Disease, Am J Gastroenterol, 2006 Apr, 101 : 812-822 In Vitro Studies Czerucka D et al. Saccharomyces boulardii preserves the barrier function and modulates the signal transduction pathway induced in EPEC-infected T84 cells. Infection and Immunity 2000, 68 (10): 5998-6004. Dahan S et al. Saccharomyces boulardii interferes with Enterohaemorrhagic Escherichia coli¬induced signaling pathways in T84 cells. Infection and Immunity. 2003, 71(2): 766-73. Gedek B.R et al. Adherence of Escherichia coli serogroup 0157 and the Salmonella typhimurium mutant DT 104 to the surface of Saccharomyces boulardii. Mycoses 1999, (42): 261-264.	240

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Streptococcus thermophilus					
		Maintenance of healthy Immune system	At least 107 cfu / day	Textbooks & peer reviewed journal articles	Indrio F, Ladisa G, Mautone A, Montagna O. (2007). Effect of a Fermented Formula on Thymus Size and Stool pH in Healthy Term Infants. Pediatr Res. 2007 Jul;62(1):98-100	942
		Lactose digestion	Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the	Clinical trial Healthy + lactose intolerant men	Rizkalla SW et al., Am J Clin Nut 200 Dec; 72(6):1474-9	2,299

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			food matrix of application 10 million bacteria per portion/dose			
		Digestive health	Strains must be: Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 100 million bacteria per portion/dose	Overview of evidence Human trials	Gomes AMP et al., Trends in Food Science & Technology 1999; 10: 139-157	2,295

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Cholesterol control	Strains must be: Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 100 million bacteria per portion/dose	Clinical trial Healthy humans and animals Clinical trial Healthy women	Xiao JZ et al., J Dairy Sci 2003, 86:2452-2461 Kiessling G et al., Eur J Clin Nut 2002 Sept, 56(9);843-9	2,298
		Beneficial effect on intestinal microflora, gut integrity, digestion	At least 107 cfu / day			928

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks & peer reviewed journal articles	Saavedra, JM., Bauman NA, Oung I, Perman JA, Yolken RH. (1994). Feeding of bifidobacterium bifidum and streptococcus thermophilus to infants in hospital for the treatment of diarrhoea and shedding of rotavirus; Lancet; 344:1046-9 Saavedra, JM., Abi-Hanna, A., Moore, N., Yolken, R.H. (2004). Long-term Prevention of Antibiotic-Associated Diarrhea in Children: A Meta-Analysis of Randomized Controlled Trials. The Journal of Pediatrics. Sept. 367-372. Szajewska., H., Ruszczynski, M., Radzikowski, A. (2006). Probiotics in The Tannock, G. W. 1999. Analysis of the intestinal microflora: a renaissance. Antonie Leeuwenhoek 76:265-278. Madsen, KL. (2001). The use of probiotics in gastrointestinal disease. Can J Gastroenterol. 2001 Dec;15(12):817-22.	
		Contains Probiotic that confers a benefit on the host	At least 107 cfu / day			914

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks, peer reviewed journal articles and scientific opinions by official scientific bodies.	WHO definition of probiotic FAO/WHO (2001). Guidelines for the Evaluation of Probiotics in Food. Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada, April 30 and May 1, 2002. Gorbach SL and Goldin BR. (1992). Nutrition and the gastrointestinal microflora. Nutr Rev. 1992 Dec;50(12):378-81 Rolfe, RD. (2000). The role of probiotic cultures in the control of gastrointestinal health. J Nutr. Feb;130(2S Suppl): 396S-402S. Fuller, R and Perdigon, G. (2003). Gut flora, nutrition, immunity and Health. Edited by R Fuller and G Perdigon. Blackwell Publishing.	
		Hypercholesterolemic action	Strains must be: Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their	Overview of evidence Animal trials	Gomes AMP et al., Trends in Food Science & Technology 1999; 10: 139-157	2,297

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			ability to survive in the acid environment and in the presence of bile Assessed for side effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 100 million bacteria per portion/dose			
		Immune health	Strains must be: Probiotic (when administered in adequate amounts, must confer a beneficial health effect on the host) Morphologically and biochemically identifiable in accordance with accepted identification methods. Deposited in an international culture collection Evaluated for the absence of transmittable plasmids which may confer resistance to antibiotics Analysed regarding their ability to survive in the acid environment and in the presence of bile Assessed for side	Clinical trial Healthy infants Clinical trial Healthy adults	Saaveda JM et al., Am J Clin Nut 2004 Feb; 79(2):261-7 Donnet-Huges A et al., J Dairy Sci 1999 May, 82(5): 863-9	2,293

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			effects during clinical trials Present in adequate numbers at the end of shelf life to confer the claimed benefit Proven cell counts at the end of shelf life in the food matrix of application 100 million bacteria per portion/dose			

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Streptococcus thermophilus I-3428					
		Immune defenses / support of immunity	at least 1x10[9] cfu/day	Human studies	Individual Human Studies Majamaa H, Isolauri E, Saxelin M, Vesikari T. Lactic acid bacteria in the treatment of acute rotavirus gastroenteritis. J Pediatr Gastroenterol Nutr. 1995 Apr;20(3):333-8. Saavedra JM, Bauman NA, Oung I, Perman JA, Yolken RH. Feeding of Bifidobacterium bifidum and Streptococcus thermophilus to infants in hospital for prevention of diarrhoea and shedding of rotavirus. Lancet. 1994 Oct 15;344(8929):1046-9. Thibault H, Aubert-Jacquin C, Goulet O. Effects of long-term consumption of a fermented infant formula (with Bifidobacterium breve c50 and Streptococcus thermophilus 065) on acute diarrhea in healthy infants. J Pediatr Gastroenterol Nutr. 2004 Aug;39(2):147-52.	271
		Digestive health	at least 1x10[9] cfu/day			241

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human studies	Individual Human Studies Elli M, Callegari ML, Ferrari S, Bessi E, Cattivelli D, Soldi S, Morelli L, Goupil Feuillerat N, Antoine JM. Survival of yogurt bacteria in the human gut. Appl Environ Microbiol. 2006 Jul;72(7):5113-7. Majamaa H, Isolauri E, Saxelin M, Vesikari T. Lactic acid bacteria in the treatment of acute rotavirus gastroenteritis. J Pediatr Gastroenterol Nutr. 1995 Apr;20(3):333-8. Saavedra JM, Bauman NA, Oung I, Perman JA, Yolken RH. Feeding of Bifidobacterium bifidum and Streptococcus thermophilus to infants in hospital for prevention of diarrhoea and shedding of rotavirus. Lancet. 1994 Oct 15;344(8929):1046-9. Thibault H, Aubert-Jacquin C, Goulet O. Effects of long-term consumption of a fermented infant formula (with Bifidobacterium breve c50 and Streptococcus thermophilus 065) on acute diarrhea in healthy infants. J Pediatr Gastroenterol Nutr. 2004 Aug;39(2):147-52.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Yeo Valley yoghurt products containing the probiotic bacteria Bifidobacterium animalis ssp. lactis BB-12 ® and Lactobacillus acidophilus LA-5 ®					
		Intestinal flora/ digestive system	Consumption of a minimum 1 x 10e9 cfu of BB-12® and LA-5® per day			708

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Peer-reviewed scientific journals	Fermented Milk/Human studies: Masako Shioya, Keisuke Nakaoka, Naomine Iizuka and Yoshimi Benno. Journal of Nutritional Food 3 (1), 19-32, 2000 (Japanese study, to be translated into English) Masako Shioya, Keisuke Nakaoka, Naomine Iizuka, Mutsuku Sato and Yoshimi Benno. Journal of Nutritional Food 3 (1), 33-44, 2000 (Japanese study, to be translated into English) #412 Sheu BS, J Wu, CY Lo, HW Wu, JH Chen, YS Lin & MD Lin. 2002. Impact of supplement with Lactobacillus- and Bifidobacterium-containing yoghurt on triple therapy for Helicobacter pylori eradication. Aliment. Pharmacol. Ther. 16, 1669-1675 #420 Laake KO, Line PD, Aabakken L, Løtveit T, Bakka A, Eide J, Røseth A, Grzyb K, Bjørneklett A, Vatn MH. 2003. Assessment of Mucosal inflammation and circulation in response to probiotics in patients operated with ileal pouch anal anastomosis for ulcerative colitis. Scand J Gastroenterol.: 4; 409-414. #473 Laake K.O., Bjørneklett A., Aamodt G., Aabakken L., Jacobsen, M., Bakka, A., Vatn, M.H. 2005. Outcome of four weeks intervention with probiotics on symptoms and endoscopic appearance after surgical reconstruction with a J-configurated ileal-pouch-anal-anastomosis in ulcerative colitis. Scandinavian Journal of Gastroenterology (40) 43-51. Additional human studies: #92 Black, F.T., Einarsson, K., Lidbeck, A.,	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

Orrhage, K., Nord, C.E. Effect of lactic acid producing bacteria on the human intestinal microflora during ampicillin treatment. 1991. Scand. J. Infect. Dis., 23: 247-254

#186 Nord, C.E., Lidbeck, A., Orrhange, K., Sjostedt, S. Oral supplementation with lactic acid bacteria during intake of clindamycin. 1997. Clinical Microbiology and Infection, 3 (1): 124-132.

#383 Laake, K.O., Bjorneklett, A., Bakka, A., Midtvedt, T., Norin, K.E., Eide, T.J., Jacobsen, M.B., Lingaas, E., Axelsen, A.K., Lotveit, T., Vatn, M.H. Influence of fermented milk on clinical state, fecal bacterial counts and biochemical characteristics in patients with ileal- pouch- anal-anastomosis. 1999. Microbial Ecology in Health and Disease, 11: 211-217.

#466 Laake, K.O., P.D. Line, K. Grzyb, G. Aamodt, L. Aabakken, A. Røset, A.B. Hvinden, A. Bakka, J. Eide, A. Bjørneklett, M.H. Vatn. 2004. Assessment of mucosal inflammation and blood flow in response to four weeks intervention with probiotics in patients operated with a J-configurated Ileal-Pouch-Anal-Anastomosis (IPAA). Scand. J. Gastroenterol. (12) 1228-1235.

#499 Wildt S, Munck LK, Vinter-Jensen L, Hansen BF, Nordgaard-Lassen I, Christensen S, Avnstroem S, Rasmussen SN, Rumessen J. 2006. Probiotic treatment of collagenous colitis: A randomized, double-blind, placebo-controlled trial with L. acidophilus and Bifidobacterium animalis subsp. lactis. Inflamm Bowel Dis 12 (5): 395-401.

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Animal study: #505 Lesniewska V, Rowland I, Laerke HN, Grant G, Naughton PJ. 2006. Relationship between dietary-induced changes in intestinal commensal microflora and duodenojujenal myoelectric activity monitored by radiotelemetry in the rat in vivo. Experimental Physiology 91(1): 229-237.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Yoghurt containing the combination of three probiotic ingredients; Lactobacillus casei F19, Bifidobacterium lactis Bb12 and Lactobacillus acidophilus La5					
		Intestinal flora/digestive health:	Daily intake 1x10E10 cfu of each probiotic strain			778

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Scientific investigations Scientific reviews	Black F, Einarsson K, Lidbeck A, Orrhage K, Nord CE 1991 Effect of lactic acid producing bacteria on the human intestinal microflora during ampicillin treatment SWcand J Infect Dis 23:247-254 Jernberg C, Sullivan A, Edlund C, Jansson JK. 2005 Monitoring of antibiotic-induced alterations in the human intestinal microflora and detection of probiotic strains by use of terminal restriction fragment length polymorphism. Appl Environ Microbiol. 71:501-6. Lidbeck A, Edlund C, Gustafsson JA, Kager L, Nord CE. 1988 Impact of Lactobacillus acidophilus on the normal intestinal microflora after administration of two antimicrobial agents. Infection. 16:329-36. Nord CE, Lidbeck A, Orrhage K, Sjostedt S. 1997 Oral supplementation with lactic acid-producing bacteria during intake of clindamycin. Clin Microbiol Infect. 3:124-132. Orrhage K, Brismar B, Nord CE 1994 Effets of supplements with Bifidobacterium longum and Lactobacillus acidophilus on the intestinal microbiota during administration of clindamycin. Microb Ecol Health Dis 7:17-25. Sullivan A, Barkholt L, Nord CE. 2003 Lactobacillus acidophilus, Bifidobacterium lactis and Lactobacillus F19 prevent antibiotic-associated ecological disturbances of Bacteroides fragilis in the intestine. J Antimicrob Chemother. 52:308-11. Crittenden, R., Saarela, M., Mättö, J., Ouwehand, A.C., Salminen, S., Pelto, L.,	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Vaughan, E.E., de Vos, W.M., von Wright, A., Fondén, R., Mattila-Sandholm, T. 2002. Lactobacillus paracasei subsp. paracasei F19: survival, ecology and safety in the human intestinal tract - a survey of feeding studies within the PROBDEMO project. Microbial Ecology in Health and Disease Suppl. (Lactobacillus F19 – Closing the broken circle) 3:22-26 Sullivan, Å., Palmgren, A.C., Nordh, C.E. 2001. Effect of Lactobacillus paracasei on intestinal colonisation of Lactobacilli, Bifidobacteria and Clostridium difficile in elderly persons. Anerobe 07: 67-70 Sullivan, Å., Bennet, R., Viitanen, M., Palmgren, A.C., Nord, C.E. 2002. Influence of Lactobacillus F19 on intestinal microflora in children and elderly persons and impact on Helicobacter pylori infections. Microbial Ecology in Health and Disease Suppl. (Lactobacillus F19 – Closing the broken circle) 3:17-21 Sullivan A, Barkholt L, Nord CE. 2003 Lactobacillus acidophilus, Bifidobacterium lactis and Lactobacillus F19 prevent antibiotic-associated ecological disturbances of Bacteroides fragilis in the intestine. J Antimicrob Chemother. 52:308-11	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
PROTEIN						

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Amino Acids					
		" Amino acids for enhanced muscle activity."	No RDA / RNI			2,408

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					"Graham-Thiers PM, Kronfeld DS. Amino acid supplementation improves muscle mass in aged and young horses. J Anim Sci. 2005 Dec;83(12):2783-8. Killewich LA, Tuvdendorj D, Bahadorani J, Hunter GC, Wolfe RR. Amino acids stimulate leg muscle protein synthesis in peripheral arterial disease. J Vasc Surg. 2007 Mar;45(3):554-9. Ohtani M, Maruyama K, Sugita M, Kobayashi K. Amino acid supplementation affects hematological and biochemical parameters in elite rugby players. Biosci Biotechnol Biochem. 2001 Sep;65(9):1970-6. Paddon-Jones D, Wolfe RR, Ferrando AA. Amino acid supplementation for reversing bed rest and steroid myopathies. J Nutr. 2005 Jul;135(7):1809S-1812S. Rennie MJ. Exercise- and nutrient-controlled mechanisms involved in maintenance of the musculoskeletal mass. Biochem Soc Trans. 2007 Oct;35(Pt 5):1302-5. Scognamiglio R, Avogaro A, Negut C, Piccolotto R, de Kreutzenberg SV, Tiengo A. The effects of oral amino acid intake on ambulatory capacity in elderly subjects. Aging Clin Exp Res. 2004 Dec;16(6):443-7. Volpi E, Kobayashi H, Sheffield-Moore M, Mittendorfer B, Wolfe RR. Essential amino acids are primarily responsible for the amino acid stimulation of muscle protein anabolism in healthy elderly adults. Am J Clin Nutr. 2003 Aug;78(2):250-8."	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

1. Natural Medicines Comprehensive Database 2000

2. The Complete German Commission E Monographs Therapeutic Guide to Herbal Medicines 1998 American Botanical Council

3. PDR for Herbal Medicines 2nd Edition 2000 Medical Economics Co. Inc.

4. The Review of Natural Products Facts and Comparisons Wolters Kluwer Health Inc. 2003

5. A Dictionary of Natural Products George MacDonald Hawking, 1997 Plexus Publishing

6. The Natural Pharmacy 2nd Edition Prima Health 1999 Healthnotes Inc.

7. Pharmacognosy and Pharmacobiotechnology Robbers, Speedie and Tyler. 1996 Williams and Wilkins

8. Encyclopedia of Common Natural Ingredients used in Food, Drugs, and Cosmetics 2nd Ed. Albert Leung and Steven Foster 1996 John Wiley & Sons, Inc.

9. Arch Latinoam Nutr. 2006 Mar;56(1):77-82 Manaca, sweet potato and yam: possible substitutes of wheat in foods for two ethnic population in Venezuelan Amazon

10. J Agric Food Chem. 2006 Jun 14;54(12):4162-7 Total oxidant scavenging capacity of Euterpe oleracea Mart. (açaí) seeds and identification of their polyphenolic compounds.

11. J Ethnopharmacol. 2006 Sep

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

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13. Int J Food Sci Nutr. 2005 Feb;56(1):53-64. Total oxidant scavenging capacities of Euterpe oleracea Mart. (Açaí) fruits.

14. J Agric Food Chem. 2004 Mar 24;52(6):1539-45 Phytochemical composition and pigment stability of Açai (Euterpe oleracea Mart.).
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• Andersen, O.M. Flavonoids: Chemistry, Biochemistry and Applications. CRC Press,

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Boca Raton FL 2006. • G. M. Robinson, Robert Robinson (1931). "A survey of anthocyanins. I". Biochem J. 25 (5): 1687–1705.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Arginine					
		For muscle integrity and haematopoiesis (red blood cells building)	75-150 mg	Bibliographic references , reviews, clinical practice, human studies	Lerman A, Burnett Jr JC, Higano ST, McKinley LJ, Holmes Jr DR: Long-term L-Arginine Supplementation Improves Small-Vessel Coronary Endothelial Function in Humans. Circulation 1998:97: 2123-2128. Appleton J Arginine: Clinical potential of a semi-essential amino acid. Alt Med Review 2002,7(6): 512-522. Unknown. Protein and amino acids. Recommended Dietary Allowances, 10th Edition, Washington, National Academy Press 1989; 52-77. Wu G, Meininger CJ Arginine nutrition and cardiovascular function. J Nutr 2000;130: 2626-2629	2,481
		For immune system functions	75 – 150 mg			2,480

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Bibliographic references , reviews, clinical practice, human studies	Lerman A, Burnett Jr JC, Higano ST, McKinley LJ, Holmes Jr DR: Long-term L-Arginine Supplementation Improves Small-Vessel Coronary Endothelial Function in Humans. Circulation 1998:97: 2123-2128. Appleton J Arginine: Clinical potential of a semi-essential amino acid. Alt Med Review 2002,7(6): 512-522. Unknown. Protein and amino acids. Recommended Dietary Allowances, 10th Edition, Washington, National Academy Press 1989; 52-77. Wu G, Meininger CJ Arginine nutrition and cardiovascular function. J Nutr 2000;130: 2626-2629	
		Vascular health/Blood circulation	1500 mg per day 75-150 mg			344

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Published Review	Morris SM (2006) Arginine: beyond protein. Am J Clin Nutr; 83(2): 508-512. Rassaf T, Kleinbongard P, Kelm M (2006) The L-arginine nitric oxide pathway: avenue for a multiple level approach to assess vascular function. Biol Chem; 387(10): 1347-1349. Raghavan SA, Dikshit M (2004) Vascular regulation by the L-arginine metabolites nitric oxide and agmatine. Pharmacol Res; 49(5): 397-414. Grillo MA, Colombatto S (2004) Arginine revisited: minireview article. Amino acids: 26(4): 345-351. Scibior D, Czeczot H (2004) Arginine: metabolism and functions in the human organism. Postepy Hig Med Dosw; 58: 321-332. Tapiero H, Mathe G, Couvreur P et al (2002) Arginine. Biomed Pharmacother; 56(9): 439-445. Flynn NE, Meininger CJ, Haynes TE et al (2002) The metabolic basis of arginine nutrition and pharmacotherapy. Biomed Pharmacother; 56(9): 427-438. Wu G, Meininger CJ, Knabe DA et al (2000) Arginine nutrition in development, health and disease. Curr Opin Clin Nutr Metab Care; 3(1): 59-66. Blantz RC, Satriano J, Gabbai F et al (2000) Biological effects of arginine metabolites. Acta Physiol Scand; 168(1): 21-25.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				clinical practice, individual studies	ARGININE and Vascular health Authoritative/Scientific Bodies Encyclopedia of Human Nutrition (1st Edition) p 203, 1397, 1666, 1856 Editors: M. J. Sadler, J. J. Strain, B. Caballero Reviews Boger SH, Ron SE, L-Arginine improves vascular function by overcoming deleterious effects of ADMA, a novel cardiovascular risk factor. Altern,Med. Rev 2005;10:14-23 - Boger SH, Zoccali C, ADMA: a novel risk factor that explains excess cardiovascular event rate in patients with end-stage renal disease. Atheroscler. Suppl. 2003; 4: 23 – 28 - Curran JN, Winter DC, Bouchier-Hayes D, Biological fate and clinical implications of arginine metabolism in tissue healing. Wound Repair Regen. 2006; 14: 376 – 386 - Gornik HL, Creager MA, Arginine and endothelial and vascular health. J. Nutr. 2004; 134: 2880S-2887S Individual human studies Adams MR, Jessup W, Celermajer, Cigarette smoking is associated with increased human monocyte adhesion to endothelial cells: reversibility with oral L-arginine but not vitamin C. J. Am. Coll. Cardiol. 1997; 29: 491-497 Barbul A, Lazarou SA, Efron DT, et al., Arginine enhances wound healing and lymphocyte immune responses in humans. Surgery 1990; 108: 331 – 336 - Bednarz B, Jaxa-Chamiec T, Maciejewski P, et al., Efficacy and safety of orally given L-arginine in acute myocardial infarction: results of the multicenter, randomized, double-blind, placebo-controlled “ARAMI” pilot trial. Kardiol. Pol. 2005; 62: 421-426 - Blum, L. Hathaway, R. Mincemoyer, WH, et	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					al., Effects of oral L-arginine on endothelium-dependent vasodilation and markers of inflammation in healthy postmenopausal women. J Am Coll Cardiol. 2000; 35: 271 – 276 - Bode-Boger SM, Boger SH, Galland A, et al., L-arginine-induced vasodilation in healthy humans: pharmacokinetic-pharmacodynamic relationship. Br J Clin Pharmacol. 1998; 46: 489 - 497 - Clarkson P, Adams MR, Powe AJ, et al., Oral L-arginine improves endothelium-dependent dilation in hypercholesterolemic young adults. J. Clin. Invest. 1996; 97: 1989-1994 - Creager MA, Gallagher SJ, Girerd XJ, et al., L-arginine improves endothelium-dependent vasodilation in hypercholesterolemic humans. J. Clin. Invest. 1992 ; 90: 1248 – 1253 - Evans RW, Fernstrom JD, Thompson J, et al., Oral arginine reduces systemic blood pressure in type 2 diabetes: its potential role in nitric oxide generation. Nutr. Biochem. 2004; 15: 534-539 - Hambrecht R Hilbrich L, Erbs S, et al., Correction of endothelial dysfunction in chronic heart failure: additional effects of exercise training and oral L-arginine supplementation. American College of Cardiology. 2000; 35:706-713 - Huynh NT, Tayek JA, Oral arginine reduces systemic blood pressure in type 2 diabetes: its potential role in nitric oxide generation. J. Am. Coll. Nutr. 2002; 21: 422 – 427 - Lekakis JP, Papathanassiou S, Papaioannou TG, et al., Oral L-arginine improves endothelial dysfunction in patients with essential hypertension. Int. J. Cardiol.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					2002; 86: 317-323 - Lerman A, Burnett JC, Higano ST,et al., Long-term L-arginine supplementation improves small-vessel coronary endothelial function in humans. Circulation. 1998; 97: 2123 -2128 - Rytlewski K, Olszanecki R, Korbut R, et al., Effects of prolonged oral supplementation with l¬arginine on blood pressure and nitric oxide synthesis in preeclampsia. Eur. J. Clin Invest. 2005; 35: 32-37 - Schulman SP, Becker LC, Kass DA, et al., L-arginine therapy in acute myocardial infarction: the Vascular Interaction With Age in Myocardial Infarction (VINTAGE MI) randomized clinical trial. JAMA. 2006; 295, 58-64. (see: Editorial Commentary. Ignaro LJ, Bland J, JAMA, 2006, 9 No.2:1-3) - Siani A, Pagano E, Iacone R, et al., Blood pressure and metabolic changes during dietary L-arginine supplementation in humans. Am. J. Hypertens. 2000; 13: 547-551 - WascherTC, Graier WF, Dittrich P, et al., Effects of low dose L-arginine on insulin-mediated vasodilation and insulin sensitivity. Eur. J. Clin. Invest. 1997; 27: 690-695 - Wolf A, Zalpour C, Theilmeier G, et al., Dietary L-Arginine Supplementation Normalizes Platelet Aggregation in Hypercholesterolemic Humans. J. Am. Cardiol. 1997; 29: 479-485	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Bibliographic references , reviews, clinical practice, human studies	Lerman A, Burnett Jr JC, Higano ST, McKinley LJ, Holmes Jr DR: Long-term L-Arginine Supplementation Improves Small-Vessel Coronary Endothelial Function in Humans. Circulation 1998:97: 2123-2128. Appleton J Arginine: Clinical potential of a semi-essential amino acid. Alt Med Review 2002,7(6): 512-522. Unknown. Protein and amino acids. Recommended Dietary Allowances, 10th Edition, Washington, National Academy Press 1989; 52-77. Baligan M, Giardina A, Giovannini G, Laghi MG, Ambrosioni G. L-arginina e immunità. Studio in soggetti pediatrici. Minerva Pediatric 1997;49: 537-542. Wu G, Meininger CJ Arginine nutrition and cardiovascular function. J Nutr 2000;130: 2626-2629	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Beta Alanine					
		Increasing Exercise Thresholds	The product must contain at least 1.6 gram beta alanine per serving Claim to be used for foods for active individuals	Peer-reviewed scientific clinical study	Stout JR, Cramer JT, Zoeller RF, et al. (2006) Effects of beta alanine supplementation on the onset of neuromuscular fatigue and ventilatory threshold in women. Amino Acids; November 30 [Epub] Springer-Verlag.	2,187
		Increasing Muscle Carnosine Level & Acid Buffering	The product must contain at least 1.6 gram beta alanine per serving Claim to be used for foods for active individuals	Peer-reviewed scientific research review Peer-reviewed scientific clinical studies	Boldyrev AA (2000) Problems and perspectives in studying the biological role of carnosine. Biochemistry (Moscow); 65(7): 751-756. Gariballa SE and Sinclair AJ. (2000) Carnosine: physiological properties and therapeutic potential. Age and Ageing; 29: 207-210. Harris RC, Tallon MJ, Dunnett M, et al. (2006) The absorption of orally supplied beta-alanine and its effect on muscle carnosine synthesis in human vastus lateralis. Amino Acids; March 24 [Epub] Springer-Verlag. Hill CA, Harris RC, Kim HJ, et al. (2007) Influence of beta alanine supplementation on skeletal muscle carnosine concentrations and high intensity cycling capacity. Amino Acids; 32: 225-233.	1,762
		Increases muscle carnosine, the intracellular buffering agent proposed to be responsible for the beneficial effects on short-duration high	Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC. Sports foods and food supplements providing 1.6-5.2 g beta alanine per recommended daily			1,604

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		intensity exercise.	consumption	RCT	Influence of beta-alanine supplementation on skeletal muscle carnosine concentrations and high intensity cycling capacity Hill CA, Harris RC, Kim HJ, Harris BD, Sale C, Boobis LH, Kim CK, Wise JA Amino Acids 32(2):225-233, 2007. Effects of beta-alanine supplementation on the onset of neuromuscular fatigue and ventilatory threshold in women Stout JR, Cramer JT, Zoeller RF, Torok D, Costa P, Hoffman JR, Harris RC, O'kroy J Amino Acids 32(3):381-386, 2007. The absorption of orally supplied beta-alanine and its effect on muscle carnosine synthesis in human vastus lateralis Harris RC, Tallon MJ, Dunnett M, Boobis L, Coakley J, Kim HJ, Fallowfield JL, Hill CA, Sale C, Wise JA Amino Acids 30(3):279-289, 2006.	
		Increasing Time to Exhaustion	The product must contain at least 1.6 gram beta alanine per serving Claim to be used for foods for active individuals	Peer-reviewed scientific clinical study	Stout JR, Cramer JT, Zoeller RF, et al. (2006) Effects of beta alanine supplementation on the onset of neuromuscular fatigue and ventilatory threshold in women. Amino Acids; November 30 [Epub] Springer-Verlag.	2,188
		Increasing Training Volume & Work	The product must contain at least 1.6 gram beta alanine per serving Claim to be used for foods for active individuals	Peer-reviewed scientific clinical studies	Hill CA, Harris RC, Kim HJ, et al. (2007) Influence of beta alanine supplementation on skeletal muscle carnosine concentrations and high intensity cycling capacity. Amino Acids; 32: 225-233.	2,189

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Beta-alanine					
		Physical performance	1.6-5.2 g beta alanine per day			346

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Randomised double blind placebo controled trials	BETA-ALANINE and Physical performance Human studies Kim HJ, Cho J, Kim CK, Harris RC, Harris DB, Sale C, Wise JA. Effect On Muscle Fibre Morphology And Carnosine Content After 12 Days Training Of Korean Speed Skaters. Med Sci Sport Ex. 2005; 37 (5): 988. Suzuki Y, Ito O, Mukai N, Takahashi H, Takamatsu K. High levels of skeletal muscle carnosine contributes to the later half of exercise performance during maximal cycle ergometer sprinting. Jap J Physiol. 2002; 52: 199 - 205. In vitro (animal) Studies - Cameron JN. Intracellular buffering by dipeptides at. high and low temperature in the blue crab. Callinectes sapidus. J Exp Biol. 1989; 143: 543 – 548 - Dunnet and Harris 1999 Influence of oral beta-alanine and L-histidine supplementation on the carnosine content of the gluteus medius. Equine Vet J Suppl. 1999 Jul;30:499-504 - Horinishi H, Grillo M, Margolis FL. Purification and characterization of carnosine synthetase from mouse olfactory bulbs. J Neurochem. 1978; 31: 909 - 19. - Plowman JE, Close EA. An evaluation of a method to differentiate the species of origin of meats on the basis of the contents of anserine, beta-alanine and carnosine in skeletal muscle. J Sci Fd Agric. 1988; 45: 69 - 78. - Suyama M, Suzuki T, Maruyama M, Saito K. Determination of carnosine, anserine and balenine in the muscle of animals. Bull Jpn Soc Sci Fish. 1970; 36: 1048 - 1053. - Tamaki N, Tsunemori F, Wakabayashi M, Hama T . Effect of histidine-free and -excess diets on anserine and carnosine contents in rat gastrocnemius muscle. J Nutr Sci Vitaminol	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					(Tokyo). 1977; 23 (4): 331 - 40. In vitro (human) studies - Bakardjiev A, Bauer WJ. Transport of b-alanine and biosynthesis of carnosine by skeletal muscle cells in primary culture. Eur J Biochem. 1994; 225: 617 - 623. - Harris RC, Dunnett M, Greenhaff PL. Carnosine and Taurine contents in individual fibres of human vastus lateralis muscle. J Sport Sci. 1998; 16: 639 - 643. - Lenney JF, Peppers SC, Kucera-Orallo CM, George RP. Characterization of human tissue carnosinase. Biochem J. 1985; 228: 653 -660. - Mannion AF, Jakeman PM, Dunnett M, Harris RC, Willan PL. Carnosine and anserine concentrations in the quadriceps femoris muscle of healthy humans. Eur J Appl Physiol Occup Physiol. 1992; 64 (1): 47 - 50. - Tallon MJ, Harris RC, Boobis LH. Carnosine contents in the vastus lateralis of extremely hypertrophied skeletal muscle. J Strength Cond Sci. 2005; 19 (4): 725 - 729.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Branched chain amino acids					
		RECOVERY. Increased protein synthesis in skeletal muscle during recovery from sustained strength exercise.	Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC A ratio of 2:1:1 of essential amino acids L-Leucine, l-Isoleucine and L-Valine and a an amount of L-leucine 14mg/kg body weight/day, L-Isoleucine 10 mg/kg body weigt/day and L-Valine 10 mg/kg body weight/day is to be fulfilled.			1,605

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Review RCT Review of a number of trials	Branched-Chain Amino Acids Activate Key Enzymes in Protein Synthesis after Physical Exercise Blomstrand E, Eliasson J, Karlsson HKR and Köhnke R J. Nutr. 136:269S-273S, 2006 BCAA intake affects protein metabolism in muscle after but not during exercise in humans Blomstrand E and Saltin B Am J Physiol Endocrinol Metab 281: E365-E374, 2001 Branched-chain amino acids increase p70S6k phosphorylation in human skeletal muscle after resistance exercise Karlsson HKR, Nilsson P-A, Nilsson J, Chibalin AV, Zierath JR and Blomstrand E Am. J. Physiol. 287:E1-E7, 2004. Branched Chain Amino Acids Activate Messenger Ribonucleic Acid Translation Regulatory Proteins in Human Skeletal Muscle, and Glucocorticoids Blunt This Action. Liu Z, Jahn LA, Long W, Fryburg DA, Wei L and Barrett EJ The Journal of Clinical Endocrinology & Metabolism 86 (5): 2136-2143, 2001 Postexercise net protein synthesis in human muscle from orally administered amino acids Tipton KD, Ferrando AA, Phillips SM, Doyle D Jr, Wolfe RR. Am J Physiol. 276(4 Pt 1):E628-634, 1999. Acute response of net muscle protein balance reflects 24-h balance after exercise and amino acid ingestion Tipton KD, Borsheim E, Wolf SE, Sanford AP,	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Wolfe RR. Am J Physiol Endocrinol Metab. 284: 76-89, 2003. Branched-chain amino acid supplementation during repeated prolonged skiing exercises at altitude Bigard AX, Lavier P, Ullmann L, Legrand H, Douce P, Guezennec CY Int J Sport Nutr. 6(3): 295-307, 1996. Effect of a selected amino acid mixture on the recovery from muscle fatigue during and after eccentric contraction exercise training Siguta M, Ohtani M, Ishil N, Maruyama K, Kobayashi K Biosci Biotechnol Biochem. 67: 372-376, 2003. Amino acid mixture improves training efficiency in athletes Ohtani M, Sugita M, Maruyama K J Nutr. 136: 538S-543S, 2006. Branched-chain amino acids augment ammonia metabolism while attenuating protein breakdown during exercise Maclean DA, Graham TE, Saltin B Am J Physiol. 267:E1010-E1022, 1994. Effect of infused branched-chain amino acids on muscle and whole-body amino acid metabolism in man. Louard RJ, Barrett EJ, Gelfand RA. Clin Sci (Lond). 79(5):457-66, 1990. Leucine as a regulator of whole body and skeletal muscle protein metabolism in humans. K. S. Nair, R. G. Schwartz and S. Welle Am J Physiol Endocrinol Metab 263: E928-E934, 1992.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Branched chain amino acids (Leucine, Isoleucine, valine)					
		Muscle metabolism	Min 3g per day, taken during and immediately following the exercise			361

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Reviews/peer-reviewed Clinical studies	BRANCHED CHAIN AMINO ACIDS (LEUCINE, ISOLEUCINE, VALINE) and Muscle metabolism Authoritative/Scientific Bodies - Encyclopedia of Human Nutrition (1st edition), p 1842, 1856 - Editors: M. J. Sadler, J. J. Strain, B. Caballero Reviews - Blomstrand E, Newsholme EA, The plasma level of some amino acids and physical and mental fatigue. Experientia 1996; 15: 413-415 - Ohtani M, Sugita M, Maruyama K, Amino acid mixture improves training efficiency in athletes J. Nutr. 2006; 136, 538S-543S Individual human studies - Blomstrand E, Saltin B, BCAA intake affects protein metabolism in muscle after but not during exercise in humans. Am. J. Physiol. Endocrinol. Metab. 2001, 281: E365-E374 - Blomstrand, Hassmen P, Ek E, et al., Effects of branched-chain amino acid supplementation on serum creatine kinase and lactate. Acta Physiol. Scand. 1997; 159: 41-49 - Blomstrand E, Newsholme EA, Effect of branched-chain amino acid supplementation on the exercise-induced change in aromatic amino acid concentration in human muscle. Acta Physiol. Scand. 1992; 146: 293-298 - Borsheim E, Tipton KD, Wolf SE, Wolfe RR, Effects of branched-chain amino acid supplementation on serum creatine kinase and lactate. Am. J. Physiol. Endocrinol. Metab. 2002; 283: E648– E657 - Coombes JS, McNaughton LR, Effects of branched-chain amino acid supplementation on serum creatine kinase and lactate. The Journal	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					of Sports Medicine and Physical Fitness 2000; 40: 240-246 - Crowe MJ, Jarrad N, Weatherson JN, et al., Effects of dietary leucine supplementation on exercise performance. Eur. J. Appl. Physiol. August 2005 - Karlsson HKR, Nilsson PA, Nilsson J, et al., Branched-chain amino acids increase p70S6k phosphorylation in human skeletal muscle after resistance exercise. Am. J. Physiol. Endocrinol. Metab. 2004 ; 287: E1-E7 - Mittleman KD, Ricci MR, Bailey SP, Branched-chain amino acids prolong exercise during heat stress in men and women. J. Sports Med. Phys. Fitness 2000; 40: 240-246 - Nosaka K, Sacco P, Mawatari K, Effects of Amino Acid Supplementation on Muscle Soreness and Damage. Int. J. Sport. Nutr. Exerc. Metab. 2006; 16: 620-635 - Parry-Billings P, Budgett R, Koutedakis Y, et al., Plasma amino acid concentrations in the overtraining syndrome: possible effects on the immune system. Med. Sci. Sports Exerc. 1992; 24: 1353-1358 - Rasmussen BB, Tipton KD, Miller SL, et al., An oral essential amino acid-carbohydrate supplement enhances muscle protein anabolism after resistance exercise. J. Appl. Physiol. 2000 ; 88: 386-392 - Schena F, Guerrini F, Tregnaghi P, et al., Branched-chain amino acid supplementation during trekking at high altitude. The effects on loss of body mass, body composition, and muscle power. Eur. J. Appl. Physiol. 1992; 65: 394-398 - Shimomura Y, Yamamoto Y, Bajotto G, et al., Nutraceutical effects of branched-chain amino acids on skeletal muscle. J. Nutr. 2006 ; 136 : 1S-4S - Van Hall G, Saltin B, Wagenmakers AJ,	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Muscle protein degradation and amino acid metabolism during prolonged knee-extensor exercise in humans. Clin Sci (Lond). 1999; 97: 557-567 - Watson P, Shirreffs SM, Maughan RJ, The effect of acute branched-chain amino acid supplementation on prolonged exercise capacity in a warm environment. Eur. J. Appl. Physiol. 2004; 93: 306-314	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Branched-chain amino acids					
		Vital component of muscle tissue		Textbook	Van Gammeren, D. Endurance performance (2001). In: Sports Supplements (edited by J. Antonio & Stout, J.R.), pp. 279-300. Pennsylvania: Lippincott Williams & Wilkins	2,450
		Attenuates the decline in power output following exercise at high altitude	11.5g per day	Human RCTs	Schena F, Guerrini F, Tregnaghi P, Kayser B. Branched-chain amino acid supplementation during trekking at high altitude. The effects on loss of body mass, body composition, and muscle power. Eur J Appl Physiol Occup Physiol. 1992;65(5):394-8 Bigard AX, Lavier P, Ullmann L, Legrand H, Douce P, Guezennec CY. Branched-chain amino acid supplementation during repeated prolonged skiing exercises at altitude. Int J Sport Nutr. 1996 Sep;6(3):295-306	2,445
		Promotes recovery after exercise	77 mg per kg of bodyweight before exercise			2,448

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human RCTs	Coombes JS, McNaughton LR. Effects of branched-chain amino acid supplementation on serum creatine kinase and lactate dehydrogenase after prolonged exercise. J Sports Med Phys Fitness. 2000 Sep;40(3):240-6 Blomstrand E, Newsholme EA. Effect of branched-chain amino acid supplementation on the exercise-induced change in aromatic amino acid concentration in human muscle. Acta Physiol Scand. 1992 Nov;146(3):293-8 Tang FC. Influence of branched-chain amino acid supplementation on urinary protein metabolite concentrations after swimming. J Am Coll Nutr. 2006 Jun;25(3):188-94 Bassit RA, Sawada LA, Bacurau RF, Navarro F, Martins E Jr, Santos RV, Caperuto EC, Rogeri P, Costa Rosa LF. Branched-chain amino acid supplementation and the immune response of long-distance athletes. Nutrition. 2002 May;18(5):376-9 Bassit RA, Sawada LA, Bacurau RF, Navarro F, Costa Rosa LF. The effect of BCAA supplementation upon the immune response of triathletes. Med Sci Sports Exerc. 2000 Jul;32(7):1214-9 Parry-Billings M, Budgett R, Koutedakis Y, Blomstrand E, Brooks S, Williams C, Calder PC, Pilling S, Baigrie R, Newsholme EA. Plasma amino acid concentrations in the overtraining syndrome: possible effects on the	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					immune system. Med Sci Sports Exerc. 1992 Dec;24(12):1353-8 Shimomura Y, Yamamoto Y, Bajotto G, Sato J, Murakami T, Shimomura N, Kobayashi H, Mawatari K. Nutraceutical effects of branched-chain amino acids on skeletal muscle. J Nutr. 2006 Feb;136(2):529S-532S Blomstrand E, Saltin B. BCAA intake affects protein metabolism in muscle after but not during exercise in humans. Am J Physiol Endocrinol Metab. 2001 Aug;281(2):E365-74 Rohde T, MacLean DA, Richter EA, Kiens B, Pedersen BK. Prolonged submaximal eccentric exercise is associated with increased levels of plasma IL-6. Am J Physiol. 1997 Jul;273(1 Pt 1):E85-91 MacLean DA, Graham TE, Saltin B. Branched-chain amino acids augment ammonia metabolism while attenuating protein breakdown during exercise. Am J Physiol. 1994 Dec;267(6 Pt 1):E1010-22	
		Promotes muscle recovery after exercise	77 mg per kg of bodyweight before exercise			2,449

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human RCTs	Coombes JS, McNaughton LR. Effects of branched-chain amino acid supplementation on serum creatine kinase and lactate dehydrogenase after prolonged exercise. J Sports Med Phys Fitness. 2000 Sep;40(3):240-6 Blomstrand E, Newsholme EA. Effect of branched-chain amino acid supplementation on the exercise-induced change in aromatic amino acid concentration in human muscle. Acta Physiol Scand. 1992 Nov;146(3):293-8 Tang FC. Influence of branched-chain amino acid supplementation on urinary protein metabolite concentrations after swimming. J Am Coll Nutr. 2006 Jun;25(3):188-94 Shimomura Y, Yamamoto Y, Bajotto G, Sato J, Murakami T, Shimomura N, Kobayashi H, Mawatari K. Nutraceutical effects of branched-chain amino acids on skeletal muscle. J Nutr. 2006 Feb;136(2):529S-532S MacLean DA, Graham TE, Saltin B. Branched-chain amino acids augment ammonia metabolism while attenuating protein breakdown during exercise. Am J Physiol. 1994 Dec;267(6 Pt 1):E1010-22	
		BCAAs improve performance during sustained exercise	90 mg per kg of bodyweight during exercise 90 mg per kg of bodyweight during exercise			2,452

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human RCTs	Blomstrand E, Hassmen P, Ekblom B, Newsholme EA. Administration of branched-chain amino acids during sustained exercise—effects on performance and on plasma concentration of some amino acids. Eur J Appl Physiol Occup Physiol. 1991;63(2):83-8 Blomstrand E, Hassmen P, Ek S, Ekblom B, Newsholme EA. Influence of ingesting a solution of branched-chain amino acids on perceived exertion during exercise. Acta Physiol Scand. 1997 Jan;159(1):41-9	
		Reduces protein breakdown after exercise	77 mg per kg of bodyweight prior to exercise			2,444

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human RCTs	Coombes JS, McNaughton LR. Effects of branched-chain amino acid supplementation on serum creatine kinase and lactate dehydrogenase after prolonged exercise. J Sports Med Phys Fitness. 2000 Sep;40(3):240-6 Blomstrand E, Newsholme EA. Effect of branched-chain amino acid supplementation on the exercise-induced change in aromatic amino acid concentration in human muscle. Acta Physiol Scand. 1992 Nov;146(3):293-8 Tang FC. Influence of branched-chain amino acid supplementation on urinary protein metabolite concentrations after swimming. J Am Coll Nutr. 2006 Jun;25(3):188-94 Blomstrand E, Saltin B. BCAA intake affects protein metabolism in muscle after but not during exercise in humans. Am J Physiol Endocrinol Metab. 2001 Aug;281(2):E365-74 Rohde T, MacLean DA, Richter EA, Kiens B, Pedersen BK. Prolonged submaximal eccentric exercise is associated with increased levels of plasma IL-6. Am J Physiol. 1997 Jul;273(1 Pt 1):E85-91 MacLean DA, Graham TE, Saltin B. Branched-chain amino acids augment ammonia metabolism while attenuating protein breakdown during exercise. Am J Physiol. 1994 Dec;267(6 Pt 1):E1010-22	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Improves mental performance after exercise	5.3g during a race	Human RCTs	Hassmen P, Blomstrand E, Ekblom B, Newsholme EA. Branched-chain amino acid supplementation during 30-km competitive run: mood and cognitive performance. Nutrition. 1994 Sep-Oct;10(5):405-10 Blomstrand E, Hassmen P, Ekblom B, Newsholme EA. Administration of branched-chain amino acids during sustained exercise—effects on performance and on plasma concentration of some amino acids. Eur J Appl Physiol Occup Physiol. 1991;63(2):83-8 Blomstrand E, Hassmen P, Newsholme EA. Effect of branched-chain amino acid supplementation on mental performance. Acta Physiol Scand. 1991 Oct;143(2):225-6 Blomstrand E, Hassmen P, Ek S, Ekblom B, Newsholme EA. Influence of ingesting a solution of branched-chain amino acids on perceived exertion during exercise. Acta Physiol Scand. 1997 Jan;159(1):41-9	2,447
		Help maintain a healthy immune system	6 g per day			2,451

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human RCTs	Bassit RA, Sawada LA, Bacurau RF, Navarro F, Martins E Jr, Santos RV, Caperuto EC, Rogeri P, Costa Rosa LF. Branched-chain amino acid supplementation and the immune response of long-distance athletes. Nutrition. 2002 May;18(5):376-9 Bassit RA, Sawada LA, Bacurau RF, Navarro F, Costa Rosa LF. The effect of BCAA supplementation upon the immune response of triathletes. Med Sci Sports Exerc. 2000 Jul;32(7):1214-9 Parry-Billings M, Budgett R, Koutedakis Y, Blomstrand E, Brooks S, Williams C, Calder PC, Pilling S, Baigrie R, Newsholme EA. Plasma amino acid concentrations in the overtraining syndrome: possible effects on the immune system. Med Sci Sports Exerc. 1992 Dec;24(12):1353-8	
		Increases protein synthesis	A total of 100mg per kg of bodyweight during and after exercise	Human RCTs	Karlsson HK, Nilsson PA, Nilsson J, Chibalin AV, Zierath JR, Blomstrand E. Branched-chain amino acids increase p70S6k phosphorylation in human skeletal muscle after resistance exercise. Am J Physiol Endocrinol Metab. 2004 Jul;287(1):E1-7 Blomstrand E, Saltin B. BCAA intake affects protein metabolism in muscle after but not during exercise in humans. Am J Physiol Endocrinol Metab. 2001 Aug;281(2):E365-74	2,446

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Branched-chain amino acids (BCAA) **L-leucine** **L-valine** **L-isoleucine**					
		Improvement of muscle recovery after exercise Improvement of muscle protein synthesis	AMOUNT RECOMMENDATION: Min 3g ADVISORY STATEMENT: Do not take more than 12 g BCAA per day (higher dose may lead to ammonia build-up) INTAKE RECOMMENDATION: Take during and immediately following the exercise AD HOC RECCOMENDATION: Provide sufficient intake of carbohydrates, fluids			1,155

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human intervention studies; Reviews; Observational human studies; Textbook (1): claim supportive (2): non-supportive	Human intervention studies (1) • Nosaka et al., Int. J. Sport. Nutr. Exerc. Metab. 2006, 16: 620-635 Blomstrand et al., Acta Physiol. Scand. 1997, 159: 41-49 • Blomstrand & Newsholme, Acta Physiol. Scand. 1992, 146: 293-298 • Schena et al., Eur. J. Appl. Physiol. 1992, 65: 394-398 • Børsheim et al., Am. J. Physiol. Endocrinol. Metab. 2002, 283: E648– E657 • Karlsson et al., Am. J. Physiol. Endocrinol. Metab. 2004, 287: E1-E7 • Rasmussen et al., J. Appl. Physiol. 2000, 88: 386-392 • Coombes & McNaughton, The Journal of Sports Medicine and Physical Fitness 2000, 40: 240-246 • Blomstrand & B. Saltin, Am. J. Physiol. Endocrinol. Metab. 2001, 281: E365-E374 • Parry-Billings et al., 1992, Med. Sci. Sports Exerc. 1992, 24: 1353-1358 Reviews • Blomstrand & Newsholme, Experientia 1996, 15: 413-415 • Ohtani et al., J. Nutr. 2006, 136, 538S-543S Human intervention studies (2) Watson et al., Eur. J. Appl. Physiol. 2004, 93: 306-314 Observational human study (2) Van Hall et al., Clin Sci (Lond). 1999, 97: 557-567 Textbook: Encyclopedia of human Nutrition (1st edition), p 1842, 1856	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	GAKIC (amino acids glycine and arginine, with alpha-ketoiscaproic acid (KIC)					
		Improves exercise performance	11.2g of GAKIC prior to exercise	RCTs	Stevens BR, Godfrey MD, Kaminski TW & Braith RW. High-intensity dynamic human muscle performance enhanced by a metabolic intervention. Med Sci Sports Exerc. 2000 Dec;32(12):2102-8. Buford BN, Koch AJ. Glycine-arginine-alpha-ketoisocaproic acid improves performance of repeated cycling sprints. Med Sci Sports Exerc. 2004 Apr;36(4):583-7.	2,441

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Glutamine					
		Increasing cell swelling / volumization	The product must contain at least 5 gram Glutamine per serving Claim to be used for foods for active individuals	Peer-reviewed scientific research articles Peer-reviewed scientific research review	Low SY, Rennie MJ, and Taylor PM (1997) Signaling elements involved in amino acid transport responses to altered muscle cell volume. FASEB J 11: 1111-1117. Silva AC, Santos-Neto MS, Soares AM, et al (1998) Efficacy of a glutamine- based oral rehydration solution on the electrolyte and water absorption in a rabbit model of secretory diarrhea induced by cholera toxin. JPGN 26(5): 13- 519. Moskovitz B, Katz Y, Singer P, et al (1994) Glutamine metabolism and utilization: relevance to major problems in health care. (Review Article) Pharmacological Research 30(1): 61-71.	1,655
		Abundance in the body	The product must contain at least 5 gram Glutamine per serving Claim to be used for foods for active individuals	Peer-reviewed scientific research reviews	Walsh NP, Blannin AK, Robson PJ, et al (1998) Glutamine, Exercise and Immune Function (Review Article). Sports Med 26(3): 177-191. Miller AL (1999) Therapeutic considerations of L-glutamine: A review of the literature. (Review Article) Alternative Medicine Review 4(4): 239-248. Stumvoll M, Perriello G, Meyer C, et al (1999) Role of glutamine in human carbohydrate metabolism in kidney and other tissues (Review Article). Kidney International 55: 778-792.	1,660
		Supporting glucose homeostasis	The product must contain at least 5 gram			1,658

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			Glutamine per serving Claim to be used for foods for active individuals	Peer-reviewed scientific research article	Iwashita S, Williams P, Jabbour K, et al (2005) Impact of glutamine supplementation on glucose homeostasis during and after exercise. J Appl Physiol 99: 1858-1865.	
		Supporting exercise recovery	The product must contain at least 5 gram Glutamine per serving Claim to be used for foods for active individuals	Peer-reviewed scientific research review	Moskovitz B, Katz Y, Singer P, et al (1994) Glutamine metabolism and utilization: relevance to major problems in health care. (Review Article) Pharmacological Research 30(1): 61-71.	1,656
		Muscle protein metabolism	The product must contain at least 5 gram Glutamine per serving Claim to be used for foods for active individuals	Peer-reviewed scientific research articles	MacLennan PA, Brown RA and Rennie MJ (1987) A positive relationship between protein synthetic rate and intracellular glutamine concentration in perfused rat skeletal muscle. FEBS Letters 215(1): 187-191. MacLennan PA, Smith K, Weryk B, et al (1988) Inhibition of protein breakdown by glutamine in perfused rat skeletal muscle. FEBS Letters 237(1,2): 133-136.	1,654
		Immune system.	Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC Glutamine should be 50 - 400 mg/kg body mass per recommended daily consumption.			1,626

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Meta-analysis Review RCT	Fuel utilization by cells of the immune system Calder PC Proceedings of the Nutrition Society 54: 65-82, 1995. Glutamine Labow BI and Souba WW World J Surg. 24(12):1503-1513, 2000. The effect of BCAA supplementation upon the immune response of triathletes Bassit RA, Sawada LA, Bacurau RFP, Navarro F, Costa Rosa LFBP Med. Sci. Sports Exerc. 32(7): 1214–1219, 2000. Effect of oral glutamine on whole body carbohydrate storage during recovery from exhaustive exercise Bowtell JL, Gelly K, Jackman ML, Patel A, Simeoni M, Rennie MJ J. Appl. Physiol. 86(6): 1770–1777, 1999. The effects of oral glutamine supplementation on athletes after prolonged, exhaustive exercise Castell LM and Newsholme EA Nutrition 13 (7-8): 738-742, 1997. Plasma amino acid concentrations in the overtraining syndrome: possible effects on the immune system. Parry-Billings M, Budgett R, Koutedakis Y, Blomstrand E, Brook S, Williams C, Calder PC, Pilling S, Baigrie R, Newsholme EA Medicine & Science in Sports & Exercise. 24(12):1353-1358, 1992. The effects of high-intensity intermittent exercise on the plasma concentrations of	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					glutamine and organic acids. Walsh NP, Blannin AK, Clark AM, Cook L, Robson PJ, GleesonM Eur J Appl Physiol Occup Physiol 77 (5): 434-438, 1998 Does glutamine contribute to immunosuppression after major burns? Parry-Billings M, Evans J, Calder PC, Newsholme EA. Lancet 336(8714):523-525, 1990.	
		Immune health	50-400 mg/kg per day The product must contain at least 5 gram Glutamine per serving Claim to be used for foods for active individuals			407

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				authorative medical text regarding the biochemical and physiological properties of glutamine	Reviews - Child (1999) Running and tissue damage. In 'Improving performance in middle and long distance running: A scientific approach to race preparation.' Advisory panel Bangsbo J., Clarkson P.M., Hargreaves M., Williams C. Eds. J.L. Fallowfield and D.M. Wilkinson, John Wiley & Sons, Chichester, pages 122-139. - Furst and Stehle 2004 What Are the Essential Elements Needed for the Determination of Amino Acid Requirements in Humans? J. Nutr. 134: 1558S–1565S, 2004. - Hood and Turjung (1990) Amino acid metabolism during exercise and following endurance training. Sports Med. 9; 23-35. - Millward (1999) Inherent difficulties in defining amino acid requirements. In Protein and Amino Acids, pages 169-216. - Wagenmakers (1998) Muscle amino acid at rest and during exercise: Role in human physiology and metabolism. Exercise and Sports Science Reviews 26; 287-314. Text book - Newsholme, EA, Leech, AR: Biochemistry for the Medical Sciences. John Wiley & Sons, Chichester/New York, 1995 93 - Souba, W. W. Glutamine Physiology, Biochemistry, and Nutrition in. Critical Illness. Austin: R.G. Landes Co., 1992. Peer reviewed papers - Kerksick CM, Rasmussen CJ, Lancaster SL, Magu B, Smith P, Melton C, Greenwood M, Almada AL, Earnest CP, Kreider RB. The effects of protein and amino acid supplementation on performance and training adaptations during ten weeks of resistance training. J Strength Cond Res. 2006	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Aug;20(3):643-53. - Tang FC. Influence of branched-chain amino acid supplementation on urinary protein metabolite concentrations after swimming. J Am Coll Nutr. 2006 Jun;25(3):188-94. - Malandain H. Transglutaminases: a meeting point for wheat allergy, celiac disease, and food safety. Allerg Immunol (Paris). 2005 Dec;37(10):397-403. Review. - Ohtani M, Sugita M, Maruyama K. Amino acid mixture improves training efficiency in athletes. J Nutr. 2006 Feb;136(2):538S-543S. - Kargotich S, Rowbottom DG, Keast D, Goodman C, Dawson B, Morton AR. Plasma glutamine changes after high-intensity exercise in elite male swimmers. Res Sports Med. 2005 Jan-Mar;13(1):7-21. - Blomstrand E, Moller K, Secher NH, Nybo L. Effect of carbohydrate ingestion on brain exchange of amino acids during sustained exercise in human subjects. Acta Physiol Scand. 2005 Nov;185(3):203-9. - Durham WJ, Miller SL, Yeckel CW, Chinkes DL, Tipton KD, Rasmussen BB, Wolfe RR. Leg glucose and protein metabolism during an acute bout of resistance exercise in humans. J Appl Physiol. 2004 Oct;97(4):1379-86. . - Krieger JW, Crowe M, Blank SE.Chronic glutamine supplementation increases nasal but not salivary IgA during 9 days of interval training. J Appl Physiol. 2004 Aug;97(2):585-91. - Bailey DM, Davies B, Castell LM, Collier DJ, Milledge JS, Hullin DA, Seddon PS, Young IS. Symptoms of infection and acute mountain sickness; associated metabolic sequelae and problems in differential diagnosis. High Alt Med Biol. 2003 Fall;4(3):319-31. - Hiscock N, Petersen EW, Krzywkowski K,	

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- Bacurau RF, Bassit RA, Sawada L, Navarro F, Martins E Jr, Costa Rosa LF. Carbohydrate supplementation during intense exercise and the immune response of cyclists. Clin Nutr. 2002 Oct;21(5):423-9.
- Mourtzakis M, Graham TE. Glutamate ingestion and its effects at rest and during exercise in humans. J Appl Physiol. 2002 Oct;93(4):1251-9.
- Bassit RA, Sawada LA, Bacurau RF, Navarro F, Martins E Jr, Santos RV, Caperuto EC, Rogeri P, Costa Rosa LF. Branched-chain amino acid supplementation and the immune response of long-distance athletes. Nutrition. 2002 May;18(5):376-9.
- Dalsgaard MK, Ide K, Cai Y, Quistorff B, Secher NH. The intent to exercise influences the cerebral O(2)/carbohydrate uptake ratio in humans. J Physiol. 2002 Apr 15;540(Pt 2):681-9.
- Khogali SE, Pringle SD, Weryk BV, Rennie MJ. Is glutamine beneficial in ischemic heart disease? Nutrition. 2002 Feb;18(2):123-6.
- Antonio J, Sanders MS, Kalman D, Woodgate D, Street C. The effects of high-dose glutamine ingestion on weightlifting performance. J Strength Cond Res. 2002 Feb;16(1):157-60.
- Krzywkowski K, Petersen EW, Ostrowski K, Kristensen JH, Boza J, Pedersen BK. Effect of glutamine supplementation on exercise-induced changes in lymphocyte function. Am J Physiol Cell Physiol. 2001 Oct;281(4):C1259-65.

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					- Blomstrand E, Saltin B. BCAA intake affects protein metabolism in muscle after but not during exercise in humans. Am J Physiol Endocrinol Metab. 2001 Aug;281(2):E365-74. - Lambert GP, Broussard LJ, Mason BL, Mauermann WJ, Gisolfi CV. Gastrointestinal permeability during exercise: effects of aspirin and energy-containing beverages. J Appl Physiol. 2001 Jun;90(6):2075-80. - Engelen MP, Wouters EF, Deutz NE, Does JD, Schols AM. Effects of exercise on amino acid metabolism in patients with chronic obstructive pulmonary disease.Am J Respir Crit Care Med. 2001 Mar;163(4):859-64. - Blanchard MA, Jordan G, Desbrow B, MacKinnon LT, Jenkins DG. The influence of diet and exercise on muscle and plasma glutamine concentrations. Med Sci Sports Exerc. 2001 Jan;33(1):69-74. - Bassit RA, Sawada LA, Bacurau RF, Navarro F, Costa Rosa LF. The effect of BCAA supplementation upon the immune response of triathletes. Med Sci Sports Exerc. 2000 Jul;32(7):1214-9. - Nieman DC. Exercise immunology: future directions for research related to athletes, nutrition, and the elderly.Int J Sports Med. 2000 May;21 Suppl 1:S61-8. Review. - Walsh NP, Blannin AK, Bishop NC, Robson PJ, Gleeson M. Effect of oral glutamine supplementation on human neutrophil lipopolysaccharide-stimulated degranulation following prolonged exercise. Int J Sport Nutr Exerc Metab. 2000 Mar;10(1):39-50. - van Hall G, Saris WH, van de Schoor PA, Wagenmakers AJ. The effect of free glutamine and peptide ingestion on the rate of muscle glycogen resynthesis in man. Int J Sports Med. 2000 Jan;21(1):25-30. - Bailey SP, Zacher CM, Mittleman KD.	

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Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Peer-reviewed scientific research articles Peer-reviewed scientific research review	Krieger JW, Crowe M, and Blank SE (2004) Chronic glutamine supplementation increases nasal but not salivary IgA during 9 days of interval training. J Appl Physiolo 97: 585-591. Parry-Billings M, Budgett R, Koutedakis, et al (1992) Plasma amino acid concentrations in the overtraining syndrome: possible effects on the immune system. Med Sci Sports Exerc Dec; 24(12): 1353-1358. Calder PC and Yaqoob (1999) Glutamine and the immune system (Review Article). Amino Acids 17: 227-241.	
		Muscle function	50 - 900 mg/kg per day			408

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				authoritative medical text: Biochemical and physiological properties of glutamine	Reviews - Furst and Stehle 2004 What Are the Essential Elements Needed for the Determination of Amino Acid Requirements in Humans? J. Nutr. 134: 1558S–1565S, 2004. - Hood and Turjung (1990) Amino acid metabolism during exercise and following endurance training. Sports Med. 9; 23-35. - Millward (1999) Inherent difficulties in defining amino acid requirements. In Protein and Amino Acids, pages 169-216. - Wagenmakers (1998) Muscle amino acid at rest and during exercise: Role in human physiology and metabolism. Exercise and Sports Science Reviews 26; 287-314. Text book - Newsholme, EA, Leech, AR: Biochemistry for the Medical Sciences. John Wiley & Sons, Chichester/New York, 1995 - Souba, W. W. Glutamine Physiology, Biochemistry, and Nutrition in. Critical Illness. Austin: R.G. Landes Co., 1992. Peer reviewed papers - Kargotich S, Rowbottom DG, Keast D, Goodman C, Dawson B, Morton AR. Plasma glutamine changes after high-intensity exercise in elite male swimmers. Res Sports Med. 2005 Jan-Mar;13(1):7-21. - Krieger JW, Crowe M, Blank SE.Chronic glutamine supplementation increases nasal but not salivary IgA during 9 days of interval training. J Appl Physiol. 2004 Aug;97(2):585-91. - Hiscock N, Petersen EW, Krzywkowski K, Boza J, Halkjaer-Kristensen J, Pedersen BK. Glutamine supplementation further enhances exercise-induced plasma IL-6.J Appl Physiol. 2003 Jul;95(1):145-8. - Bacurau RF, Bassit RA, Sawada L,	

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					Navarro F, Martins E Jr, Costa Rosa LF. Carbohydrate supplementation during intense exercise and the immune response of cyclists. Clin Nutr. 2002 Oct;21(5):423-9. - Krzywkowski K, Petersen EW, Ostrowski K, Kristensen JH, Boza J, Pedersen BK. Effect of glutamine supplementation on exercise-induced changes in lymphocyte function. Am J Physiol Cell Physiol. 2001 Oct;281(4):C1259-65. - Walsh NP, Blannin AK, Bishop NC, Robson PJ, Gleeson M. Effect of oral glutamine supplementation on human neutrophil lipopolysaccharide-stimulated degranulation following prolonged exercise. Int J Sport Nutr Exerc Metab. 2000 Mar;10(1):39-50. - van Hall G, Saris WH, van de Schoor PA, Wagenmakers AJ. The effect of free glutamine and peptide ingestion on the rate of muscle glycogen resynthesis in man. Int J Sports Med. 2000 Jan;21(1):25-30. - Bowtell JL, Gelly K, Jackman ML, Patel A, Simeoni M, Rennie MJ.Effect of oral glutamine on whole body carbohydrate storage during recovery from exhaustive exercise. J Appl Physiol. 1999 Jun;86(6):1770-7. - Robson PJ, Blannin AK, Walsh NP, Castell LM, Gleeson M. Effects of exercise intensity, duration and recovery on in vitro neutrophil function in male athletes. Int J Sports Med. 1999 Feb;20(2):128-35. - Rohde T, Asp S, MacLean DA, Pedersen BK. Competitive sustained exercise in humans, lymphokine activated killer cell activity, and glutamine--an intervention study. Eur J Appl Physiol Occup Physiol. 1998 Oct;78(5):448-53. - Rohde T, MacLean DA, Pedersen BK. Effect of glutamine supplementation on changes in the immune system induced by repeated exercise. Med Sci Sports Exerc. 1998	

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					Jun;30(6):856-62. - Castell LM, Newsholme EA. The effects of oral glutamine supplementation on athletes after prolonged, exhaustive exercise. Nutrition. 1997 Jul-Aug;13(7-8):738-42. - Kinscherf R, Hack V, Fischbach T, Friedmann B, Weiss C, Edler L, Bartsch P, Droge W. Low plasma glutamine in combination with high glutamate levels indicate risk for loss of body cell mass in healthy individuals: the effect of N-acetyl-cysteine. J Mol Med. 1996 Jul;74(7):393-400.	
		Mental health	Min 100 mg per day			409

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				monographs, peer reviewed publications, textbooks	Monographs - HAGER-ROM 2004, Springer Verlag, Heidelberg; Ebel, S.; Schlager, H.; Rommelspacher, H.; L-Glutamin - Martindale: The Extra Pharmacopoeia; Thirty-fifth edition published 2007; Pharmaceutical Press 2007; Glutamine; pp. 1785-86 Peer reviewed publications - Arwert, L.I.; Deijen, J.B.; Drent, M.L.; Effects of an oral mixture containing glycine, glutamine and niacin on memory, GH and IGF-I secretion in middle-aged and elderly subjects, Nutritional neuroscience, 6, 5, 2003, pp. 269 - 275 - Blonde-Cynober, F. et al.; Use of ornithine a-ketoglutarate in clinical nutrition of elderly patients; Nutrition 2003; 19: 73-5 - Falcao De Arruda, I.S.; De Aguilar-Nascimento, J.E.; Benefits of early enteral nutrition with glutamine and probiotics in brain injury patients, Clinical science, 106, 3, 2004, pp. 287 - 292 - Field, C.J.; Johnson, I.; Pratt, V.C.; 2000, Glutamine and arginine: imunonutrients for improved health; Med. Sci. Sports Exercise 32 (Suppl 7), 377-388 - Hertz, L. et al (Eds.): Glutamine, glutamate and GABA in the central nervous system; Alan Liss, New York 1983 - Mcentee, W.J.; CROOK, T.H.: Glutamate: its role in learning, memory, and the aging brain. Psychopharmacology Berl 111 (1993) 391 - Novak, F. et al.; Glutamine supplementation in serious illness: a systematic review of the evidence; Crit Care Med 2002; 30:2022-9 - Vrba, R.; Studies on metabolic function of	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					the brain and on its relation to physical stress. V. Role of glutamin in restorative processes of the brain, Physiologia Bohemoslovaca, 5, 3, 1956, pp. 257 – 268	
		Supporting glycogen replenishment	The product must contain at least 5 gram Glutamine per serving Claim to be used for foods for active individuals	Peer-reviewed scientific research articles Peer-reviewed scientific research review Peer-reviewed scientific meta analysis	Bowtell JL, Gelly K, Jackman ML, et al (1999) Effect of oral glutamine on whole body carbohydrate storage during recovery from exhaustive exercise. J Appl Physiol; 86: 1770-1777. Varnier M, Leese GP, Thompson J, et al (1995) Stimulatory effect of glutamine on glycogen accumulation in human skeletal muscle. Am J Physiol; 269: E309-E315.	1,657

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Glutamine and glutamine peptide					
		Metabolic stress/protein synthesis/gut permeablity/carbohydrate metabolism	min.5 g glutamine per day			406

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				generally accepted roles (6), meta-analyses and critical expert reviews (4) and human intervention studies (5)	Authoritative/Scientific Bodies - Encyclopedia of Human Nutrition (1st Edition): p70, 80, 203, 204, 1402, 1651,1819, 1824, 1856 Editors: M. J. Sadler, J. J. Strain, B. Caballero Generally accepted role(s) Battezzati et al (2004), Am J Physiol Endocrinol Metab 286, E129-E135, Nonhepatic glucose production in humans. C. Duffan, J. Gannon, and W.A. Walker (2002) Am.J.Clin.Nutr. 75(5):789-808. Protective nutrients and functional foods for the gastrointestinal tract. - Lacey JM & Wilmore DW (1990) Nutrition Reviews; 48; 297-309. Is glutamine a conditionally essential amino acid? - Newsholme et al (2003) Cell Biochem Funct 21, 1-9. Glutamine and glutamate – their central role in cell metabolism and function Stumvoll M et al (1999) Kidney International 55, 778-92. Role of glutamine in human carbohydrate metabolism in kidney and other tissues. - Souba, WW (1991) Ann Rev Nutr 11, 283-308. Glutamine: a key substrate for the splachnic bed. - Ziegler TR et al (2003) Annu Rev Nutr 23, 229-61. Trophic and cytoprotective nutrition for intestinal adaptation, mucosal repair, and barrier function. Meta-analyses and Critical Expert Reviews - Kreymann KG et al, Clinical Nutrition (2006) 25, 210–223. ESPEN Guidelines on Enteral Nutrition:Intensive care (“Glutamine should be supplemented in patients suffering from burns or trauma”) - Rowbottom DG et al (1996) Sports Medicine 21(2), 80-97. The emerging role of glutamine as an indicator of exercise stress and overtraining.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Newsholme EA et al (1991) In : Medicine and Sport Science 32 - Advances in Nutrition and Top Sport (ed. Brouns F) , 79-93, Karger, Basel. A biochemical mechanism to explain some characteristics of overtraining. Reviews Castell LM, Poortmans JR, and Newsholme EA,. Does glutamine have a role in reducing infections in athletes. Eur. J. Appl. Physiol. & Occup. Physiol. 1996; 73: 488-490 - Castell LM, and Newsholme EA, The relation between glutamine and the immuno-depression observed in exercise. Amino Acids 2001; 20: 49-61 - Castell LM and Newsholme EA, Glutamine and the effects of exhaustive exercise upon the immune response. Can. J. Physiol. Pharmacol. 1998; 76: 524-532 - Garcia-de-Lorenzo A, Zarazaga A, Garcia-Luna PP, et al., Clinical evidence for enteral nutritional support with glutamine. Nutrition 2003; 19: 805-811 - Neu J, DeMarco V, Li N., Glutamine: clinical applications and mechanisms of action. Curr. Opin. Clin. Nutr. Metab. Care 2002; 5: 69-75 - Newsholme P. Why is L-glutamine metabolism important to cells of the immune system in health, post-injury, surgery or infection? J. Nutr. 2001; 131: 2515S-2522S - Reeds PJ , Burrin DG, Glutamine and the bowel. J. Nutr. 2001; 131: 2505S-2508S 92 Tubman TRJ, Thompson SW, McGuire W, Cochrane database of systematic reviews(Online) 2005, No1 CD001457 Walsh NP, Blannin AK, Robson PJ, et al., Glutamine, exercise and immune function.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Links and possible mechanisms. Sports Med. 1998; 26: 177-191 Individual human studies Bowtell JL et al (1999) J Appl Physiol 86(6), 1770-1777, Effect of oral glutamine on whole body carbohydrate storage during recovery from exhaustive exercise Codffier M et al (2003), Am J Physiol Gastrointest Liver Physiol 285, 266-273. Enteral glutamine stimulates protein synthesis and decreases ubiquitin mRNA level in human gut mucosa Hammarqvist et al (2005), Clinical Nutrition 24, 236–243, Free amino acid and glutathione concentrations in muscle during short-term starvation and refeeding. Krzywkowski K, Petersen EW, Ostrowski K, et al., Effect of glutamine and protein supplementation on exercise-induced decreases in salivary IgA. Am. J. Physiol. Cell Physiol. 2001; 281: 50-54 Perriello et al (1997) Am J Physiol 272, E437-E445, Regulation of gluconeogenesis by glutamine in normal postabsorptive humans - Rohde T, MacLean DA. Hartkopp A, et al., The immune system and serum glutamine during a triathlon. Eur. J. Appl. Physiol. 1997; 74: 428-434 - Varnier M et al (1995) Am J of Physiol 269, E309-E315. Stimulatory effect of glutamine on glycogen accumulation in human skeletal muscle. Yoshida S, Matsui M, Shirouzu Y, Fujita H, Yamana H, Shirouzu K. Effects of glutamine supplements and radiochemotherapy on systemic immune and gut barrier function in patients with advanced esophageal cancer. Annals of Surgery. 1998; 227: 485-91 Ziegler TR, Young LS, Benfell K, et al., Clinical	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					and Metabolic Efficacy of Glutamine supplemented Parenteral Nutrition after Bone Marrow Transplantation. Ann. Internal Med. 1992; 116: 821-828	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	L-Citrulline					
		Citrulline helps to optimize blood flow throughout the body and promote healthy energy levels.	No RDA / RNI			2,409

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					"Hickner RC, Tanner CJ, Evans CA, Clark PD, Haddock A, Fortune C, Geddis H, Waugh W, McCammon M. L-citrulline reduces time to exhaustion and insulin response to a graded exercise test. Med Sci Sports Exerc. 2006 Apr;38(4):660-6. Abstract available at <http://www.acsm-msse.org/pt/re/msse/abstract.00005768-200604000 00008.htm;jsessionid=HDvWvy2p604kT5XwBc6cckmxMtJX6K2Jhxw3rSm1r4vF7Cl0Wnc3!160024619 5!181195629!8091!-1>.	
					Brown MD, Srinivasan M, Hogikyan RV, Dengel DR, Glickman SG, Galecki A, Supiano MA. Nitric oxide biomarkers increase during exercise-induced vasodilation in the forearm. Int J Sports Med. 2000 Feb;21(2):83-9. Abstract available at <http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=ShowDetailView&TermToSearch=10727066&ordinalpos=13&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum>	
					Schwedhelm E, Maas R, Freese R, Jung D, Lukacs Z, Jambrecina A, Spickler W, Schulze F, Böger RH. Pharmacokinetic and pharmacodynamic properties of oral L-citrulline and L-arginine: impact on nitric oxide metabolism. Br J Clin Pharmacol. 2007 Jul 27; [Epub ahead of print]. Abstract available at <http://www.blackwell-synergy.com/doi/abs/10.1111/j.1365-2125.2007.02990.x>.	
					2. - Nelson, D. L.; Cox, M. M. "Lehninger, Principles of Biochemistry" 3rd Ed. Worth Publishing: New York, 2000. ISBN	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					1-57259-153-6.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	L-glutamine					
		Maintains healthy gastrointestinal tract and immune functions in stressful conditions	Healthy adults concerned with maintaining healthy gastrointestinal tract and immune functions in stressful conditions AMOUNT RECOMMENDATION: Min 5 g glutamine per day			1,157

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human intervention studies; Reviews; Textbook 1): claim supportive (2): non-supportive	Human intervention studies (1) • Rohde T, MacLean DA. Hartkopp A, and Pedersen BK, Eur. J. Appl. Physiol. 1997, 74: 428-434 Reviews (1) • Castell LM, Poortmans JR, and Newsholme EA,.Eur. J. Appl. Physiol. & Occup. Physiol. 1996, 73:488-490 • Reeds PJ , and Burrin DG, J. Nutr. 2001, 131: 2505S-2508S • Newsholme P. J. Nutr. 2001, 131: 2515S-2522S • Castell LM, and Newsholme EA, Amino Acids 2001, 20: 49-61 • Castell LM and Newsholme EA, Can. J. Physiol. Pharmacol. 1998, 76: 524-532 • Walsh NP, Blannin AK, Robson PJ, Gleeson M, Sports Med. 1998, 26: 177-191 • Garcia-de-Lorenzo A, Zarazaga A, Garcia-Luna PP, Gonzalez-Huix F, Lopez-Martinez J, Mijian A, Quecedo L, Casimiro C, Usan L, del Llano J, Nutrition 2003, 19: 805-811 • Neu J, DeMarco V, Li N., Curr. Opin. Clin. Nutr. Metab. Care 2002, 5: 69-75 Human studies (2) Reviews (2) Tubman TRJ, Thompson SW, McGuire W, Cochrane database of systematic reviews(Online) 2005, No1 CD001457 Textbook Encyclopedia of Human Nutrition (1st Edition): p70, 80, 203, 204, 1402, 1651,1819, 1824, 1856	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	L-methionine					
		Improvement of protein quality. Modulation of lipids metabolism	Human data generally show an observed safe level of intake as 5 times the daily requirement, but uncertainty factor would have to be applied. Overweight adults AMOUNT RECOMMENDATION:: 2 - 5 g methionine per day	Reviews, peer-reviewed clinical studies, clinical studies	• Naomi K.Fukagawa , J. Nutr., 2006, 136: 1676S-1681s • Fomon et al., Am. J.Clin. Nutr. 1979, 32: 2460- • Hiroaki Oda, J. Nutr., 2006, 136: 1666S-1669S • Di Buono M,Wykes LJ,Cole, J. Nutrition 2003, 133: 733-9 • Raguso C. ,Regan MM, Young VR., Am J. Clin. Nutr. 2000, 71: 491-9 • M.C.G. van de Poll, C.H.C. Dejong , Soeters P. B. , J.Nutr. , 2006, 136: 1694-1700S • Harvey Mudd S,Braverman N.,Pomper M.,et al., Mol gen Metab 2003, 79: 6-16 • Garlick P.J., J. Nutr., 2006, 136: 1722S-1725S • Fujisawa Kiyohito et al. , Am J Clin Nutr 1995, 61: 603-	1,158

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lysine					
		For cardiovascular system functions	50 - 500 mg, in general for groups with insufficient intake of animal proteins	WHO/FAO/UNU report	Protein and Amino Acid Requirements in Human Nutrition. Report of a Joint WHO/FAO/UNU Expert Consultation Technical Report Series, No 935. 2006	2,479
		For immune systems functions	50 - 500 mg, in general for groups with insufficient intake of animal proteins	WHO/FAO/UNU report	Protein and Amino Acid Requirements in Human Nutrition. Report of a Joint WHO/FAO/UNU Expert Consultation Technical Report Series, No 935. 2006	2,478
		To improve cereal protein quality needed for body tissues synthesis	50 - 500 mg, in general for groups with insufficient intake of animal proteins	WHO/FAO/UNU report Bibliographic references	1. Protein and Amino Acid Requirements in Human Nutrition. Report of a Joint WHO/FAO/UNU Expert Consultation Technical Report Series, No 935. 2006 2. Civitelli R, Villareal DT, Agnusdei D, Nardi P, Avioli LV, Gennari C. Dietary L-lysine and calcium metabolism in humans. Nutrition 1992; 8 (6):400-405 3. Pereira SM, Begum A, Jesudian G, Sundararaj R. Lysine-supplemented wheat and growth of preschool children. Am J Clin Nutr 1969; 22 (5):606-611 4. Pereira SM, Begum A, Jesudian G, Sundararaj R. Lysine-supplemented wheat and growth of preschool children. Am J Clin Nutr 1969; 22 (5):606-611	2,477
		To increase metabolism	50 - 500 mg, in general for groups with insufficient intake of animal proteins s			2,476

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				WHO/FAO/UNU report Bibliographic references	1. Protein and Amino Acid Requirements in Human Nutrition. Report of a Joint WHO/FAO/UNU Expert Consultation Technical Report Series, No 935. 2006 2. Civitelli R, Villareal DT, Agnusdei D, Nardi P, Avioli LV, Gennari C. Dietary L-lysine and calcium metabolism in humans. Nutrition 1992; 8 (6):400-405 3. Pereira SM, Begum A, Jesudian G, Sundararaj R. Lysine-supplemented wheat and growth of preschool children. Am J Clin Nutr 1969; 22 (5):606-611 4. Pereira SM, Begum A, Jesudian G, Sundararaj R. Lysine-supplemented wheat and growth of preschool children. Am J Clin Nutr 1969; 22 (5):606-611	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Lysine, L-lysine, L-lycine HCl					
		Body tissues	.50 - 500 mg, in general for groups with insufficient intake of animal proteins .			421

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				revise/peer-reviewed clinical studies	Authoritative/Scientific Bodies Encyclopedia of Human Nutrition (1st Edition) p 334. Editors: M. J. Sadler, J. J. Strain, B. Caballero Reviews - Pellett PL, Ghosh S, Lysine fortification: past, present, and future. Food Nutr. Bull. 2004; 25: 107-113 Individual human studies - Bressani R, Wilson DL, behar M et al., Supplementation of cereal proteins with amino acids II. J. Nutr. 1958; 66: 501-513 - Bressani R, Wilson DL, Behar M, et al., Supplementation of cereal proteins with amino acids III. J. Nutr. 1960; 70 : 176-186 - Graham GG, Placko RP, Acevedo G, et al., Lysine enrichment of wheat flour: evaluation in infants.Am. J. Clin. Nutr. 1969; 22: 1459-1468 - Hussain T, Abbas S, , Khan MA et al., Lysine fortification of wheat flour improves selected indices of the nutritional status of predominantly cereal-eating families in Pakistan. Food Nutr. Bull. 2004; 25: 114-122 117 Hoffman WS, McNeil GC, The enhancement of the nutritive value of wheat gluten by the supplementation with lysine, as determined from nitrogen balance indices in human subjects. J. Nutr. 1949; 38: 331-343. - Smriga M, Ghosh S, Mouneimne Y,et al., Lysine fortification reduces anxiety and lessens stress in family members in economically weak communities in Northwest Syria. Proc. Natl. Acad. Sci USA 2004; 101: 8285-8288 - Scrimshaw NS, Bressani R, Behar M, et al., Supplementation of cereal proteins with amino acids I. J. Nutr. 1958; 66: 458-499	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Zhao W, Zhai F, Zhang D, et al., Lysine-fortified wheat flour improves the nutritional and immunological status of wheat-eating families in northern China. Food Nutr. Bull. 2004; 25: 123-129	
				WHO/FAO/UNU report	1. Protein and Amino Acid Requirements in Human Nutrition. Report of a Joint WHO/FAO/UNU Expert Consultation Technical Report Series, No 935. 2006	
				Bibliographic references	2. Civitelli R, Villareal DT, Agnusdei D, Nardi P, Avioli LV, Gennari C. Dietary L-lysine and calcium metabolism in humans. Nutrition 1992; 8 (6):400-405 3. Pereira SM, Begum A, Jesudian G, Sundararaj R. Lysine-supplemented wheat and growth of preschool children. Am J Clin Nutr 1969; 22 (5):606-611 4. Pereira SM, Begum A, Jesudian G, Sundararaj R. Lysine-supplemented wheat and growth of preschool children. Am J Clin Nutr 1969; 22 (5):606-611	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Methionine					
		Normal liver function		Published Review	Lieber CS (2002) S-adenosyl-l-methionine: its role in the treatment of liver disorders. Am J Clin Nutr; 76(5): 1183-1187. Avila MA, Garcia ER, Martinez ML et al (2002) S-adenosylmethionine revisited: its essential role in the regulation of liver function. Alcohol; 27(3): 163-167. Corrales FJ, Perez I, Sanchez MM et al (2002) Regulation of mammalian liver methionine adenosyltransferase. J Nutr; 132(8S): 2377-2381. Mato JM, Corrales FJ, Lu SC et al (2002) S-adenosylmethionine: a control switch that regulates liver function. FASEB J; 16(1): 15-26. Friedl HA, Goa KL, Benfield P (1989) S-adenosyl_l-methionine. A review of its pharmacological properties and therapeutic potential in liver dysfunction and affective disorders in relation to its physiological role in cell function. Drugs; 38(3): 389-416. Osman E, Owen JS, Burroughs AK (1993) Review article: S-adenosyl-l-methionine-anew therapeutic agent in liver disease? Aliment Pharmacol Ther; 7(1): 21-28.	544
		Normal immune function		Published Review	Grimble RF (2006) The effects of sulphur amino acid intake on immune function in humans. J Nutr; 136(6S): 1660-1665	543
		Normal growth and metabolism,				542

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		including development and functioning of the brain and nervous system.		Published Review	Brosnan JT, daSilva R, Brosnan ME (2007) Amino acids and the regulation of methyl balance in humans. Curr Opin Clin Nutr Metab Care; 10(1): 52-57. Mudd SH, Brosnan JT, Brosnan ME et al (2007) Methyl balance and transmethylation fluxes in humans. Am J Clin Nutr; 85(1): 19-25. Stead LM, Brosnan JT, Brosnan ME et al (2006) Is it time to reevaluate methyl balance in humans? Am J Clin Nutr; 83(1): 5-10. Zeisel SH (2006) The fetal origins of memory: the role of dietary choline in optimal brain development. J Pediatr; 149(5S): 131-136. Loenen WA (2006) S-adenosylmethionine: jack of all trades and master of everything? Biochem Soc Trans; 34(2): 330-333. Brosnan JT, Brosnan ME (2006) The sulphur containing amino acids: an overview. J Nutr; 136(6S): 1636-1640. Rees WD, Wilson FA, Maloney CA (2006) Sulphur amino acid metabolism in pregnancy: the impact of methionine in the maternal diet. J Nutr; 136(6S): 1701-1705. Dean W, Lucifero D, Santos F (2005) DNA methylation in mammalian development and disease. Birth Defects Res; 75(2): 98-111. Grillo MA, Colombatto S (2005) S-adenosylmethionine and protein methylation. Amino Acids; 28(4): 357-363. Hermann A, Gowher H, Jeltsch A (2004) Biochemistry and biology of mammalian DNA	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					methyltransferases. Cell Mol Life Sci; 61(19): 2571-2587. Jeltsch A (2002) Beyond Watson & Crick: DNA methylation and molecular enzymology of DNA methyltransferases. Chembiochem; 3(4): 274-293. Hoshi T, Heinemann SH (2001) Regulation of cell function by methionine oxidation and reduction. J Physiol; 531:1-11. Chiang PK, Gordon RK, Tal J et al (1996) S-adenosylmethionine and methylation. FASEB J;10(4): 471-480. Clarke S (1993) Protein methylation. Curr Opin Cell Biol; 5(6): 977-983.	
		Lipid metabolism	2-5 g per day			423

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				reviews, clinical studies	Individual human studies - Borschel MW, Baggs GE, Cysteine and Methionine intakes associated with normal growth of healthy term infants fed casein hydrolyzate. FASEB J. 1998; 12: A848 - Di Buono M, Wykes LJ, Cole, Regulation of sulfur amino acid metabolism in men in response to changes in sulfur amino acid intakes. J. Nutr. 2003; 133: 733-9 - Fomon S, Ziegler EE, Filer LJ, et al., Methionine fortification of a soy protein formula bed fed to infants. Am. J.Clin. Nutr. 1979; 32: 2460- 2471 - Fukagawa N, Sparing of Methionine Requirements: Evaluation of human data intakes sulfur amino acids beyond protein. J. Nutr. 2006; 136: 1676S-1681S - Garlick PJ, Toxicity of Methionine in Humans. J. Nutr. 2006; 136: 1722S-1725S - Mudd S, Braverman N, Pomper M, et al., Infantile hypermethioninemia and hyperhomocysteinemia due to high methionine intake: a diagnostic trap. Mol gen Metab 2003; 79: 6-16 - Raguso C, Regan MM, Young VR, Cysteine kinetics and oxidation at different intakes of methionine and cystine in young adults. Am J. Clin. Nutr. 2000; 71: 491-499 - Oda H, Functions of Sulfur-Containing Amino Acids in Lipid Metabolism. J. Nutr., 2006; 136: 1666S-1669S van de Poll MCG, Dejong CHC, Soeters PB, Adequate range for sulfur-containing amino acids and biomarkers for their excess: lessons from enteral and parenteral nutrition. J.Nutr. 2006; 136: 1694S - 1700S	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Phenylalanine					
		Mental health	750-3000 mg per day			426

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				monographs, peer-reviewed publications	Reviews: Meyers S. Use of neurotransmitter precursors for treatment of depression. Altern Med Rev. 5 (1): 64-71; Feb (2000) Fugh-Berman A, Cott JM. Dietary supplements and natural products as psychotherapeutic agents. Psychosom Med. 61 (5): 712-28; Sep-Out (1999) Human studies: Birkmayer W, Riederer P, Linauer W, Knoll J. L-deprenyl plus L-phenylalanine in the treatment of depression. J Neural Transm. 1984;59(1):81-7. - Gardos G, Cole JO, Matthews JD, Nierenberg AA, Dugan SJ, The acute effects of a loading dose of phenylalanine in unipolar depressed patients with and without tardive dyskinesia. Neuropsychopharmacology. 1992 Jun;6(4):241-7 - Mosnik DM, Spring B, Rogers K, Baruah S, Tardive dyskinesia exacerbated after ingestion of phenylalanine by schizophrenic patients, Neuropsychopharmacology. 1997 Feb;16(2):136-46 - Sabelli HC, Fawcett J, Gusovsky F, et al. Clinical studies on the phenylethylamine hypothesis of affective disorder: urine and blood phenylacetic acid and phenylalanine dietary supplements. J Clin Psychiatry. 1986;47:66-70 - Beckmann H, Ludolph E. [DL-phenylalanine as an antidepressant. Open study (author's transl)], Arzneimittelforschung. 1978;28(8):1283-4 - Beckmann H, Strauss MA, Ludolph E. Dl-phenylalanine in depressed patients: an open study. J Neural Transm. 1977;41(2-3):123-34	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Animal studies: - Kostiuk PG, Martyniuk AE, [Possible molecular mechanisms of brain dysfunction in phenylketonuria], Patol Fiziol Eksp Ter. 1992 Jul-Aug;(4):34-6	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Protein					
		Bone health	MUST AT LEAST BE A SOURCE OF PROTEIN AS PER ANNEX TO REGULATION 1924/2006	Reviews	Bell J, Whiting SJ. Elderly women need dietary protein to maintain bone mass. Nutr Rev. 2002;60(10 Pt 1):337-41.	133
				Reviews	Bonjour JP, Schurch MA, Chevalley T, Ammann P, Rizzoli R. Protein intake, IGF-1 and osteoporosis. Osteoporos Int. 1997;7 Suppl 3:S36-42.	
				Reviews	Bonjour JP, Ammann P, Chevalley T, Rizzoli R. Protein intake and bone growth. Can J Appl Physiol. 2001;26 Suppl:S153-66.	
				Reviews	Bonjour JP. Dietary proteins: an essential nutriment for bone health. J Am Coll Nutr. 2005, 24(6 Suppl):526S-36S. Review	
				Reviews	Heaney RP. Protein intake and bone health: the influence of belief systems on the conduct of nutritional science. Am J Clin Nutr. 2001;73(1):5-6.	
				Reviews	Kerstetter JE, O'Brien KO, Insogna KL. Dietary protein, calcium metabolism, and skeletal homeostasis revisited. Am J Clin Nutr. 2003;78(3 Suppl):584S-592S.	
				Reviews	Massey LK. Dietary animal and plant protein and human bone health: a whole foods approach. J Nutr. 2003;133(3):862S-865S.	
				Reviews	Naot D, Grey A, Reid IR, Cornish J. Lactoferrin - a novel bone growth factor. Clin Med Res. 2005;3:93-101.	
				Reviews	Rizzoli R, Bonjour JP. Dietary protein and bone health. J Bone Miner Res. 2004;19(4):527-31.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Intervention Studies	Cadogan J, Eastell R, Jones N, Barker ME. Milk intake and bone mineral acquisition in adolescent girls: randomised, controlled intervention trial. BMJ. 1997; 315:1255-60.	
				Intervention Studies	Dawson-Hughes B, Harris SS, Rasmussen H, Song L, Dallal GE. Effect of dietary protein supplements on calcium excretion in healthy older men and women. J Clin Endocrinol Metab. 2004;89(3):1169-73.	
				Intervention Studies	Dawson-Hughes B, Harris SS. Calcium intake influences the association of protein intake with rates of bone loss in elderly men and women. Am J Clin Nutr. 2002;75(4):773-9.	
				Intervention Studies	Delmi M, Rapin CH, Bengoa JM, Delmas PD, Vasey H, Bonjour JP. Dietary supplementation in elderly patients with fractured neck of the femur. Lancet. 1990;335(8696):1013-6.	
				Intervention Studies	Kerstetter JE, O'Brien KO, Caseria DM, Wall DE, Insogna KL. The impact of dietary protein on calcium absorption and kinetic measures of bone turnover in women. J Clin Endocrinol Metab. 2005;90(1):26-31.	
				Intervention Studies	Kerstetter JE, O'Brien KO, Insogna KL. Dietary protein affects intestinal calcium absorption. Am J Clin Nutr. 1998;68(4):859-65.	
				Intervention Studies	Roughead ZK, Johnson LK, Lykken GI, Hunt JR. Controlled high meat diets do not affect calcium retention or indices of bone status in healthy postmenopausal women. J Nutr. 2003;133(4):1020-6	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Intervention Studies	Schurch MA, Rizzoli R, Slosman D, Vadas L, Vergnaud P, Bonjour JP. Protein supplements increase serum insulin-like growth factor-I levels and attenuate proximal femur bone loss in patients with recent hip fracture. A randomized, double-blind, placebo-controlled trial. Ann Intern Med. 1998;128(10):801-9.	
				Intervention Studies	Tkatch L, Rapin CH, Rizzoli R, Slosman D, Nydegger V, Vasey H, Bonjour JP. Benefits of oral protein supplementation in elderly patients with fracture of the proximal femur. J Am Coll Nutr 1992;11:519-525.	
				Observational Studies	Feskanich D, Willett WC, Stampfer MJ, Colditz GA. Protein consumption and bone fractures in women. Am J Epidemiol. 1996;143(5):472-9.	
				Observational Studies	Garnero P, Sornay-Rendu E, Delmas PD. Low serum IGF-1 and occurrence of osteoporotic fractures in postmenopausal women. Lancet. 2000;355(9207):898-9.	
				Observational Studies	Hannan MT, Tucker KL, Dawson-Hughes B, Cupples LA, Felson DT, Kiel DP. Effect of dietary protein on bone loss in elderly men and women: the Framingham Osteoporosis Study. J Bone Miner Res. 2000;15(12):2504-12.	
				Observational Studies	Munger RG, Cerhan JR, Chiu BC. Prospective study of dietary protein intake and risk of hip fracture in postmenopausal women. Am J Clin Nutr. 1999;69(1):147-52.	
				Observational Studies	Promislow JH, Goodman-Gruen D, Slymen DJ, Barrett-Connor E. Protein consumption and bone mineral density in the elderly : the Rancho Bernardo Study. Am J Epidemiol. 2002;155(7):636-44.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Observational Studies	Wengreen HJ, Munger RG, West NA, et al. Dietary protein intake and risk of osteoporotic hip fracture in elderly residents of Utah. J Bone Miner Res. 2004;19(4):537-45.	
				Preclinical Studies	Ammann P, Bourrin S, Bonjour JP, Meyer JM, Rizzoli R. Protein undernutrition-induced bone loss is associated with decreased IGF-I levels and estrogen deficiency. J Bone Miner Res. 2000;15(4):683-90.	
				Preclinical Studies	Ammann P, Laib A, Bonjour JP, Meyer JM, Ruegsegger P, Rizzoli R. Dietary essential amino acid supplements increase bone strength by influencing bone mass and bone microarchitecture in ovariectomized adult rats fed an isocaloric low-protein diet. J Bone Miner Res. 2002;17(7):1264-72.	
				Preclinical Studies	Bourrin S, Ammann P, Bonjour JP, Rizzoli R. Dietary protein restriction lowers plasma insulin-like growth factor I (IGF-I), impairs cortical bone formation, and induces osteoblastic resistance to IGF¬I in adult female rats. Endocrinology. 2000;141(9):3149-55.	
				Preclinical Studies	Chevalley T, Rizzoli R, Manen D, Caverzasio J, Bonjour JP. Arginine increases insulin-like growth factor-I production and collagensynthesis in osteoblast-like cells.Bone. 1998;23:103-9	
				Textbook	Barker ME & Blumsohn A (2005) Nutrition and the skeleton In: Human Nutrition Eleventh edition. [Geissler C & Powers H, eds] Elsevier, London.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Nutrition textbook	Chs 7 and 10 in Nutritional aspects of bone health. Eds SA New and JP Bonjour. Royal Society of Chemistry 2005	
				Nutrition textbook	Barker ME & Blumsohn A (2005) Nutrition and the skeleton In: Human Nutrition Eleventh edition. (Geissler C & Powers H, eds) Elsevier, London.	
				Review	Bonjour JP, Ammann TC & Rizzoli R (2004) Protein Intake and Bone Health In: Nutrition and bone health (Holic MF & Dawson-Hughes	
				Review	B, Eds) Humana Press, New Jersey.	
				Review	Rizzoli R, Bonjour JP. Dietary protein and bone health. J Bone Miner Res. 2004;19(4):527-31.	
				Review	Kerstetter JE, O'Brien KO, Insogna KL. Dietary protein, calcium metabolism, and skeletal homeostasis revisited. Am J Clin Nutr. 2003;78(3 Suppl):584S-592S.	
				Review	Massey LK. Dietary animal and plant protein and human bone health: a whole foods approach. J Nutr. 2003;133(3):862S-865S Bell J, Whiting SJ. Elderly women need dietary protein to maintain bone mass. Nutr Rev. 2002;60(10 Pt 1):337-41.	
					Heaney RP. Protein intake and bone health: the influence of belief systems on the conduct of nutritional science. Am J Clin Nutr. 2001;73(1):5-6.	
					Bonjour JP, Schurch MA, Chevalley T, Ammann P, Rizzoli R. Protein intake, IGF-1 and osteoporosis. Osteoporosis Int. 1997;7 Suppl 3:S36-42.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Satiety / Weight management	Conditions of "high protein" from HC regulation 1924/2006 (i.e.20% E from protein)	Reviews	Anderson GH, Moore SE. Dietary proteins in the regulation of food intake and body weight in humans. J Nutr. 2004 Apr;134(4):974S-9S.	134
				Reviews	Astrup A. Dietary approaches to reducing body weight. Baillieres Clin. Endo. Metab. 1999;13:109-120.	
				Reviews	Eisenstein J, Roberts SB, Dallal G, Saltzman E. High-protein weight-loss diets: are they safe and do they work? A review of the experimental and epidemiologic data. Nutr Rev. 2002 Jul;60(7 Pt 1):189-200.	
				Reviews	Halton TL, Hu FB. The effects of high protein diets on thermogenesis, satiety and weight loss: a critical review. J Am Coll Nutr. 2004 Oct;23(5):373-85.	
				Reviews	Harvey Anderson G et al. Dietary proteins in the regulation of food intake and body weight in humans. Journal of Nutrition 2004; 134: 974S-979S.	
				Reviews	Schaafsma G. Health issues of whey proteins: Weight management. Current topics in nutraceutical research. 2006May:4(2):123-26.	
				Reviews	Stubbs RJ. Macronutrient effects on appetite. Int. J. Obes. Relat. Metab. Disord. 1995;19(Suppl 5):S11-S9.	
				Reviews	Westerterp-Plantenga MS, Lejeune MP. Protein intake and body-weight regulation. Appetite. 2005 Oct;45(2):187-90.	
				Reviews	Westerterp-Plantenga MS. The significance of protein in food intake and body weight regulation. Curr Opin Clin Nutr Metab Care. 2003 Nov;6(6):635-8.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Intervention Studies	Baba NH, Sawaya S, Torbay N, Habbal Z, Azar S, Hashim SA. High protein vs high carbohydrate hypoenergetic diet for the treatment of obese hyperinsulinemic subjects. Int. J. Obes. Relat. Metab. Disord. 1999;23(11):1202-1206.	
				Intervention Studies	Barkeling B, Rossner S, Bjorvell H. Effects of a high-protein meal (meat) and a high-carbohydrate meal (vegetarian) on satiety measured by automated computerized monitoring of subsequent food intake, motivation to eat and food preferences. Int. J. Obes. 1990;14(9):743-751.	
				Intervention Studies	Boirie Y, Dangin M, Gachon P, Vasson M-P, Maubois J-L, Beaufrere B. Slow and fast dietary proteins differently modulate postprandial protein accretion. Proc. Natl. Acad. Sci. 1997;94:14930-14935.	
				Intervention Studies	French SJ. 'The effects of specific nutrients on the regulation of feeding behaviour in human subjects Proc. Nutr. Soc. 1999;58:533-540.	
				Intervention Studies	Lang V, Bellisle F, Alamowitch C, Craplet C, Bornet FRJ, Slama G, Guy-Grand B. Varying the protein source in mixed meal modifies glucose, insulin and glucagon kinetics in healthy men, has weak effects on subjective satiety and fails to effect food intake. Eur. J. Clin. Nutr. 1999;53:959 965.	
				Intervention Studies	Latner J. The Effects of a High-carbohydrate, High-protein or Balanced Lunch upon Later Food Intake and Hunger Ratings. Appetite 1999;33(1):119-128.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Intervention Studies	Mikkelsen PB, Toubro S, Astrup A. Effect of fat-reduced diets on 24-h energy expenditure: comparisons between animal protein, vegetable protein, and carbohydrate. Am J Clin Nutr. 2000 Nov;72(5):1135-41.	
				Intervention Studies	Skov AR, Toubro S, Ronn B, Holm L, Astrup A. Randomized trail on protein vs carbohydrate in ad libitum fat reduced diet for the treatment of obesity. Int. J. Obes. 1999;23:528-536.	
				Intervention Studies	Stubbs RJ. Breakfast high in protein, fat or carbohydrate: effect on within-day appetite and energy balance. Eur. J. Clin. Nutr. 1996;50:409-417.	
				Intervention Studies	Weigle DS, Breen PA, Matthys CC, Callahan HS, Meeuws KE, Burden VR, Purnell JQ. A high-protein diet induces sustained reductions in appetite, ad libitum caloric intake, and body weight despite compensatory changes in diurnal plasma leptin and ghrelin concentrations. Am J Clin Nutr. 2005 Jul;82(1):41-8.	
				Intervention Studies	Westerterp-Plantenga MS, Lejeune MP, Nijs I, van Ooijen M, Kovacs EM. High protein intake sustains weight maintenance after body weight loss in humans. Int J Obes Relat Metab Disord. 2004 Jan;28(1):57-64.	
				Intervention Studies	Westerterp-Plantenga MS, Rolland V, Wilson SA, Westerterp KR. Satiety related to 24h diet-induced thermogenesis during high protein/carbohydrate vs high fat diets measured in a respiration chamber. Eur. J. Clin. Nutr. 1999;53:495-502.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				JHCI	JHCI, Final technical report http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf	
				IOM DRV report	Institute of Medicine Dietary Reference Intakes for calcium, phosphorus, magnesium, vitamin D, and fluoride. Washington D.C. National Academy Press, 1997.	
				SCF report	Report of the Scientific Committee for Food (Thirty-first series) on 'Nutrient and energy intakes for the European Community' (1992).	
				EVM report	Review of Phosphorus. Expert Group on Vitamins and Minerals. August 2002. http://www.food.gov.uk/multimedia/pdfs/reviewofphosphorous.pdf	
				Nutrition text book	Encyclopaedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				Nutrition text book	Human Nutrition and Dietetics. 10th edition. JS Garrow, WPT James, A Ralph. Churchill Livingstone 2000.	
		Satiety/prolonged satiety weight management	High protein claim according to reg. 1924/2006 (requires a minimum level of 20 E% protein)			742

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Scientific reviews Scientific investigation Human studies RCT Mechanistic studies	Halton TL, Hu FB. The effects of high protein diets on thermogenesis, satiety and weight loss: a critical review. J Am Coll Nutr. 2004 Oct;23(5):373-85 Leidy HJ, Carnell NS, Mattes RD, Campbell WW. Higher protein intake preserves lean mass and satiety with weight loss in pre-obese and obese women. Obesity (Silver Spring). 2007 Feb;15(2):421-9 Westerterp-Plantenga MS, Lejeune MP. Protein intake and body-weight regulation. Appetite. 2005 Oct;45(2):187-90 Weigle et al. A high-protein diet induces sustained reductions in appetite, ad libitum caloric intake, and body weight despite compen-satory changes in diurnal plasma leptin and ghrelin concentrations. Am J Clin Nutr. 2005 Jul;82(1):41-8. Astrup A (2006) How to maintain a healthy body weight. Int J Vitam Nutr Res 76; 208-215. Astrup A (1999) Dietary approaches to reducing body weight. Baillieres Clin Endo Metab 13; 109-120. French SJ (1999) The effects of specific nutrients on the regulation of feeding behaviour in human subjects Proc Nutr Soc 58; 533-540. Stubbs RJ (1995) Macronutrient effects on appetite. Int J Obes Relat Metab Disord 19 S11-S9. Westerterp-Plantenga MS & Lejeune MP (2005) Protein intake and body-weight regulation. Appetite 45; 187-190.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

Westerterp-Plantenga MS (2003) The significance of protein in food intake and body weight regulation. Curr Opin Clin Nutr Metab Care 6; 635-638.

Baba NH et al (1999) High protein vs high carbohydrate hypoenergetic diet for the treatment of obese hyperinsulinemic subjects. Int J Obes Res Metab Disord 23; 1202-1206.

Barkeling B, Rossner S & Bjorvell H (1990) Effects of a high-protein meal (meat) and a high-carbohydrate meal (vegetarian) on satiety measured by automated computerized monitoring of subsequent food intake, motivation to eat and food preferences. Int J Obes 14; 743-751.

Blaak EE (2006) Prevention and treatment of obesity and related complications: a role for protein? Int J Obes (Lond) 3; S24-27.

Boirie Y et al (1997) Slow and fast dietary proteins differently modulate postprandial protein accretion. Proc Natl Acad Sci 94; 14930-14935.

Harper A et al (2007) Increased satiety after intake of a chocolate milk drink compared with a carbonated beverage, but no difference in subsequent ad libitum lunch intake. Br J Nutr 97; 579-583.

Lang V et al (1999) Varying the protein source in mixed meal modifies glucose, insulin and glucagon kinetics in healthy men, has weak

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					effects on subjective satiety and fails to effect food intake. Eur J Clin Nutr 53; 959-965. Latner J (1999) The Effects of a High-carbohydrate, High-protein or Balanced Lunch upon Later Food Intake and Hunger Ratings. Appetite 33; 119-128. Skov AR et al (1999) Randomized trial on protein vs carbohydrate in ad libitum fat reduced diet for the treatment of obesity. Int. J Obes Relat Metab Disord 23; 528-536. Stubbs RJ (1996) Breakfast high in protein, fat or carbohydrate: effect on within-day appetite and energy balance. Eur J Clin Nutr 50; 409-417. Westerterp-Plantenga MS et al (1999) Satiety related to 24h diet-induced thermogenesis during high protein/carbohydrate vs high fat diets measured in a respiration chamber. Eur J Clin Nutr 53; 495-502. Westerterp-Plantenga MS et al (2006) Dietary protein, metabolism, and body-weight regulation: dose-response effects. Int J Obes (Lond) 3; S16-23. Williams G et al (2006) High protein high fibre snack bars reduce food intake and improve short term glucose and insulin profiles compared with high fat snack bars. Asia Pac J Clin Nutr 15; 443-50.	
		Supply of metabolic energy	MUST AT LEAST BE A SOURCE OF PROTEIN AS PER ANNEX TO REGULATION 1924/2006	Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000.	131

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbook	Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002.	
				Textbook	Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Muscle maintenance and recovery	High protein claim according to reg. 1924/2006 (requires a minimum of 20E% protein)	Scientific reviews Scientific investigation	Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13	743
		Supports muscle recovery	The product must contain at least 10 grams high quality protein per serving Claim to be used for foods for active individuals			1,752

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Peer-reviewed scientific research articles	Biolo G, Tipton KD, Klein S, Wolfe RR. (1997) An abundant supply of amino acids enhances the metabolic effect of exercise on muscle protein. Am J Physiol, Jul;273(1 Pt 1):E122-9. Bolster DR, Pikosky MA, Gaine PC, Martin W, Wolfe RR, Tipton KD, Maclean D, Maresh CM, Rodriguez NR. (2005) Dietary protein intake impacts human skeletal muscle protein fractional synthetic rates after endurance exercise. Am J Physiol Endocrinol Metab., Oct;289(4):E678-83. Epub 2005 May 24. Borsheim E, Tipton KD, Wolf SE, Wolfe RR. (2002) Essential amino acids and muscle protein recovery from resistance exercise. Am J Physiol Endocrinol Metab., Oct;283(4):E648-57. Esmarck B, Andersen JL, Olsen S, Richter EA, Mizuno M, Kjaer M. (2001) Timing of postexercise protein intake is important for muscle hypertrophy with resistance training in elderly humans. J Physiol, Aug 15;535(Pt 1):301-11. Levenhagen DK, Carr C, Carlson MG, Maron DJ, Borel MJ, Flakoll PJ. (2002) Postexercise protein intake enhances whole-body and leg protein accretion in humans. Med Sci Sports Exerc, May;34(5):828-37. Levenhagen DK, Gresham JD, Carlson MG, Maron DJ, Borel MJ, Flakoll PJ. (2001) Postexercise nutrient intake timing in humans is critical to recovery of leg glucose and protein homeostasis. Am J Physiol Endocrinol Metab, Jun;280(6):E982-93.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Hoffman JR and Falvo MJ. (2004) Protein – Which is Best? J Sports Sci Med, 3: 118-130. Lemon PW, Berardi JM, Noreen EE. (2002) The role of protein and amino acid supplements in the athlete's diet: does type or timing of ingestion matter? Curr Sports Med Rep. 2002 Aug; 1(4): 214-21. Phillips SM, Hartman JW, Wilkinson SB. (2005) Dietary protein to support anabolism with resistance exercise in young men. J Am Coll Nutr, Apr;24(2):134S-139S. Rennie MJ, Tipton KD. (2000) Protein and amino acid metabolism during and after exercise and the effects of nutrition. Annu Rev Nutr, 20:457-83. Tipton KD, Wolfe RR. (2001) Exercise, protein metabolism, and muscle growth. Int J Sport Nutr Exerc Metab, Mar; 11(1): 109-32.	
		Supports skeletal muscle protein accretion	The product must contain at least 10 grams high quality protein per serving Claim to be used for foods for active individuals			1,751

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Peer-reviewed scientific research articles	Biolo G, Tipton KD, Klein S, Wolfe RR. (1997) An abundant supply of amino acids enhances the metabolic effect of exercise on muscle protein. Am J Physiol, Jul;273(1 Pt 1):E122-9. Bolster DR, Pikosky MA, Gaine PC, Martin W, Wolfe RR, Tipton KD, Maclean D, Maresh CM, Rodriguez NR. (2005) Dietary protein intake impacts human skeletal muscle protein fractional synthetic rates after endurance exercise. Am J Physiol Endocrinol Metab., Oct;289(4):E678-83. Epub 2005 May 24. Brown EC, DiSilvestro RA, Babaknia A, Devor ST. (2004) Soy versus whey protein bars: effects on exercise training impact on lean body mass and antioxidant status. Nutr J, Dec 8; 3:22. Candow DG, Burke NC, Smith-Palmer T, Burke DG. (2006) Effect of whey and soy protein supplementation combined with resistance training in young adults. Int J Sport Nutr Exerc Metab, Jun;16(3):233-44. Cribb PJ, Hayes A. (2006) Effects of supplement timing and resistance exercise on skeletal muscle hypertrophy. Med Sci Sports Exerc, Nov;38(11):1918-25. Esmarck B, Andersen JL, Olsen S, Richter EA, Mizuno M, Kjaer M. (2001) Timing of postexercise protein intake is important for muscle hypertrophy with resistance training in elderly humans. J Physiol, Aug 15;535(Pt 1):301-11. Levenhagen DK, Carr C, Carlson MG, Maron DJ, Borel MJ, Flakoll PJ. (2002)	

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					Postexercise protein intake enhances whole-body and leg protein accretion in humans. Med Sci Sports Exerc, May;34(5):828-37. Levenhagen DK, Gresham JD, Carlson MG, Maron DJ, Borel MJ, Flakoll PJ. (2001) Postexercise nutrient intake timing in humans is critical to recovery of leg glucose and protein homeostasis. Am J Physiol Endocrinol Metab, Jun;280(6):E982-93. Hoffman JR and Falvo MJ. (2004) Protein – Which is Best? J Sports Sci Med, 3: 118-130. Lemon PW, Berardi JM, Noreen EE. (2002) The role of protein and amino acid supplements in the athlete's diet: does type or timing of ingestion matter? Curr Sports Med Rep. 2002 Aug; 1(4): 214-21. Phillips SM, Hartman JW, Wilkinson SB. (2005) Dietary protein to support anabolism with resistance exercise in young men. J Am Coll Nutr, Apr;24(2):134S-139S. Rennie MJ, Tipton KD. (2000) Protein and amino acid metabolism during and after exercise and the effects of nutrition. Annu Rev Nutr, 20:457-83 Tipton KD, Wolfe RR. (2001) Exercise, protein metabolism, and muscle growth. Int J Sport Nutr Exerc Metab, Mar; 11(1): 109-32. Tipton KD, Wolfe RR. (2004) Protein and amino acids for athletes. J Sports Sci., Jan; 22(1):65-79.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Protein/ essential amino acids					
		Essential for growth, development and maintenance of the body/body tissues/body function.	MUST AT LEAST BE A SOURCE OF PROTEIN AS PER ANNEX TO REGULATION 1924/2006	Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000.	132
				Textbook	Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002.	
				Textbook	Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Protein/essential amino acids					
		Essential for growth, development & maintenance of the body/body tissues/body function	Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.			881

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				COMA Report International Scientific Bodies/Expert Reports Textbook	Department of Health (1991) Report on Health and Social subjects 41 Dietary reference Values for Food Energy and Nutrients for the United Kingdom, Report of the Panel on Dietary Reference Values of the Committee on Medical Aspects of Food Policy, London; HMSO. FAO/WHO. Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation. Rome: FAO, 1990. FAO/WHO. Energy and Protein Requirements. Report of a Joint FAO/WHO ad hoc Expert Committee. Rome: FAO, 1997. FAO/WHO/UNU. Energy and Protein Requirements. WHO Technical Report Series 724. Geneva: WHO: 1985. Bender DA & Milward DJ (2000) Protein metabolism and requirements In: Human Nutrition Eleventh Edition [Geissler C & Powers H, editors] Elsevier Churchill Livingstone, London. Brosnan JT & Young VR (2003) Integration of Metabolism 2: Protein and Amino Acids In: Nutrition and Metabolism [Gibney MJ, MacDonald IA & Roche HM, editors] Blackwell Publishing, London. Dietary proteins and amino acids (2001) In: Manual of Dietetic Practice Third Edition [Thomas B, editor] Blackwell Science, London. Garlick PJ & Reeds PJ (2000) Proteins In: Human Nutrition and Dietetics 10th edition [Garrow JS, James WPT & Ralph A, editors] Churchill Livingstone, London. Young VR & Reeds PJ (2002) Nutrition and Metabolism of Proteins and Amino Acids In: Introduction to Human Nutrition. [Gibney MJ, Vorster HH & Kok FJ, editors] Blackwell Publishing, London.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Soy Protein					
		Antioxidant health	The product must contain at least 10 grams high quality Claim to be used for foods for active individuals	Peer-reviewed scientific research articles	Box W, Hill S, DiSilvestro RA. (2005) Soy intake plus moderate weight resistance exercise: effects on serum concentrations of lipid peroxides in young adult women. J Sports Med Phys Fitness, Dec; 45(4): 524-8. Hill S, Box W, DiSilvestro RA. (2004) Moderate intensity resistance exercise, plus or minus soy intake: effects on serum lipid peroxides in young adult males. Int J Sport Nutr Exerc Metab. 2004 Apr; 14(2): 125-32.	1,759

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Soya protein					
		Reduction of blood cholesterol	Must include a statement to the affect that at least 25g of soya protein per day must be consumed as part of a diet low in saturated fat. Products carrying this claim should: i) Not imply that consumption of more, or less, than 25g per day is advantageous. ii) Not imply that consumption of 25g soya protein per day is a dietary requirement. iii) Contain a minimum of 5g* of soya protein per serving (*Amended 260903). iv) State what constitutes a serving and the amount of soya protein provided in each serving expressed as grams or millilitres, e.g. ‘One 200ml glass’; ‘One 125g pot’ etc. v) State the proportion (i.e. a ‘fifth’, ‘quarter’, ‘third’, ‘half’ etc) of the 25g daily intake in each serving, e.g. ‘A 100g serving contains 8.34g of soya protein, which is one third of 25g’.	JHCI	Joint Health Claims Initiative, 2004 (http://www.jhci.org.uk/approv/FINALJHCI%20Soya%20Submission.pdf)	2,352

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			vi) The claim relates to soya protein that has retained its naturally occurring isoflavones			
		Reduces blood cholesterol (total and LDL)	Must be at least a source of protein as per Annex Regulation 1924/2006 25g soya protein per day			1,706

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative Body FDA Scientific Body JHCI Individual human clinical double blind randomised controlled trial Individual human clinical partially blinded randomised controlled trial	FDA (1999) Food labelling, Health Claims; Soy Protein and Coronary Heart Disease – Final rule. Federal Register 64, 57699-57733. JHCI - www.jhci.co.uk : 27/07/02 Generic health claim for soya protein and blood cholesterol Allen JK, Becker DM, Kwiterovich PO, Lindenstruth KA, Curtis C. Effect of soy protein-containing isoflavones on lipoproteins in postmenopausal women. Menopause 2007; 14: 106-14. Maesta N, Nahas EA, Nahas-Neto J, Orsatti FL, Fernandes CE, Traiman P, Burini RC. Effects of soy protein and resistance exercise on body composition and blood lipids in postmenopausal women. Maturitas 2007; 56: 350-8. Ma Y, Chiriboga D, Olendzki BC, Nicolosi R, Merriam PA, Ockene IS. Effect of soy protein containing isoflavones on blood lipids in moderately hypercholesterolemic adults: a randomized controlled trial. J Am Coll Nutr 2005; 24: 275-85. Sagara M, Kanda T, M NJ, Teramoto T, Armitage L, Birt N, Birt C, Yamori Y. Effects of dietary intake of soy protein and isoflavones on cardiovascular disease risk factors in high risk, middle-aged men in Scotland. J Am Coll Nutr 2004; 23: 85-91. Teixeira SR, Potter SM, Weigel R, Hannum S, Erdman JW, Jr., Hasler CM. Effects of feeding 4 levels of soy protein for 3 and 6 wk on blood lipids and apolipoproteins in moderately	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

hypercholesterolemic men. Am J Clin Nutr 2000; 71: 1077-84.

Baum JA, Teng H, Erdman JW, Jr., Weigel RM, Klein BP, Persky VW, Freels S, Surya P, Bakhit RM, Ramos E, Shay NF, Potter SM. Long-term intake of soy protein improves blood lipid profiles and increases mononuclear cell low-density-lipoprotein receptor messenger RNA in hypercholesterolemic, postmenopausal women. Am J Clin Nutr 1998; 68: 545-51.

Anderson JW, Fuller J, Patterson K, Blair R, Tabor A. Soy compared to casein meal replacement shakes with energy-restricted diets for obese women: randomized controlled trial. Metabolism 2007; 56: 280-8.

Anderson JW and Hoie LH. Weight loss and lipid changes with low-energy diets: comparator study of milk-based versus soy-based liquid meal replacement interventions. J Am Coll Nutr 2005; 24: 210-6.

Allison DB, Gadbury G, Schwartz LG, Murugesan R, Kraker JL, Heshka S, Fontaine KR, Heymsfield SB. A novel soy-based meal replacement formula for weight loss among obese individuals: a randomized controlled clinical trial. Eur J Clin Nutr 2003; 57: 514-22.

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Tyrosine					
		Helps to support cognitive performance during exposure to environmentally adverse conditions	100 mg per kilogram of bodyweight 40-80 minutes prior to testing (1)	RCTs	Banderet LE, Lieberman HR. Treatment with tyrosine, a neurotransmitter precursor, reduces environmental stress in humans. Brain Res Bull. 1989 Apr;22(4):759-62. PMID: 2736402 Deijen JB, Orlebeke JF. Effect of tyrosine on cognitive function and blood pressure under stress. Brain Res Bull. 1994;33(3):319-23. PMID: 8293316 Neri DF, Wiegmann D, Stanny RR, Shappell SA, McCardie A, McKay DL. The effects of tyrosine on cognitive performance during extended wakefulness. Aviat Space Environ Med. 1995 Apr;66(4):313-9. PMID: 7794222 Thomas JR, Lockwood PA, Singh A, Deuster PA. Tyrosine improves working memory in a multitasking environment. Pharmacol Biochem Behav. 1999 Nov;64(3):495-500. PMID: 10548261	2,440

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Whey Protein					
		Muscle mass maintenance in the elderly	Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.	Expert report	Cribb PJ. 2006. Sarcopenia and whey proteins-implications, mechanisms and potential for nutritional intervention. U.S. Dairy Expert Council. 1-16.	794
				Scientific Review	Dangin M, Boirie Y, Guillet C and Beaufrere B. 2002. Influence of the protein digestion rate on protein turnover in young and elderly subjects. J Nutr. 132 (10): 3228S-3233S.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				RCT	Dangin M, Guillet C, Garcia-Rodenas C, Gachon P, Bouteloup-Demange C, Reiffers-Magnani K, Fauquant J, Ballevre O and Beaufrere B. 2003. The rate of protein digestion affects protein gain differently during aging in humans. J Physiol. 549(2): 635-644. Katsanos CS, Kobayashi H, Sheffield-Moore M, Aarsland A and Wolfe RR. 2006. A high proportion of leucine is required for optimal stimulation of the rate of muscle protein synthesis by essential amino acids in the elderly. Am J Physiol Endocrinol Metab. 291: E381-E387. Volpi E, Hisamine K, Sheffield-Moore M, Mittendorfer B and Wolfe RR. 2003. Essential amino acids are primarily responsible for the amino acid stimulation of muscle protein anabolism in healthy elderly adults. Am J Clin Nutr. 78: 250-258. Tayek JA, Bistrian BR, Hehir DJ, Martin R, Moldawer LL & Blackburn GL. 1986. Improved protein kinetics and albumin synthesis by branched-chain amino acid-enriched total parenteral nutrition in cancer cachexia. A perspective randomised cross over trial. Cancer. 58 (1):147-157. Shaw JH, Humberstone DA, Douglas RG & Koea J. 1991. Leucine kinetics in patients with benign disease, non-weight-loosing cancer, and cancer cachexia:studies at the whole-body and tissue level and the response to nutritional support. Surgery. 109 (1):37-50.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Animal	Rieu I, Balage M, Sornet C, Debras E, Ripes S, Rochon-Bonhomme C, Pouyet C, Grizard J and Dardevet D. 2007. Increased availability of leucine with leucine-rich whey proteins improves postprandial muscle protein synthesis in aging rats. Nutr. 23: 323-331. Eley HL, Russell ST & Tisdale MJ. 2007. Effect of branched-chain amino acids on muscle atrophy in cancer cachexia. Biochem J.407 (1): 113-120.	
		Physical Performance	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.	Export Report	Cribb PJ. 2005. U.S. Whey Proteins in Sports Nutrition. U.S. Dairy Export Council. 1-12.	796
				Scientific Review	Ha E and Zemel MB. 2003. Functional properties of whey, whey components, and essential amino acids:mechanisms underlying health benefits for active people (Review). J Nutr Biochem. 14:251-258. Marshall K. 2004. Therapeutic Applications of Whey Protein. Alt Med Rev. 9(2): 136-14.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				RCT	Lemon PW, Berardi JM and Noreen EE. 2002. The role of protein and amino acid supplements in the athlete's diet: does type or timing of ingestion matter? Nutr. 4: 214-221. Cribb PJ, Williams AD, Stathis CG, Carey MF, Hayes A. 2007. Effects of whey isolate, creatine, and resistance training on muscle hypertrophy. Med Sci Sports Exerc. 39:298-307. Coburn JW, Housh DJ, Housh TJ, Malek MH, Beck TW, Cramer JT, Johnson GO, Donlin PE. 2006. Effects of leucine and whey protein supplementation during eight weeks of unilateral resistance training. J Strength Cond Res. 20:284-291. Lands LC, Grey VL and Smountas AA. 1999. Effect of supplementation with a cysteine donor on muscular performance. J Appl Physiol. 87: 1381-1385. Tipton KD, Elliot TA, Cree MG, Wolfe SE, Sanford AP and Wolfe RR. 2004. Ingestion of casein and whey proteins result in muscle anabolism after resistance exercise. Med Sci Sports Exerc. 36 (12): 2073-2081. Coombes JS and McNaughton LR. 2000. Effects of branched-chain amino acid supplementation on serum creatine kinase and lactate dehydrogenase after prolonged exercise. J Sports Med Phys Fitness. 40: 240-246. Wilkinson SB, Tarnopolsky MA, Macdonald MJ, Macdonald JR, Armstrong D & Phillips SM. 2007. Consumption of fluid skim milk promotes greater muscle protein accretion after resistance exercise than does consumption of an isonitrogenous and isoenergetic soy-protein beverage. 85 (4):1031-1040. Cribb PJ & Hayes A. 2006. Effects of supplement timing and resistance exercise on skeletal muscle hypertrophy. 38	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					(11):1918-1925.	
		Weight management	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.	Scientific Review	Layman DK. 2004. Protein quantity and quality at levels above the RDA improves adult weight loss. J Am Coll Nutr. 23 (6):631S-636S. Westerterp-Plantenga MS. 2003. The significance of protein in food intake and body weight regulation. Curr Opin Clin Nutr Metab Care. 6 (6):635-638. Halton T & Hu F. 2004. The effect of high protein diets on thermogenesis, satiety and weight loss: a critical review. J Am Coll Nutr.23 (5):373-385. Anderson G & Moore S. 2004. Dietary proteins in the regulation of food intake and body weight in humans. J Nutr. 134:974S-979S. Zemel M. 2004. Role of calcium and dairy products in energy partitioning and weight management. Amer J Clin Nutr. 79:907S-912S. Zemel M. 2005. The role of dairy foods in weight management. J Am Coll Nutr. 24 (6):537S-546S. Zemel M. 2003. Mechanisms of dairy modulation of adiposity. J Nutr. 133:252S-256S.	797

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				RCT	Sun X & Zemel MB. 2004. Calcium and dairy products inhibit weight and fat regain during ad libitum consumption following energy restriction in Ap2-agouti transgenic mice. J Nutr. 134 (11):3054-3060. O'Donnell J & Baer D. 2006. Study finds whey protein improves body composition and reduces waist circumference. US Whey Protein Research Consortium. Arlington, USA. Johnston C, Day C & Swan P. 2002. Postprandial thermogenesis is increased 100% on a high protein, low fat diet versus a high carbohydrate, low fat diet in healthy, young women. J Am Coll Nutr.21 (1):55-61. Massiera F, Seydoux J, Geloen A, Quignard-Boulange A, Terban S, Saint-Marc P, Fukamizu A, Negrel R, Ailhaud G & Teboul M. 2001. Angiotensinogen-deficient mice exhibit impairment of diet-induced weight gain with alteration in adipose tissue development and increased locomotor activity. Endocrin. 142:5220-5225. Bouthegourd JC, Roseau S, Lahham L, Leruyet P, Tomé D & Even P. 2002. A pre-exercise a-lactalbumin-enriched whey protein meal preserves lipid oxidation and decreases adiposity in rats. Am J Physiol Endocrinol Metab. 283: E565-E572. Pihlanto-Leppälä A, Koskinen P, Piilola K, Tupasela T & Korhonen H. 2000. Angiotensin 1-converting enzyme inhibitory properties of whey protein digest: concentration and characterisation of active peptides. J Dairy Res. 67 (1): 53-64.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Stress and mental health	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.	RCT	Scrutton H, Carbonnaer A, Cowen PJ & Harmer CJ. 2007. Effects of {alpha}-lactalbumin on emotional processing in healthy women. J Psychopharmacol. 21 (5):519-524. Markus CR, Olivier B & de Hann EH. 2002. Whey protein rich in alpha-lactalbumin increases the ratio of plasma tryptophan to the sum of the other large neutral amino acids and improves cognitive performance in stress vulnerable subjects. Am J Clin Nutr. 75 (6):1051-1056. Merens W, Booij L, Markus R, Zitman FG, Onkenhout W & van Derd Does AJ. 2005. The effects of a diet enriched with alpha-lactalbumin on mood and cortisol response in unmedicated recovered depressed subjects and controls. Brit J Nutr. 94 (3): 415-422. Markus CR, Olivier B, Panhuisen G, Guten J, Alles M, Tuiten A, Westenberg H, Fekkes D, Koppeschaar H & de Haan E. 2000. The bovine protein alpha-lactalbumin increases the plasma ratio of tryptophan to other large neutral amino acids, and in vulnerable subjects raises brain serotonin activity, reduces cortisol concentration, and improves mood under stress. Am J Clin Nut. 71:1536-1544.	805
		Absorption rate and muscle accretion	The product must contain at least 10 grams high quality protein per serving Claim to be used for foods for active individuals Must meet minimum requirements for use of			1,754

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			the claim "Source of protein" as per Annex to Regulation 1924/2006.	Peer-reviewed scientific research articles	Anthony TG, McDaniel BJ, Knoll P, Bunpo P, Paul GL, McNurlan MA. (2007) Feeding meals containing soy or whey protein after exercise stimulates protein synthesis and translation initiation in the skeletal muscle of male rats. J Nutr, Feb; 137(2): 357-62. Boirie Y, Dangin M, Gachon P, Vasson MP, Maubois JL, Beaufrere B. (1997) Slow and fast dietary proteins differently modulate postprandial protein accretion. Proc Natl Acad Sci U S A, Dec 23; 94(26): 14930-5. Cribb PJ, Williams AD, Carey MF, Hayes A. (2006) The effect of whey isolate and resistance training on strength, body composition, and plasma glutamine. Int J Sport Nutr Exerc Metab, Oct; 16(5): 494-509. Dangin M, Boirie Y, Garcia-Rodenas C, Gachon P, Fauquant J, Callier P, Ballevre O, Beaufrere B. (2001) The digestion rate of protein is an independent regulating factor of postprandial protein retention. Am J Physiol Endocrinol Metab, Feb; 280(2): E340-8. Dangin M, Boirie Y, Guillet C, Beaufrere B. (2002) Influence of the protein digestion rate on protein turnover in young and elderly subjects. J Nutr, Oct; 132(10): 3228S-33S. Dangin M, Guillet C, Garcia-Rodenas C, Gachon P, Bouteloup-Demange C, Reiffers-Magnani K, Fauquant J, Ballevre O, Beaufrere B. (2003) The rate of protein digestion affects protein gain differently during	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					aging in humans. J Physiol, Jun 1; 549(Pt 2): 635-44. Epub 2003 Mar 28. Hall WL, Millward DJ, Long SJ, Morgan LM. (2003) Casein and whey exert different effects on plasma amino acid profiles, gastrointestinal hormone secretion and appetite. Br J Nutr, Feb; 89(2): 239-48. Tipton KD, Elliott TA, Cree MG, Wolf SE, Sanford AP, Wolfe RR. (2004) Ingestion of casein and whey proteins result in muscle anabolism after resistance exercise. Med Sci Sports Exerc, Dec; 36(12): 2073-81. Lemon PW, Berardi JM, Noreen EE. (2002) The role of protein and amino acid supplements in the athlete's diet: does type or timing of ingestion matter? Curr Sports Med Rep. 2002 Aug; 1(4): 214-21.	
		Increases satiety	48 grams of whey protein per serving Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.	Human RCTs	Bowen J, Noakes M, Clifton PM. Appetite regulatory hormone responses to various dietary proteins differ by body mass index status despite similar reductions in ad libitum energy intake. J Clin Endocrinol Metab. 2006 Aug;91(8):2913-9. PMID: 16735482 Bowen J, Noakes M, Trenerry C, Clifton PM. Energy intake, ghrelin, and cholecystokinin after different carbohydrate and protein preloads in overweight men. J Clin Endocrinol Metab. 2006 Apr;91(4):1477-83. PMID: 16434457	582

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Hall WL, Millward DJ, Long SJ, Morgan LM. Casein and whey exert different effects on plasma amino acid profiles, gastrointestinal hormone secretion and appetite. Br J Nutr. 2003 Feb;89(2):239-48. PMID: 12575908 Leidy HJ, Carnell NS, Mattes RD & Campbell WW. 2007. Higher protein intakes preserves lean mass and satiety with weight loss in pre-obese and obese women. Obesity (Silver Spring) 15 (2):41-49.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Nilsson M, Holst JJ & Bjorck I. 2007. Metabolic effects of amino acid mixtures and whey protein in healthy subjects: studies using glucose-equivalent drinks. Am J Clin Nutr.85:996-1004. Frid AH, Nilsson M, Holst JJ & Bjorck IM. 2005. Effect of whey on blood glucose and insulin responses to composite breakfast and lunch meals in type 2 diabetic subjects. Am J Clin Nutr. 82(1):69-75. Bellissimo N, Desantadina MV, Pencharz PB, Berall GB, Thomas SG & Anderson GH. 2007. A comparison of short-term appetite and energy intakes in normal weight and obese boys following glucose and whey-protein drinks. Int J Obes (Lond). In Press. Layman DK, Boileau R, Erickson D, Painter J, Shiue H, Sathar C & Christou D. 2003. A reduced rate of dietary carbohydrate to protein improves body composition and blood lipid profiles during weight loss in adult women. Am Soc Nutr Sci. 133:411-417. Moran LJ, Luscombe-Marsh ND, Noakes M, Rittert GA, Keogh JB & Clifton PM. 2005. The satiating effect of dietary protein is unrelated to post-prandial ghrelin secretion. J Clin Endocrinol Metab. 90(9):5205-5211. Apolzan J, Carnell N, Mattes R & Campbell W. 2007. Inadequate dietary protein increases hunger and desire to eat in younger and older men. J Nutr. 137:1478-1482.	
				Scientific review	Layman DK. 2003. The role of leucine in weight loss diets & glucose homeostasis. J Nutr. 133: 261S-267S.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Muscle strength and body composition	The product must contain at least 10 grams high quality protein per serving Claim to be used for foods for active individuals	Peer-reviewed scientific research study	Cribb PJ, Williams AD, Carey MF, Hayes A. (2006) The effect of whey isolate and resistance training on strength, body composition, and plasma glutamine. Int J Sport Nutr Exerc Metab, Oct; 16(5): 494-509.	1,755
		Cognitive function	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.	RCT	Markus CR, Olivier B & de Hann E. 2002. Whey protein rich in a-lactalbumin increases the ratio of plasma tryptophan to the sum of the other large neutral amino acids and improves cognitive performance in stress-vulnerable subjects. Am J Clin Nutr. 75:1051-1056. Kaplan RJ, Greenwood CE, Winocur G & Wolever T. 2001. Dietary protein, carbohydrate, and fat enhanced memory performance in the healthy elderly. Am J Clin Nutr. 74:687-693. Markus CR, Jonkman LM, Lammers JH, Deutz NE, Messer MH & Rigtering N. 2005. Evening intake of alpha-lactalbumin increases plasma tryptophan availability and improves morning alertness and brain measures of attention. Am J Clin Nutr. 81 (5):1026-1033.	798
		Supports a decrease in body fat when combined with exercise and a hypocaloric diet	20 grams per day Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.	Human RCTs	Cribb PJ, Williams AD, Carey MF, Hayes A. The effect of whey isolate and resistance training on strength, body composition, and plasma glutamine. Int J Sport Nutr Exerc Metab. 2006 Oct;16(5):494-509. PMID: 17240782 Demling RH, DeSanti L. Effect of a hypocaloric diet, increased protein intake and resistance training on lean mass gains and fat mass loss in overweight police officers. Ann Nutr Metab. 2000;44(1):21-9. PMID: 10838463	577

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Lands LC, Grey VL, Smountas AA. Effect of supplementation with a cysteine donor on muscular performance. J Appl Physiol. 1999 Oct;87(4):1381-5. PMID: 10517767	
		Is rapidly digested	Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.	Human RCTs	Dangin M, Guillet C, Garcia-Rodenas C, Gachon P, Bouteloup-Demange C, Reiffers-Magnani K, Fauquant J, Ballevre O, Beaufrere B. The rate of protein digestion affects protein gain differently during aging in humans. J Physiol. 2003 Jun 1;549(Pt 2):635-44. PMID: 12665610 Dangin M, Boirie Y, Garcia-Rodenas C, Gachon P, Fauquant J, Callier P, Ballevre O, Beaufrere B. The digestion rate of protein is an independent regulating factor of postprandial protein retention. Am J Physiol Endocrinol Metab. 2001 Feb;280(2):E340-8. PMID: 11158939	580
		Supports an increase in strength when combined with resistance exercise	1.2 grams of whey protein per kg of bodyweight per day Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.	Human RCTs	Cribb PJ, Williams AD, Stathis CG, Carey MF, Hayes A. Effects of whey isolate, creatine, and resistance training on muscle hypertrophy. Med Sci Sports Exerc. 2007 Feb;39(2):298-307. PMID: 17277594 Cribb PJ, Williams AD, Carey MF, Hayes A. The effect of whey isolate and resistance training on strength, body composition, and plasma glutamine. Int J Sport Nutr Exerc Metab. 2006 Oct;16(5):494-509. PMID: 17240782 Candow DG, Burke NC, Smith-Palmer T, Burke DG. Effect of whey and soy protein supplementation combined with resistance training in young adults. Int J Sport Nutr Exerc Metab. 2006 Jun;16(3):233-44. PMID: 16948480	579

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Burke DG, Chilibeck PD, Davidson KS, Candow DG, Farthing J, Smith-Palmer T. The effect of whey protein supplementation with and without creatine monohydrate combined with resistance training on lean tissue mass and muscle strength. Int J Sport Nutr Exerc Metab. 2001 Sep;11(3):349-64. PMID: 11591884	
		Promotes protein synthesis when taken after resistance exercise	20 grams of whey protein after exercise Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.	Human RCTs	Tipton KD, Elliott TA, Cree MG, Aarsland AA, Sanford AP, Wolfe RR. Stimulation of net muscle protein synthesis by whey protein ingestion before and after exercise. Am J Physiol Endocrinol Metab. 2007 Jan;292(1):E71-6. PMID: 16896166 Tipton KD, Elliott TA, Cree MG, Wolf SE, Sanford AP, Wolfe RR. Ingestion of casein and whey proteins result in muscle anabolism after resistance exercise. Med Sci Sports Exerc. 2004 Dec;36(12):2073-81. PMID: 15570142	574
		Maintenance and growth of muscle	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.	Expert Report Scientific Review	Cribb PJ. 2005. U.S. Whey Proteins in Sports Nutrition. U.S. Dairy Export Council. 1-12. Ha E and Zemel MB. 2003. Functional properties of whey, whey components, and essential amino acids:mechanisms underlying health benefits for active people (Review). J Nutr Biochem. 14:251-258. Marshall K. 2004. Therapeutic applications of Whey Protein. Alt Med Rev. 9(2): 136-14.	795

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				RCT	Koopman R, Wagenmakers AJ, Manders RI, Zorec AH, Senden JM, Gorselink M, Keizer HA and Van Loon LJ. 2005. Combined ingestion of protein and free leucine with carbohydrate increases post exercise muscle protein synthesis in vivo in male subjects. Am J Physiol Endocrinol Metab. 288 (4): e645-e653. Koopman R, Verdijk L, Manders RJF, Gijsen AP, Gorselink M, Pijpers E, Wagenmakers AJM and Loon LJC. 2006. Co-ingestion of protein and leucine stimulates muscle protein synthesis rates to the same extent in young and elderly lean men. Am J Clin Nutr. 84:623-632. Cribb PJ, Williams AD, Carey MF and Hayes A. 2006. The Effect of whey isolate and resistance training on strength, body composition, and plasma glutamine. Int J Sport Nutr Exerc Metab. 16 (5): 494-509. Kerksick CM, Rasmussen CJ, Lancaster SL, Magu B, Smith P, Melton C, Greenwood M, Almada AL, Earnest CP, Kreider RB. 2006. The effects of protein and amino acid supplementation on performance and training adaptations during ten weeks of resistance training. J Strength Cond Res. 20:643-653. Burke DG, Chilibeck PD, Davidson KS, Candow DG, Farthing J and Smith-Palmer T. 2001. The effect of whey protein supplementation with and without creatine monohydrate combined with resistance training on lean tissue mass and muscle strength. Int J Sport Nutr Exerc Metab. 11 (3): 349-364. Boza JJ, Martinez-Ausustin O, Baro L, Suarez MD & Gil A. 1995. Protein versus enzymic protein hydrolosates. Nitrogen utilisation in starved rats. Brit J Nutr. 73 (1):65-71.	
		Supports a healthy immune system	20 grams per day			581

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.	Human RCTs and textbook	Lands LC, Grey VL, Smountas AA. Effect of supplementation with a cysteine donor on muscular performance. J Appl Physiol. 1999 Oct;87(4):1381-5. PMID: 10517767 Middleton N, Jelen P, Bell G. Whole blood and mononuclear cell glutathione response to dietary whey protein supplementation in sedentary and trained male human subjects. Int J Food Sci Nutr. 2004 Mar;55(2):131-41. PMID: 14985185 Kohut, M. Immune system modulators. In: Sports Supplements. ISBN 078172241-1	
		Supports a gain in lean body mass during periods of energy restriction	0.7 grams of whey protein per kg of bodyweight per day Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.	Human RCTs	Cribb PJ, Williams AD, Carey MF, Hayes A. The effect of whey isolate and resistance training on strength, body composition, and plasma glutamine. Int J Sport Nutr Exerc Metab. 2006 Oct;16(5):494-509. PMID: 17240782 Demling RH, DeSanti L. Effect of a hypocaloric diet, increased protein intake and resistance training on lean mass gains and fat mass loss in overweight police officers. Ann Nutr Metab. 2000;44(1):21-9. PMID: 10838463	578
		Supports an increase in lean body mass when combined with exercise and a hypercaloric diet	0.7 grams of whey protein per kg of bodyweight per day Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.	Human RCTs	Cribb PJ, Williams AD, Stathis CG, Carey MF, Hayes A. Effects of whey isolate, creatine, and resistance training on muscle hypertrophy. Med Sci Sports Exerc. 2007 Feb;39(2):298-307. PMID: 17277594 Cribb PJ, Williams AD, Carey MF, Hayes A. The effect of whey isolate and resistance training on strength, body composition, and plasma glutamine. Int J Sport Nutr Exerc Metab. 2006 Oct;16(5):494-509. PMID: 17240782	575

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Candow DG, Burke NC, Smith-Palmer T, Burke DG. Effect of whey and soy protein supplementation combined with resistance training in young adults. Int J Sport Nutr Exerc Metab. 2006 Jun;16(3):233-44. PMID: 16948480 Burke DG, Chilibeck PD, Davidson KS, Candow DG, Farthing J, Smith-Palmer T. The effect of whey protein supplementation with and without creatine monohydrate combined with resistance training on lean tissue mass and muscle strength. Int J Sport Nutr Exerc Metab. 2001 Sep;11(3):349-64. PMID: 11591884 Demling RH, DeSanti L. Effect of a hypocaloric diet, increased protein intake and resistance training on lean mass gains and fat mass loss in overweight police officers. Ann Nutr Metab. 2000;44(1):21-9. PMID: 10838463	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Whey protein branched-chain amino acids					
		Immune health	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.	Scientific Review	Melis GC, ter Wengel L, Boelens PG & Van Leeuwen PA. 2004. Glutamine: recent developments in research on the clinical significance of glutamine. Curr Opin Clin Nutr Metab Care. 7 (1): 59-70.	799
				RCT	Grey V, Mohammad SR, Smountas AA, Bahlool R & Lands LC. 2003. Improved glutathione status in young adult patients with cystic fibrosis supplemented with whey protein. J Cyst Fibros. 2 (4): 195-198. Micke P, Beeh KM & Buhl R. 2002. Effects of long term supplementation with whey proteins on plasma glutathione levels of HIV-infected patients. Eur J Nutr. 41 (1):12-18. Moreno YF, Sgarbieri VC, da Silva MN, Toro AA & Vilela MM. 2006. Features of whey protein concentrate supplementation in children with rapidly progressive HIV infection. J Trop Pediatr.52 (1): 34-38. Lothian JB, Grey V & Lands LC. 2006. Effect of whey protein to modulate immune response in children with atopic asthma. Int J Food Sci Nutr.57 (3-4):204-211.	
				Animal Study	Bounous G, Kongshavn PA & Gold P. 1988. The immunoenhancing property of dietary whey protein concentrate. Clin Invest Med.11 (4):271-278.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Whey protein Hydrolysate					
		Muscle Recovery	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.	RCT	Van Hall G, Saris WH, van de Schoor PA & Wagenmakers AJ. 2000. The effect of free glutamine and peptide ingestion on the rate of muscle glycogen resynthesis in man. Int J Sports Med. 21 (1): 25-30. Cribb PJ, Williams AD, Carey MF & Hayes A. 2006. The effect of whey isolate and resistance training on strength, body composition, and plasma glutamine. Int J Sports Nutr Exerc Metab. 16 (5): 494-509. Boza JJ, Matinez-Augustin O, Baro L, Suarez MD & Gil A. 1995. Protein versus enzymic protein hydrolysates. Nitrogen utilisation in starved rats. Brit J Nutr. 73 (1): 65-71.	800

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Whey protein isolate (Lacprodan DI-9212)					
		Increase muscle synthesis	0.25 g/kg BW Lacprodan?DI-9212 Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.	Scientific investigations	Studies supporting our claim: Tipton, K.D. et al (2004) Ingestion of Casein and Whey Proteins Result in Muscle Anabolism after Resistance Exercise. Med. Sci. Sports Exerc. 36: 2073–2081 Tracy G. et al. (2007) Feeding Meals Containing Soy or Whey Protein after Exercise Stimulates Protein Synthesis and Translation Initiation in the Skeletal Muscle of Male Rats. Journal of Nutrition 137: 357–362 Douglas Paddon-Jones et al (2006) Differential stimulation of muscle protein synthesis in elderly humans following isocaloric ingestion of amino acids or whey protein. Experimental Gerontology 41: 215–219 Esmarck, B. et al. (2001) Timing of postexercise protein intake is important for muscle hypertrophy with resistance training in elderly humans. Journal of Physiology 535: 301-311	774

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Whey protein peptides					
		Maintaining vascular health	Must meet minimum requirements for use of the claim "source of protein" as per Annex to Regulation 1924/2006.	Animal intervention study	Miguel et al., (2007). Vascular effects and antihypertensive properties of ?-casein macropeptide. International Dairy Journal, 17, 1473-1477.	802
				Review	Pfeuffer & Schrezenmeir (2006). Milk and metabolic syndrome. Obesity Reviews, 8, 10-118. Groziak & Miller (2000). Natural bioactive substances in milk and colostrum; effects on the arterial blood pressure system. British Journal of Nutrition, 84, S119-S125. Shah (2000). Effects of milk-derived bioactives: an overview. British Journal of Nutrition, 84, S3-S10. FitzGerald et al., (2004). Hypotensive peptides from milk proteins. Journal of Nutrition, 134, 980S-988S.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
VITAMINS						

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	All vitamins					
		Reproduction	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults 'All vitamins' refers to all vitamins listed in Annex 1 to the Food Supplements Directive (2002/46/EC)	IOM DRV Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals	59
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Reports	Reports of the European Scientific Committee on Food	
				EVM Reports	Draft reports of the UK Expert Group on Vitamins and Minerals	
				Nutrition textbook	Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002.	
				Nutrition textbook	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	
				Nutrition Textbooks	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Growth	MUST AT LEAST BE A			61

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults 'All vitamins' refers to all vitamins listed in Annex 1 to the Food Supplements Directive (2002/46/EC)	Authoritative Body	CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	
				Authoritative Body	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	
				Authoritative Body	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	
				IOM DRV Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Reports	Reports of the European Scientific Committee on Food	
				EVM Reports	Draft reports of the UK Expert Group on Vitamins and Minerals	
				Nutrition textbook	Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002.	
				Nutrition textbook	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.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Metabolism and equilibrium	MUST MEET MINIMUM REQUIREMENTS FOR USE OF THE CLAIM SOURCE OF VITAMINS AND/OR MINERALS AS PER ANNEX TO REGULATION 1924/2006. All vitamins' refers to all vitamins listed in Annex 1 to the Food Supplements Directive (2002/46/EC)	Authoritative Body	CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	63
				Authoritative Body	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	
				Authoritative Body	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	
				Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				IOM DRV Report	Institute of Medicine (1998) Vitamin B12 In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 9, pp 306-356 Institute of Medicine. Dietary Reference intakes for Vitamin C, Vitamin E, Selenium and Carotenoids. National Academic Press, Washington, 2000. Institute of Medicine. Dietary Reference intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium and Zinc. National Academic Press. Washington, 2001 Institute of Medicine. Dietary Reference intakes for Calcium, Phosphorus, Magnesium, Vitamin D and Fluoride. National Academic Press, Washington, 1997,	
		Conception	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults 'All vitamins' refers to all vitamins listed in Annex 1 to the Food Supplements Directive (2002/46/EC)	IOM DRV Reports Nutrition textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals	60

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Nutrition textbook	Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002.	
				Nutrition textbook	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.	
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Body maintenance	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults 'All vitamins' refers to all vitamins listed in Annex 1 to the Food Supplements Directive (2002/46/EC)	Authoritative Body	CH - Switzerland - Ordonnance du March 1995 sur les dennrees 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	62
				Authoritative Body	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	
				Authoritative Body	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	
				IOM DRV Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Reports	Reports of the European Scientific Committee on Food	
				EVM Reports	Draft reports of the UK Expert Group on Vitamins and Minerals	
				Nutrition textbook	Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002.	
				Nutrition textbook	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.	
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Beta Carotene					
		Anitoxidants and aging	Agency guidance for supplements is that products containing >7 mg of beta-carotene should carry the label advisory statement "[Beta-carotene] should not be taken by heavy smokers" Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.	studies	1/ Stahl W et al. Physical quenching of singlet oxygen and cis-trans isomerization of carotenoids. Ann N Y Acad Sci 1993; 691: 10-9. 2/ Eichler O et al. Divergent optimum levels of lycopene, beta-carotene and lutein protecting against UVB irradiation in human fibroblasts. Photochem Photobiol. 2002 May; 75(5): 503-6. (from CIAA list)"	1,214
		Protection of body tissues and cells from oxidative damage	720µg (15% RDA equivalent) Agency guidance for supplements is that products containing >7 mg of beta-carotene should carry the label advisory statement "[Beta-carotene] should not be taken by heavy smokers"	Authoritative body	Stahl W et al. Physical quenching of singlet oxygen and cis-trans isomerization of carotenoids. Ann N Y Acad Sci 1993; 691:10-9 Eichler O et al. Divergent optimum levels of lycopene, beta-carotene and lutein protecting against UVB irradiation in human fibroblasts. Photochem. Photobiol. 2002 May; 75(5): 503-6.	1,560

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Beta carotene in combination with vitamin E and vitamin C					
		Eye health and vision	At least 15% RDA of beta-carotene (as vitamin A, conversion factor 6), vitamin E and vitamin C. Agency guidance for supplements is that products containing beta-carotene should carry the advisory statement '[Beta-carotene]* should not be taken by heavy smokers.			352

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual human intervention studies (RCTs), supported by epidemiological evidence	BETA-CAROTENE IN COMBINATION WITH VITAMIN E AND VITAMIN C - Eye health and vision Human intervention studies ARC and AMC related AREDS Research Group, "The Age-related Eye Disease Study (AREDS): design implications - AREDS report No. 1", Contr. Clin. Trials, 20 573-600 (1999). - AREDS Research Group, "A randomized, placebo-controlled, clinical trial of high-dose supplementation with vitamins C and E and beta carotene for age-related cataract and vision loss - AREDS report no. 9", Arch. Ophthalmol., 119 (10), 1439-1452 (2001). - AREDS Research Group, "A randomized, placebo-controlled, clinical trial of high-dose supplementation with vitamins C and E, b-carotene, and zinc for age-related macular degeneration and vision loss: AREDS report no. 8", Arch. Ophthalmol., 119 (10), 1417-1436 (2001). - ATBC Study Group, "The effect of vitamin E and beta-carotene on the incidence of lung cancer and other cancers in male smokers." N Engl J Med, 330 1029-1035 (1994). - Christen, W., Glynn R., Sperduto R., et al., "Age-related cataract in a randomized trial of beta-carotene in women." Ophthalmic Epidemiol., 11 (5), 401-412 (2004). - Christen, W.G., Manson J.E., Glynn R.J., et al., "A randomized trial of beta carotene and age-related cataract in US physicians." Arch Ophthalmol., 121 (3), 372-378 (2003). - Christen, W.G., Gaziano J.M.and Hennekens C.H., "Design of Physicians' Health Study II--a randomized trial of beta-carotene,	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

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Teikari, J.M., Laatikainen L., J. V., et al., "Six-year supplementation with alpha-tocopherol and beta-carotene and age-related maculopathy", Acta-Ophthalmol-Scand, 76 (2), 224-229 (1998).

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Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
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Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Beta-Carotene					
		Antioxidant properties/ Antioxidant activity/Protection of DNA	Min 15% RDA of beta-carotene (as vitamin A, conversion factor 6) Agency guidance for supplements is that products containing beta-carotene should carry the advisory statement '[Beta-carotene]* should not be taken by heavy smokers.	Published Review	Voutilainen S, Nurmi T, Mursu J et al (2006) Carotenoids and cardiovascular health. Am J Clin Nutr; 83(6): 1265-1271. Krinsky NI, Johnson EJ (2005) Carotenoid actions and their relation to health and disease. Mol Aspects Med; 26(6): 459-516. Stahl W, Sies H (2005) Bioactivity and protective effects of natural carotenoids. Biochim Biphys Acta; 1740(2): 101-107. Bendich A (2004) From 1989 to 2001: what have we learned about the biological actions of beta carotene? J Nutr; 134(1): 225-230. Paiva SA, Russell RM (1999) Beta carotene and other carotenoids as antioxidants. J Am Coll Nutr; 18(5): 426-433. Steenvoorden DP, van Henegouwen GM (1997) The use of endogenous antioxidants to improve photoprotection. J Photochem Photobiol; 41(1): 1-10.	347

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Cirtical reviews Clinical studies Experimental studies	BETA-CAROTENE and Antioxidant properties / Protection of DNA Individual human intervention studies: - Torbergsen, A.C., Collins, A.R. 2004. Recovery of human lymphocytes from oxidative DNA damage; the apparent enhancement of DNA repair by carotenoids is probably simply an antioxidant effect. European Journal of Nutrition 39: 80-85. - Zhao, X., Aldini, G., Johnson, E.J., Rasmussen, H., Kraemer, K., Woolf, H., Musaeus, N., Krinsky, N.I., Russell, R.M., Yeum, K.J. 2006. Modification of lymphocyte DNA damage by carotenoid supplementation in postmenopausal women. American Journal of Clinical Nutrition 83: 163-169. Evidence from Review articles: - Moller, P., Loft, S. 2006. Dietary antioxidants and beneficial effect on oxidatively damaged DNA. Free Radical Biology & Medicine 4(3): 388-415. - Stahl, W., Sies, H. 2005. Bioactivity and protective effects of natural carotenoids. Biochimica Biophysica Acta 1740 (2): 101-107. Evidence from experimental studies: - Astley, SB, Elliott, R.M, Archer, D.B., Southon, S. 2002. Increased cellular carotenoid levels reduce the persistence of DNA single strand breaks after oxidative challenge. Nutrition and Cancer, 43: 202-213. - Matos, H.R., Marques, S.A., Gomes, O.F., Silva, A.A., Heimann, J.C., Di Mascio, P., Medeiros, M.H. 2006. Lycopene and beta-carotene protect in vivo iron-induced oxidative stress damage in rat prostate. Brazilian Journal of Medical and Biological Research 39(2): 203-210.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Immune health in relation to UV-radiation	Up to 10 mg per day (for 4 - 10 weeks) Agency guidance for supplements is that products containing beta-carotene should carry the advisory statement '[Beta-carotene]* should not be taken by heavy smokers. Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.	Individual papers	BETA-CAROTENE and Immune health in relation to UV-radiation Evidence from human intervention studies -Fuller CJ, Faulkner H, Bendich A, Parker RS, Roe DA. Effect of beta-carotene supplementation on photosuppression of delayed-type hypersensitivity in normal young men. Am J Clin Nutr. 1992;56:684-690. -Gollnick, H, Hopfenmuller, W, Hemmes, C, Chun, SC, Schmid, C, Sundermeier, K, Biesalski, HK. Systemic beta-carotene plus topical UV sunscreen are an optimal protection against harmful effects of natural UV-sunlight: results of the Berlin-Eilath study. Eur J Dermatol. 1996;6:200-205 -Herraiz LA, Hsieh WC, Parker RS, Swanson JE, Bendich A, Roe DA. Effect of UV exposure and beta-carotene supplementation on delayed-type hypersensitivity response in healthy older men. J Am Coll Nutr. 1998;17:617-624. Recognised text books, monographs and further supporting information - Clydesdale GJ, Dandie GW, Muller HK. Ultraviolet light induced injury: immunological and inflammatory effects. Immunol Cell Biol. 2001;79:547-568 - Granstein RD, Matsui MS. UV radiation-induced immunosuppression and skin cancer. Cutis. 2004;74(Suppl):4-9 - Stahl W, Sies H: Carotenoids in systemic protection against sun-burn. In: Carotenoids in Health and Disease (Krinsky NI, Mayne ST, Sies H, eds.) Marcel Dekker, New York 2004, pp 491-502. - White WS, Kim CI, Kalkwarf HJ, Bustos P, Roe DA. Ultraviolet light-induced reductions in plasma carotenoid levels. Am J Clin Nutr. 1988;47:879-883.	350

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					- Biesalski HK, Hemmes C, Hopfenmuller W, Schmid C, Gollnick HP. Effects of controlled exposure of sunlight on plasma and skin levels of beta-carotene. Free Radic Res. 1996;24:215-224 Albers et al, Markers to measure immunomodulation in human nutrition intervention studies. Br J Nutr. 2005;94:452-481	
		Skin aging/Skin health	Minimum intake of 2 mg per day. Intake should not exceed 10 mg/d long term if ingested supplementary Agency guidance for supplements is that products containing beta-carotene should carry the advisory statement '[Beta-carotene]* should not be taken by heavy smokers. MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006			348

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual human intervention studies Peer reviewed Reviews	BETA-CAROTENE and Skin aging / Skin health References as to sunburn (erythema) development Individual human intervention studies - Garmyn M, Ribaya-Mercado JD, Russel RM, Bhawan J, Gilchrest BA. 1995. Effect of beta-carotene supplementation on the human sunburn reaction. Exp Dermatol 4(2):104-11. - Gollnick H, Hopfenmuller W, Hemmes C, Chun S, Schmid C, Sundermeier K, Biesalski HK. 1996. Systemic beta carotene plus topical UV-sunscreen are an optimal protection against harmful effects of natural UV-sunlight: results of the Berli-Eilath study. Eur J Dermatol 6(3):200-205. Stahl W, Heinrich U, Jungmann H, Sies H, Tronnier H. 2000. Carotenoids and carotenoids plus vitamin E protect against ultraviolet light-induced erythema in humans. Am J Clin Nutr 71(3):795-8. - Lee J, Jiang S, Levine N, Watson RR. 2000. Carotenoid supplementation reduces erythema in human skin after simulated solar radiation exposure. Proc Soc Exp Biol Med 223(2):170-4. - Greul AK, Grundmann JU, Heinrich F, Pfitzner I, Bernhardt J, Ambach A, Biesalski HK, Gollnick H. 2002. Photoprotection of UV-irradiated human skin: an antioxidative combination of vitamins E and C, carotenoids, selenium and proanthocyanidins. Skin Pharmacol Appl Skin Physiol 15(5):307-15. - Heinrich U, Gartner C, Wiebusch M, Eichler O, Sies H, Tronnier H, Stahl W. 2003. Supplementation with beta-carotene or a similar amount of mixed carotenoids protects humans from UV-induced erythema. J Nutr	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID

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Evidence from reviews

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					- Boelsma E, Hendriks HF, Roza L. 2001. Nutritional skin care: health effects of micronutrients and fatty acids. Am J Clin Nutr 73(5):853-64. - Chew BP, Park JS. 2004. Carotenoid action on the immune response. J Nutr 134(1):257S-261S. - Hughes DA. 1999. Effects of carotenoids on human immune function. Proc Nutr Soc 58(3):713-718. - Hughes DA. 2001. Dietary carotenoids and human immune function. Nutrition 17(10):823-827. References as to skin color and tanning: Evidence from intervention studies - Alaluf S, Heinrich U, Stahl W, Tronnier H, Wiseman S. 2002. Dietary carotenoids contribute to normal human skin color and UV photosensitivity. J Nutr 132(3):399-403. - Cesarini JP, Michel L, Maurette JM, Adhoute H, Bejot M. 2003. Immediate effects of UV radiation on the skin: modification by an antioxidant complex containing carotenoids. Photodermatol Photoimmunol Photomed 19(4):182-9. - Postaire E, Jungmann H, Bejot M, Heinrich U, Tronnier H. 1997. Evidence for antioxidant nutrients-induced pigmentation in skin: results of a clinical trial. Biochem Mol Biol Int 42(5):1023-33. Mechanistic studies in vivo and in vitro - Goralczyk R, Wertz K. accepted, to be published in 2007. Skin photoprotection by carotenoids. In: Britton G, Liaaen-Jensen S, Pfander H, ditors. Carotenoids: Part C Carotenoids against disease: Birkhauser. p Chapter 4. - Wertz K, Seifert N, Hunziker PB, Riss G, Wyss A, Lankin C, Goralczyk R. 2004.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					beta-carotene inhibits UVA-induced matrix metalloprotease 1 and 10 expression in keratinocytes by a singlet oxygen-dependent mechanism. Free Radic Biol Med 37(5):654-70. - Wertz K, Hunziker PB, Seifert N, Riss G, Neeb M, Steiner G, Hunziker W, Goralczyk R. 2005. beta-Carotene Interferes with Ultraviolet Light A-Induced Gene Expression by Multiple Pathways. J Invest Dermatol 124(2):428-34. - Wertz K, Seifert N, Hunziker PB, Riss G, Wyss A, Hunziker W, Goralczyk R. 2006. Beta-carotene interference with UVA-induced gene expression by multiple pathways. Pure and Applied Chemistry 78(8):1539-1550. - Bando N, Hayashi H, Wakamatsu S, Inakuma T, Miyoshi M, Nagao A, Yamauchi R, Terao J. 2004. Participation of singlet oxygen in ultraviolet-a-induced lipid peroxidation in mouse skin and its inhibition by dietary beta-carotene: an ex vivo study. Free Radic Biol Med 37(11):1854-63. - Cesarini JP, Michel L, Maurette JM, Adhoute H, Bejot M. 2003. Immediate effects of UV radiation on the skin: modification by an antioxidant complex containing carotenoids. Photodermatol Photoimmunol Photomed 19(4):182-9. - McArdle F, Rhodes LE, Parslew RA, Close GL, Jack CI, Friedmann PS, Jackson MJ. 2004. Effects of oral vitamin E and beta-carotene supplementation on ultraviolet radiation-induced oxidative stress in human skin. Am J Clin Nutr 80(5):1270-5. - O'Connor I, O'Brien N. 1998. Modulation of UVA light-induced oxidative stress by beta-carotene, lutein and astaxanthin in cultured fibroblasts. J Dermatol Sci 16(3):226-30. - Skoog ML, Ollinger K, Skogh M. 1997. Microfluorometry using fluorescein diacetate	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					reflects the integrity of the plasma membrane in UVA-irradiated cultured skin fibroblasts. Photodermatol Photoimmunol Photomed 13(1-2):37-42. 17 - Someya K, Totsuka Y, Murakoshi M, Kitano H, Miyazawa T. 1994. The effect of natural carotenoid (palm fruit carotene) intake on skin lipid peroxidation in hairless mice. J Nutr Sci Vitaminol (Tokyo) 40(4):303-14. - Obermuller-Jevic UC, Francz PI, Frank J, Flaccus A, Biesalski HK. 1999. Enhancement of the UVA induction of haem oxygenase-1 expression by beta-carotene in human skin fibroblasts. FEBS Lett 460(2):212-6. - Offord EA, Gautier JC, Avanti O, Scaletta C, Runge F, Kramer K, Applegate LA. 2002. Photoprotective potential of lycopene, beta-carotene, vitamin E, vitamin C and carnosic acid in UVA-irradiated human skin fibroblasts. Free Radic Biol Med 32(12):1293-303. - Trekli MC, Riss G, Goralczyk R, Tyrrell RM. 2003. Beta-carotene suppresses UVA-induced HO-1 gene expression in cultured FEK4. Free Radic Biol Med 34(4):456-64. - Eicker J, Kurten V, Wild S, Riss G, Goralczyk R, Krutmann J, Berneburg M. 2003. Betacarotene supplementation protects from photoaging-associated mitochondrial DNA mutation. Photochem Photobiol Sci 2(6):655-9. - Offord EA, Gautier JC, Avanti O, Scaletta C, Runge F, Kramer K, Applegate LA. 2002. Photoprotective potential of lycopene, beta-carotene, vitamin E, vitamin C and carnosic acid in UVA-irradiated human skin fibroblasts. Free Radic Biol Med 32(12):1293-303. - Antille C, Tran C, Sorg O, Saurat JH. 2004.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Topical beta-carotene is converted to retinyl esters in human skin ex vivo and mouse skin in vivo. Exp Dermatol 13(9):558-61. - Wei RR, Wamer WG, Lambert LA, Kornhauser A. 1998. beta-Carotene uptake and effects on intracellular levels of retinol in vitro. Nutr Cancer 30(1):53-8.	
		Immune health/Immune function	Up to 10 mg/day			349
			Agency guidance for supplements is that products containing beta-carotene should carry the advisory statement '[Beta-carotene]* should not be taken by heavy smokers. Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.			

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Published Review	Krinsky NI, Johnson EJ (2005) Carotenoid actions and their relation to health and disease. Mol Aspects Med; 26(6): 459-516. Stahl W, Sies H (2005) Bioactivity and protective effects of natural carotenoids. Biochim Biphys Acta; 1740(2): 101-107. Bendich A (2004) From 1989 to 2001: what have we learned about the biological actions of beta carotene? J Nutr; 134(1): 225-230. Chew BP, Park JS (2004) Carotenoid action on the immune response. J Nutr; 134(1): 257-261. Chandra RK (2004) Impact of nutritional status and nutrient supplements on immune responses and incidence of infection in older individuals. Ageing Res Rev; 3(1): 91-104. Bhaskaram P (2002) Micronutrient malnutrition, infection and immunity: an overview. Nutr Rev; 60(5): 40-45. Hughes DA (2001) Dietary carotenoids and human immune function. Nutrition; 17(10): 823-827 Hughes DA (1999) Effects of carotenoids on human immune function. Proc Nutr Soc; 58(3): 713-718. Kelley DS, Bendich A (1996) Essential nutrients and immunological functions. Am J Clin Nutr; 63(6): 994-996.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks and Monographs Individual papers	BETA-CAROTENE and Immune health Evidence from human studies [intervention and epidemiology] - Prabhala RH, Garewal HS,, Hicks M, Sampliner R, Watson R; The Effects of 13 -cis-Retinoic Acid and Beta-Carotene on Cellular Immunity in Humans. Cancer 1991; 67:1556-1560 - Moriguchi S, Okishima N, Sumida S, Okamura K, Doi T, Kishino Y. Beta-carotene supplementation enhances the lymphocyte proliferation with mitogens in human peripheral blood lymphocytes. Nutr Res 1996;16:211-218 - Santos MS, Meydani SN, Leka L, Wu D, Fotouhi N, Meydani M, Hennekens CH, Gaziano JM. Natural killer cell activity in elderly men is enhanced by beta-carotene supplementation.Am J Clin Nutr. 1996;64:772-777 - Santos MS, Gaziano JM, Leka LS, Beharka AA, Hennekens CH, Meydani SN. Beta-carotene¬induced enhancement of natural killer cell activity in elderly men: an investigation of the role of cytokines. Am J Clin Nutr. 1998;68:164-170. - Wood SM, Beckham1 C, Yosioka2 A, Darban3 H, Watson RR. beta-Carotene and selenium supplementation enhances immune response in aged humans. Integr. Med.. 2000;2:85-92. - Inserra PF, Jiang S, Solkoff D, Lee J, Zhang Z, Xu M, Hesslink R, Wise J, Watson RR. Immune Function In Elderly Smokers And Nonsmokers Improves During Supplementation With Fruit and Vegetable Extracts. Integr Med 1999;2:3-10 - Watzl B, Bub A, Briviba K, Rechkemmer G. Supplementation of a low-carotenoid diet with tomato or carrot juice modulates immune functions in healthy men. Ann Nutr Metab.	

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2003;47:255-261.
- van der Horst-Graat JM, Kok FJ, Schouten EG. Plasma carotenoid concentrations in relation to acute respiratory infections in elderly people. Br J Nutr. 2004;92:113-118
Watzl B, Kulling SE, Moseneder J, Barth SW, Bub A.. A 4-wk intervention with high intake of carotenoid-rich vegetables and fruit reduces plasma C-reactive protein in healthy, nonsmoking men. Am J Clin Nutr. 2005;82:1052-1058

Recognised text books, monographs and further supporting information
- Hughes DA: Carotenoids and Immune Responses. In: Carotenoids in Health and Disease (Krinsky NI, Mayne ST, Sies H, eds.) Marcel Dekker, New York 2004, pp 503-517.
- Chew BP, Park JS. Carotenoid action on the immune response. J Nutr. 2004;134:257S-261S
- Hughes DA. Effects of carotenoids on human immune function. Proc Nutr Soc. 1999;58:713-718
- Meydani SN, Wu D, Santos MS, Hayek MG. Antioxidants and immune response in aged persons: overview of present evidence. Am J Clin Nutr. 1995;62:1462S-1476S.
- Roe DA, Fuller CJ: Carotenoids and Immune Function. In: Nutrition and Immunology (Klurfeld DM, ed,) Plenum Press, New York 1993, pp 229-238.
- Bendich A. Beta-carotene and the immune response. Proc Nutr Soc. 1991;50:263-274.
- Bendich A. Carotenoids and the immune response. J Nutr. 1989;119:112-115
- Clausen SW. Carotenenemia and respiratory infections. Trans Am Pediatr Soc 1931;43:27-30
- Palozza P, Serini S, Torsello A, Di Nicuolo

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					F, Piccioni E, Ubaldi V, Pioli C, Wolf FI, Calviello G. Beta-carotene regulates NF-kappaB DNA-binding activity by a redox mechanism in human leukemia and colon adenocarcinoma cells. J Nutr. 2003;133):381-388. - Bai SK, Lee SJ, Na HJ, Ha KS, Han JA, Lee H, Kwon YG, Chung CK, Kim YM. beta-Carotene inhibits inflammatory gene expression in lipopolysaccharide-stimulated macrophages by suppressing redox-based NF-kappaB activation. Exp Mol Med. 2005;37):323-334. - Albers R, Antoine JM, Bourdet-Sicard R, Calder PC, Gleeson M, Lesourd B, Samartin S, Sanderson IR, Van Loo J, Vas Dias FW, Watzl B. Markers to measure immunomodulation in human nutrition intervention studies. Br J Nutr. 2005;94:452-481 - Imai K, Matsuyama S, Miyake S, Suga K, Nakachi K. Natural cytotoxic activity of peripheral-blood lymphocytes and cancer incidence: an 11-year follow-up study of a general population. Lancet 2000; 356: 1795-99. - Ogata K, An E, Shioi Y, Nakamura K, Luo S, Yokose N, Minami S, Dan K. Association between natural killer cell activity and infection in immunologically normal elderly people. Clin Exp Immunol. 2001;124:392-397	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Biotin					
		The role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)	Only for products with at least 100 % RDA of vitamins	textbook	1) Institute of Medicine (1998) Biotin In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 11, pp 374-389 3) Mock, D.M. (1999) Biotin In: Shils, M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 459-466 4) Mock, D.M. (2001) Biotin In Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 11, pp 397-426 4) 8753. 5) Zempleni, J (2001) Biotin In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 23, pp 241-252	1,187

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				studies	Carroll, D.; Ring, C.; Suter, M. and Willemsen, G. (2000) The effects of an oral multivitamin combination with calcium, magnesium, and zinc on psychological well-being in healthy young male volunteers: a double-blind placebo-controlled trial. Psychopharmacology (Berl) 150(2), 220-225 Benton, D.; Fordy, J. and Haller, J. (1995a) The impact of long-term vitamin supplementation on cognitive functioning. Psychopharmacol. 117(3), 298-305 Benton, D.; Haller, J. and Fordy, J. (1995a) Vitamin supplementation for 1 year improves mood. Neuropsychobiology 3, 98-105	
		Bone/Teeth/ Hair / Skin and Nail health	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006.			975

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	
		Energy and Vitality	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006.			976

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	
		Neurological system function	MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006	IOM DRV Report	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	41

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Normal structure and function of skin and mucosa	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006	Bodies	BIOTIN Authoritative/Scientific Bodies -Dietary Reference intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin and choline, 1999. http://www.nap.edu/openbook/0309065542/html/58.html	40
				Bodies	Institute of Medicine (1998) Biotin In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 11, pp 374-389	
				Bodies	Les Apports Nutritionnels Conseilles, sous la coordination d'Ambroise Martin, AFSSA/CNERNA¬CNRS, Editions Tec&Doc, Troisieme edition (2001) Guilland JC, Vitamine B8, p203	
				Review	Attwood PV, Wallace JC. Chemical and catalytic mechanisms of carboxyl transfer reactions in biotin-dependent enzymes. Acc Chem Res. 2002 Feb;35(2):113-20. Review.	
				Review	Fernandez-Mejia C: Pharmacological effects of biotin: J NUTR,BIOCHEM,2005 JUL;16(7)/424_7 Review	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Review	McMahon RJ. Biotin in metabolism and molecular biology. Annu Rev Nutr. 2002;22:221-39. Epub 2002 Jan 04. Review.	
				Review	Pacheco-Alvarez D, Solorzano-Vargas RS, Del Rio AL. Biotin in metabolism and its relationship to human disease. Arch Med Res. 2002 Sep-Oct;33(5):439-47. Review.	
				Review	Rodriguez Melendez R importance of biotin metabolism; REV INVEST CLIN 2000 Mar6APR; 52(2): 194-9 Review	
				Textbooks	Mock, D.M. (1999) Biotin. In: Shils, M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 459-466	
				Textbooks	Mock, D.M. (1999) Biotin. In: Shils, M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 459-466	
				Textbooks	Mock, D.M. (2001) Biotin In Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 11, pp 397-426	
				Textbooks	Zempleni, J (2001) Biotin In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 23, pp 241-252	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
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		Fat metabolism and energy production	MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults	IOM DRV Report	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 2000.	81
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Biotin. September 2001. (http://www.europa.eu.int/comm/food/fs/sc/scf/out106_en.pdf).	
				EVM Report	Revised Review of Biotin. Expert Group on Vitamins and Minerals. April 2002. (www.food.gov.uk/multimedia/pdfs/biotin.pdf)	
		Protein and amino acid metabolism	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION			38

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			1924/2006	Authoritative Body	CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	
				Authoritative/Scientific Bodies	Dietary Reference intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin and choline, 1999. http://www.nap.edu/openbook/0309065542/html/58.html	
				Authoritative/Scientific Bodies	Institute of Medicine (1998) Biotin In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 11, pp 374-389	
				Authoritative/Scientific Bodies	Les Apports Nutritionnels Conseilles, sous la coordination d'Ambroise Martin, AFSSA/CNERNA¬CNRS, Editions Tec&Doc, Troisieme edition (2001) Guilland JC, Vitamine B8, p203	
				Reviews	Attwood PV, Wallace JC. Chemical and catalytic mechanisms of carboxyl transfer reactions in biotin-dependent enzymes. Acc Chem Res. 2002 Feb;35(2):113-20. Review.	
				Reviews	Fernandez-Mejia C: Pharmacological effects of biotin: J NUTR,BIOCHEM,2005 JUL;16(7)/424_7 Review	
				Reviews	McMahon RJ. Biotin in metabolism and molecular biology. Annu Rev Nutr. 2002;22:221-39. Epub 2002 Jan 04. Review.	
				Reviews	Pacheco-Alvarez D, Solorzano-Vargas RS, Del Rio AL. Biotin in metabolism and its relationship to human disease. Arch Med Res. 2002 Sep-Oct;33(5):439-47. Review.	

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				Textbooks	Mock DM. Biotin. In: Present Knowledge in Nutrition. Ziegler and Filer, 7th ed, ILSI Press. page 220-235.	
				Textbooks	Mock, D.M. (1999) Biotin. In: Shils, M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 459-466	
				Textbooks	Mock, D.M. (2001) Biotin In Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 11, pp 397-426	
				Textbooks	Zempleni, J (2001) Biotin In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 23, pp 241-252	
				Textbooks	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Hair Growth & Follicle Formation	MINIMUM 15% RDA			1,024

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				In vitro study Review Human Intervention Study UK EVM Scientific Report	(1) C.K.W. Mulling, H.H. Bragulla, S. Reese, K.D. Budras and W. Steinburg, How Structures in Bovine Hoof Epidermis are Influenced by Nutritional Factors. Anat Histol Embryol 1999 May;28(2):103-108 (2) Donald M. Mock, Skin Manifestations of Biotin Deficiency. Semin Dermatol 1991 Dec;10(4):296-302 (3) R.P. Bhullar and K. Dakshinamurti, The Effect of Biotin on Cellular Functions in HeLa Cells. J Cell Physiol 1985 Jun;123(3):425-30 (4) Donald M. Mock, David L. Baswell, Herman Baker, Ralph T. Holman, and Lawrence Sweetman, Biotin deficiency complicating parenteral alimentation: Diagnosis, metabolic repercussions, and treatment, J. PEDIATR. (ST LOUIS) (USA), 1985, 106/5 (762-769) (5) Colombo VE, Gerber F, Bronhofer M, Floersheim GL Treatment of brittle fingernails and onychoschizia with biotin: scanning electron microscopy J Am Acad Dermatol. 1990 Dec;23(6 Pt 1):1127-32 (7) Hochman LG, Scher RK, Meyerson MS Brittle nails: response to daily biotin supplementation Cutis. 1993 Apr;51(4):303-5 (8) UK EVM Scientific Report, Upper Safe Levels. 2003. Page 36-37 Biotin	
		Fat, carbohydrate, energy metabolism	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006	Authoritative Body	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	39

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative Body	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	
				Bodies	BIOTIN Authoritative/Scientific Bodies -Dietary Reference intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin and choline, 1999. http://www.nap.edu/openbook/0309065542/html/58.html	
				Bodies	Institute of Medicine (1998) Biotin In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 11, pp 374-389	
				Bodies	-Les Apports Nutritionnels Conseilles, sous la coordination d'Ambroise Martin, AFSSA/CNERNA¬CNRS, Editions Tec&Doc, Troisieme edition (2001) Guilland JC, Vitamine B8, p203	
				Reviews	-Attwood PV, Wallace JC. Chemical and catalytic mechanisms of carboxyl transfer reactions in biotin-dependent enzymes. Acc Chem Res. 2002 Feb;35(2):113-20. Review.	
				Reviews	-Fernandez-Mejia C: Pharmacological effects of biotin: J NUTR,BIOCHEM,2005 JUL;16(7)/424_7 Review	
				Reviews	-McMahon RJ. Biotin in metabolism and molecular biology. Annu Rev Nutr. 2002;22:221-39. Epub 2002 Jan 04. Review.	
				Reviews	-Pacheco-Alvarez D, Solorzano-Vargas RS, Del Rio AL. Biotin in metabolism and its relationship to human disease. Arch Med Res. 2002 Sep-Oct;33(5):439-47. Review.	

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				Textbooks	-Mock DM. Biotin. In: Present Knowledge in Nutrition. Ziegler and Filer, 7th ed, ILSI Press. page 220-235.	
				Textbooks	-Mock, D.M. (1999) Biotin. In: Shils, M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 459-466	
				Textbooks	Mock, D.M. (2001) Biotin In Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 11, pp 397-426	
				Textbooks	Zempleni, J (2001) Biotin In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 23, pp 241-252	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Biotin. September 2001. (http://www.europa.eu.int/comm/food/fs/sc/scf/out106_en.pdf).	
				EVM Report	Revised Review of Biotin. Expert Group on Vitamins and Minerals. April 2002. (www.food.gov.uk/multimedia/pdfs/biotin.pdf)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Dexpanthenol					
		Energy metabolism	At least a significant amount as defined in the Annex to Directive 90/496/EEC for Pantothenic acid (being Dexpanthenol the alcoholic analogue of D-pantothenic acid)	IOM DRV Report Nutrition textbook SCF Report EVM Report	Institute of Medicine. Dietary Reference Intakes for Vitamins (Biotin, Choline, Folate, Niacin, Pantothenic acid, Riboflavin, Thiamine, Vitamin A, Vitamin B6, Vitamin B12, Vitamin C, Vitamin D, Vitamin E, Vitamin K). Washington D.C. The National Academies (www.nap.edu) 2001 Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Pantothenic Acid. April 2002. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80k_en.pdf). Review of Pantothenic Acid. Expert Group on Vitamins and Minerals. August 2002. (www.food.gov.uk/multimedia/pdfs/panto.pdf	2,471
		Fat metabolism	At least a significant amount as defined in the Annex to Directive 90/496/EEC for Pantothenic acid (being Dexpanthenol the alcoholic analogue of D-pantothenic acid)			2,472

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				IOM DRV Report Nutrition textbook SCF Report EVM Report	Institute of Medicine. Dietary Reference Intakes for Vitamins (Biotin, Choline, Folate, Niacin, Pantothenic acid, Riboflavin, Thiamine, Vitamin A, Vitamin B6, Vitamin B12, Vitamin C, Vitamin D, Vitamin E, Vitamin K). Washington D.C. The National Academies (www.nap.edu) 2001 Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Pantothenic Acid. April 2002. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80k_en.pdf). Review of Pantothenic Acid. Expert Group on Vitamins and Minerals. August 2002. (www.food.gov.uk/multimedia/pdfs/panto.pdf)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Folate					
		Red cell folate level >906 nmol/l is required for the foetal neural tube development	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], as per Annex to Regulation 1924/2006. To also present a statement which conveys that there is a risk that excess folate consumption (over 1mg/day) may mask B12 deficiency leading to late diagnosis of clinical disease particularly in the elderly and vegans.	Human study	• Lamers, Y., Prinz-Langenohl, R., Brämswig, S. & Pietrzik, K. (2006). Red blood cell folate concentrations increase more after supplementation with [6S]-5 -methyltetrahydrofolate than with folic acid in women of childbearing age. • Am J Clin Nutr 84: 156-161	559
		Healthy development of unborn baby: Cell Division; Developing neural tube; Blood formation.	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s] as per Annex to Regulation 1924/2006.	JHCI Final Technical Report: A list of well-established nutrient function statement	JHCI Ref: JHCI/76/03 A list of well-established nutrient function statements: A report by the Joint Health Claims Initiative to the Food Standard Agency. Prepared by JHCI Executive Director: JHCI Ref: JHCI/76.03	815
		Cognitive function	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.			1,569

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Meta analysis Individual studies	Fava et al. Folate, vitamin B12, and homocysteine in major depressive disorder. Am J Psychiatry. 1997 Mar; 154(3):426-8. Taylor MJ et al. Folate for depressive disorders: systematic review and meta-analysis of randomized control trials. J Psychopharmacol. 2004 Jun; 18(2): 251-6. Wang HX et al. Vitamin B (12) and folate in relation to the development of Alzheimer's disease. Neurology. 2001 May 8; 56(9): 1188-1194	
		Folic Acid, B6 and B12… These ingredients work together to naturally decrease homocysteine levels.	RNI: 0.2mg, B6 RNI: 1.4 mg a day for men,1.2 mg a day for women, B12 RNI:1.5 µg" The product must contain at least 15% of the RDA PRESUMED NOT NECESSARY TO present a statement which conveys that there is a risk that excess folate consumption (over 1mg/day) may mask B12 deficiency leading to late diagnosis of clinical disease particularly in the elderly and vegans AS PRODUCT ALSO CONTAINS RNI OF B12 Folic Acid Product Dosage 400µg/day B6 Product Dosage 2mg /day B12 Product Dosage 1µg/day			2,410

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					"McCully KS. Homocysteine, vitamins, and vascular disease prevention. Am J Clin Nutr. 2007 Nov;86(5):1563S-8S. PMID: 17991676 [PubMed - in process] Hoey L, McNulty H, Askin N, Dunne A, Ward M, Pentieva K, Strain J, Molloy AM, Flynn CA, Scott JM. Effect of a voluntary food fortification policy on folate, related B vitamin status, and homocysteine in healthy adults. Am J Clin Nutr. 2007 Nov;86(5):1405-13. PMID: 17991653 [PubMed - in process] Matthews RG, Elmore CL. Review: Defects in homocysteine metabolism: diversity among hyperhomocyst(e)inemias. Clin Chem Lab Med. 2007 Oct 15; [Epub ahead of print] PMID: 17937607 [PubMed - as supplied by publisher]" • 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 1998. • Folic Acid and the Prevention of Disease. Report of the Committee on Medical Aspects of Food and Nutrition Policy. Report on Health and Social Subjects No. 50. DH: The Stationery Office, 2000. • Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Folate. October 2000. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80e_en.pdf).	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					• Review of Folic Acid. Expert Group on Vitamins and Minerals. August 2002.	
		Developing neural tube	MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults only for products with at least 600 µg folic acid	IOM DRV Expert Report	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 1998.	6
				COMA Expert Report	Folic Acid and the Prevention of Disease. Report of the Committee on Medical Aspects of Food and Nutrition Policy. Report on Health and Social Subjects No. 50. DH: The Stationery Office, 2000.	
				SCF Expert Opinion	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Folate. October 2000. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80e_en.pdf).	
				EVM Expert Report	Review of Folic Acid. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/evm0018p.pdf).	
				Authoritative Body	CH - Switzerland - Ordonnance du March 1995 sur les dennrees 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	
				Authoritative Body	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	
				Authoritative Body	ANZFA - Food Standards Australia, New Zealand http://www.foodstandards.gov.au/	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000.	
					Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002.	
					Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
					Scientific Advisory Committee on Nutrition. Folate and disease prevention. London: TSO, 2006.	
				Authoritive guidelines	Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride (1997); Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid,Biotin, and Choline (1998); Food and Nutrition Board, Institute of Medicine, National Academies.	
					Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative Bodies	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.	
				Randomised Controlled Trial	Cuskelly GJ, McNulty H & Scott, JM (1996) Effect of increasing dietary folate on red-cel folate: implications for prevention of neural tube defects. The Lancet 347, 657-659.	
					MRC Vitamin Study Research Group (1991) Prevention of neural tube defects: results of the Medical Research Council Vitamin Study. The Lancet, 338, 131-7.	
				Longitudinal Observational Study	Smith AM, Picciano MF & Deering RH (1985) Folate intake and blood concentrations of term infants. Am J Clin Nutr 41; 590-598.	
				studies	Czeizel AE. Periconceptional folic acid containing multivitamin supplementation. Eur J Obstet Gynecol Reprod Biol 1998;78:151-61. Czeizel AE. Primary prevention of neural-tube defects and some other major congenital abnormalities. Paediatr Drugs 2000;2(6):437-49.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Folate/Folic acid					
		Homocysteine metabolism	Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC			886

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative Body Vitamins and Minerals Expert Group Report International Scientific Body Textbook Meta-Analysis Review Randomised Controlled Trial Observational Cohort Study Randomised controlled Trial	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 Expert Group on Vitamins and Minerals (May 2003) Safe Upper Levels for Vitamins and Minerals. (http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf) WHO Technical Report Series: Diet, Nutrition and the prevention of chronic diseases; Report of a joint WHO/FAO Expert Consultation (2003). Gibney MJ et al (2002) Introduction to human nutrition. Blackwell Publishing, Oxford, p 160-6. Homocysteine Lowering Trialists' Collaboration (2005) Dose-dependent effects of folic acid on blood concentrations of homocysteine: a meta-analysis of the randomized trials. Am J Clin Nutr 82; 806-812. Klerk M et al (2002) MTHFR 677C-->T polymorphism and risk of coronary heart disease: a meta-analysis. JAMA 288; 2023-2031. Verhoef P & de Groot LC (2005) Dietary determinants of plasma homocysteine concentrations. Semin Vasc Med 5; 110-123. Appel LJ et al (2000) Effect of dietary patterns on serum homocysteine. Results of a randomized, controlled feeding study. Circulation 102; 852-857. Brevik A et al (2005) Plasma concentration of	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					folate as a biomarker for the intake of fruit and vegetables: the Hordaland Homocysteine Study. Am J Clin Nutr 81, 434-439. Broekmans WMR et al (2000) Fruits and vegetables increase plasma carotenoids and vitamins and decrease homocysteine in humans. J Nutr 130, 1578-83.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Controlled, parallel intervention study Randomised controlled Trial Randomised Controlled trial Cross-Sectional Observational Population based study Prospective population based study Cross sectional observational study Review	Brouwer IA et al (1999) Dietary folate from vegetables and citrus fruit decreases plasma homocysteine concentrations in humans in a dietary controlled trial. J Nutr 129; 1135-1139. Brouwer IA et al (1999) Low-dose folic acid supplementation decreases plasma homocysteine concentrations: a randomized trial. Am J Clin Nutr 69 99-104. Brouwer IA et al (1999a) Dietary folate from vegetables: a randomized trial. Am J Clin Nutr 69, 99-104. Brussaard JH et al (1997) Folate intake and status among adults in the Netherlands. Eur J Clin Nutr 51, S46-S50. Durga J et al (2005) Low concentrations of folate, not hyperhomocysteinemia, are associated with carotid intima-media thickness. Atherosclerosis 179; 285-292. Ganji V & Kafai MR (2004) Frequent consumption of milk, yogurt, cold breakfast cereals, peppers and cruciferous vegetables and intakes of dietary folate and riboflavin but not vitamins B-12 and B-6 are inversely associated with serum total homocysteine concentrations in the US population. Am J Clin Nutr 80, 1500-1507. Gao X et al (2003) Dietary pattern is associated with homocysteine and B vitamin status in an urban Chinese population. J Nutr 133; 3636-3642. Hankey GJ & Eikelboom JW (1999) Homocysteine and vascular disease. Lancet 354, 407-413.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Cross-over intervention study Randomised, controlled trial Review Cross sectional & analytical study	Picciano MF et al (2004) Effect of cow milk on food folate bioavailability in young women. Am J Clin Nutr 80, 1565-1569. Van Oort FV et al (2003) Folic acid and reduction of plasma homocysteine concentrations in older adults: a dose-response study. Am J Clin Nutr 77; 1318-1323. Bioavailabilty and dairy folate Forssen KM et al (2000) Folates and dairy products: a critical update. J Am Coll Nutr 19; 100S-110S. Gregory JF (1997) Bioavailability of folate. Eur J Clin Nutr 51, S54-S59. Konings EJ et al (2001) Folate intake of the Dutch population according to newly established liquid chromatography data for foods. Am J Clin Nutr 73; 765-776. Picciano MF et al (2004) Effect of cow milk on food folate bioavailability in young women. Am J Clin Nutr 80; 1565-1569.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				JHCI	JHCI, Final technical report http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf	
				IOM DRV report	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 2000.	
				SCF report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Folate. October 2000. http://www.europa.eu.int/comm/food/fs/sc/scf/out80e_en.pdf	
				EVM report		
				COMA report	Review of Folic Acid. Expert Group on Vitamins and Minerals. August 2002. http://www.food.gov.uk/multimedia/pdfs/evm0018p.pdf	
				Nutrition Text book	Folic Acid and the Prevention of Disease. Report of the Committee on Medical Aspects of Food and Nutrition Policy. Report on Health and Social Subjects No. 50. DH: The Stationery Office, 2000.	
				Nutrition text book		
				Nutrition text book	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999	
					Human Nutrition and Dietetics. 10th edition. JS Garrow, WPT James, A Ralph. Churchill Livingstone 2000.	
					Gibney MJ et al (2002) Introduction to human	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					nutrition. Blackwell Publishing, Oxford, p 160-6	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Folic Acid					
		The role of water-soluble vitamins in energy metabolism / transformation of food into physiological energy	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006.	textbook	Institute of Medicine (1998) Folate In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 8, pp 196-305 Herbert, V. (1999) Folic acid In Shils, M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 433-446 Brody, T. and Shane, B. (2001) Folic acid In Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 12, pp 427-462 Bailey, L.B.; Moyers, S. and Gregory, J.F. III (2001) Folate In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 21, pp 214-229 5) Driskell, J. A. (1999a) Vitamins, in Sports Nutrition, pp 49-83, Wolinsky I. ed, CRC Press	1,160
		Vitamin/mineral supplementation to reduce fatigue and tirednes in situations of inadequate micronutrient status	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006.			1,169

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook	Institute of Medicine (1998) Folate In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 8, pp 196-305 Herbert, V. (1999) Folic acid In Shils, M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 433-446 Brody, T. and Shane, B. (2001) Folic acid In Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 12, pp 427-462 Bailey, L.B.; Moyers, S. and Gregory, J.F. III (2001) Folate In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 21, pp 214-229 Driskell, J. A. (1999a) Vitamins, in Sports Nutrition, pp 49-83, Wolinsky I. ed, CRC Press	
		Cognitive Health	Inclusion of Folic Acid in a healthy diet Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation			903

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			1924/2006.	Review Epidemiological Study Prospective Study	Selhub, J, Bagley, LC, Millar, J and Rosenberg, IH. B vitamins, homocysteine, and neurocognitive function in the elderly. The American Journal of Clinical Nutrition 71 (supplement): 614S – 620S (2000) Choumenkovitch, SF, Jacques, PF, Nadeau, MR, Wilson, PWF, Rosenberg, IH and Selhub, J. Folic Acid Fortification Increases Red Blood Cell Folate Concentrations in the Framingham Study. The Journal of Nutrition, 131: 3277-3280 (2001) Lindeman, RD, Romero, LJ, Koehler, KM, Liang, HC, La Rue, A, Baumgartner, RN and Garry, PJ. Serum vitamin B12, C and folate concentrations in the New Mexico elder health survey: correlations with cognitive and affective functions. Journal of the American College of Nutrition, 19(1): 68- 76 (2000)	
		Eye health, folic acid with vitamin E and C	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.	Study, Nurses Health Cohort Study	*Taylor A. et al. Am J Clin Nutr 75 (3) 540-9 (2002):Long term intake of vitamins and cartenoids and odds of early age-related cortical and posterior subcapsular lens opacities; * Stocker et al. Biochim Biophys Acta 1621 (1) 1-8 (2003):ESR study of biological assay on whole blood:antioxidant efficacy of various vitamins;	630
		The role of vitamins and minerals in immunity	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.			1,219

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook, studies	Courtemanche C, Huang AC, Elson-Schwab I, Kerry N, Ng BY, Ames BN: Folate deficiency and ionizing radiation cause DNA breaks in primary human lymphocytes: a comparison. FASEB J 2004a;18:209-232 Courtemanche C, Elson-Schwab I, Mashiyama ST, Kerry N, Ames BN: Folated deficiency inhibits the proliferation of primary human CD8+ T lymphocytes in vitro. J Immunol 2004b;173:3186-3192. Dietary Reference Intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin, and choline. A report of the Panel on Folate, other B Vitamins, and Choline, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes; Food and Nutrition Board, Institute of Medicine, National Academy Press, Washington, D.C., 1998; chapter 8: Folate, pp 196-305 Dhur A, Galan P, Hercberg S: Folate status and the immune system. Progr Food Nutr Sci 1991;15:43-60 5) Field CJ, Johnson IR, Schley PD: Nutrients and their role to host resistance to infection. J Leukoc Biol 2002;71:16-32.	
		Eye health	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.			629

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Studies	Cahill-M-T et a. Am-J-Ophthalmol Vol. 136/6; 1136 - 1150 (2003):Meta-analysis of homocysteine, serun folate, serum vitamin B12 and thermolabile MTHFR genotype as risk facots for retinal vascular occlusive disease; * Looker HC et al. Diabetologia 46(6) 2003:Homocysteine asa risk factor for nephropathy and retinopathy in type ii diabetes; * Kamburoglu G. et al. Graefes Arch Clin Exp Ophthalmol 244 (5) 565-569 (2006):Plasma homocysteine, vitamin B12 and folate levels in age related macular degeneration;	
		Metabolism	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.	Studies	* Stocker et al. Biochim Biophys Acta 1621 (1) 1-8 (2003) :ESR study of biological assay on whole blood:antioxidant efficacy of various vitamins;	628
		Vitamins and minerals during pregnancy and lactation	Only for combinations with at least 14 mg Iron and 400 µg Folic Acid Agency guidance for supplements is that products containing >20 mg of Iron should carry the label advisory statement "[This amount of Iron] may cause mild stomach upset in sensitive individuals"			1,234

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				studies	"Blot I, Diallo D, Tchernia G. Iron deficiency in pregnancy: effects on the newborn. Curr Opin Hematol 1999; 6: 65-70. Bothwell TH. Iron requirements in pregnancy and strategies to meet them. Am J Clin Nutr 2000; 72 (suppl): 257 S-264S. Bruinse HW, Van den Berg H. Changes of some vitamin levels during and after normal pregnancy. Europ J Obst Gyn Repr Biol 1995; 61: 31-37. Dhur A, Hercberg S. Prevalence of iron deficiency in France and Southern Europe. In ""Nutrition in the prevention of disease"". Somogyi JC, Hejda S, Eds., Bibl Nutr Dieta, Karger Publ, Basel 1989; 44: 106-113. Ek J, Magnus EM. Plasma and red blood cell folate during normal pregnancies. Acta Obstet Gynecol Scand 1981, 60: 247-251. Hallberg L, Hultén L. Iron requirements, iron balance and iron deficiency in menstruating and pregnant women. In: Hallberg L, Asp N-G, eds. Iron nutrition in health and disease. London: John Libby, 1996: 165-182. Halliday HL, McMaster D. Does iron supplementation reduce zinc bioavailability in preterm infants? In ""Vitamins and minerals in pregnancy and lactation."" Berger H. Ed., Nestlé Nutrition Workshop series, Raven Press, N.Y. 1988; 16: 411. Haste FM, Anderson HR, Brooke OG, Bland JM, Peacock JL. The effects of smoking and drinking on the anthropometric measurements	

of neonates. Paediatr Perinat Epidemiol 1991a; 5: 83-92.

Haste FM, Brooke OG, Anderson HR, Bland JM. The effect of nutritional intake on outcome of pregnancy in smokers and non-smokers. Br J Nutr 1991b; 65: 347-354.

Hindmarsh PC, Geary MPP, Rodeck CH, Jackson MR and Kingdom JCP. Effect of early maternal iron stores on placental weight and structure. The Lancet 2000; 356: 719-723.

Kadyrov M, Kosanke G, Kingdom J, Kaufmann P. Increased fetoplacental angiogenesis during first trimester in anaemic women. Lancet 1998; 352:1747-1749.

Kilpatrick S., Laros R. Maternal Hematologic Disorders in Maternal-Fetal Medicine; Principle and Practice. Eds. Creasy R., Resnik R. Saunders 975-1004. 2004.

Mahomed K. Iron and folate supplementation in pregnancy. Cochrane Database Syst Rev. 2000;(2):CD001135.

Mahomed K. Folate supplementation in pregnancy. Cochrane Database Syst Rev. 2000;(2):CD000183.
Mahomed K. Iron supplementation in pregnancy. Cochrane Database Syst Rev. 2000;(2):CD000117.

Martinez O, Roe DA. Effect of oral contraceptives on blood folate levels in pregnancy. Am J Obstet Gynecol 1977; 128: 255-261.

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Mc Ganity WJ, Dawson EB, Fogelman A. Nutrition in pregnancy and lactation. In “Modern nutrition in health and disease”. Shils ME, Olson JA, Shike M. Eds, Lea and Febiger, Philadelphia 1994: 705-727. Milman N, Bergholt T, Byg K-E, Eriksen L, Graudal N. Iron status and iron balance during pregnancy. A critical reappraisal of iron supplementation. Acta Obstet Gynecol Scand 1999; 78(9): 749-757. Pena-Rosas JP, Viteri FE. Effects of routine oral iron supplementation with or without folic acid for women during pregnancy.Cochrane Database Syst Rev. 2006 Jul 19;3:CD004736 Rolschau I, Date I, Kristoffersen K. Folic acid supplementation and intrauterine growth. Acta Obstet Gynecol Scand 1979; 58: 343-346.	
		The role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)	Only for products with at least 100 % RDA of vitamins			1,190

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook	1) Institute of Medicine (1998) Folate In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 8, pp 196-305 3) Herbert, V. (1999) Folic acid In Shils, M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 433-446 4) Brody, T. and Shane, B. (2001) Folic acid In Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 12, pp 427-462 5) Bailey, L.B.; Moyers, S. and Gregory, J.F. III (2001) Folate In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 21, pp 214-229 6) Haller, J. (2005) Vitamins and Brain Function. In: Lieberman, H.R.; Kanarek, R.B. and Prasad, C. (eds.) Nutritional Neuroscience. CRC Press, Boca Raton, 207-233	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				studies	Heseker, H.; Kübler, W.; Pudel, V. and Westenhöfer, J (1995) Interaction of vitamins with mental performance. Bibl Nutr Dieta. Basel: Karger 52, 43-55 Carroll, D.; Ring, C.; Suter, M. and Willemsen, G. (2000) The effects of an oral multivitamin combination with calcium, magnesium, and zinc on psychological well-being in healthy young male volunteers: a double-blind placebo-controlled trial. Psychopharmacology (Berl) 150(2), 220-225 Benton, D.; Fordy, J. and Haller, J. (1995a) The impact of long-term vitamin supplementation on cognitive functioning. Psychopharmacol. 117(3), 298-305 Benton, D.; Haller, J. and Fordy, J. (1995a) Vitamin supplementation for 1 year improves mood. Neuropsychobiology 3, 98-105	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Folic acid, vitamins B12, B6					
		Homocysteine metabolism	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >10 mg of vitamin B6 should carry the label advisory statement "Long term intakes [of this amount of vitamin B6] may lead to mild tingling and numbness"	Meta-analysis	Homocysteine lowering trialists' collaboration (2005) Dose-dependent effects of folic acid on blood concentrations of homocysteine: a meta-analysis of the randomized trials. American Journal of Clinical Nutrition, 82:802-12	1,570

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Niacin					
		NAD and NADP. These nucleotides are key components of oxidation-reduction reactions, ATP synthetic pathways and ADP-ribose transfer reactions.	9.5mg/day (equal to 50% of ADI (Acceptable Daily Intake) Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >20 mg of nicotinic acidb should carry the label advisory statement "[This amount of nictinic acid] may cause skin flushes in sensitive individuals"	Textbook	Dietetics. Churchill Livingstone, 2000. Nordic Nutrition Recommendations (NNR) -Integrating nutrition and physical activity. Nordic Council of Ministers, Norden, 2004. Shils ME, Olson JA, Shike M, Ross AC. Modern Nutrition in Health and Disease. Lippincott Williams & Wilkins, 1999	1,805
		Structure and function of skin	The product must contain at least 15% of the RDA Agency guidance for supplements is that products containing >20 mg of Nicotinic acid should carry the label advisory statement "[This amount of			2,337

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			Nicotinic acid]* may cause skin flushes in sensitive individuals"	IOM DRV Expert Report	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 2000	
				Encyclopaedia of Human Nutrition	Encyclopaedia of Human Nutrition 2E. Editor-in-chief Michele J. Sadler, editors J.J. Strain, Benjamin Caballero. San Diego: Academic Press c.1999	
				SCF Expert Opinion	Opinion of the Scientific Committee of Food (SCF) on the Tolerable Upper Intake Levels of Nicotinic Acid (Niacin), April 2002 (http://www.europa.eu.int/comm/food/fs/sc/scf/out80j_en.pdf).	
				EVM Expert Report	Review of Niacin – Revised Version; Expert Group on Vitamins and Minerals, August 2002 (http://www.food.gov.uk/multimedia/pdfs/evm-01-11r.pdf).	
		"The role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)"	Only for products with at least 100 % RDA of vitamins Agency guidance for supplements is that products containing >20 mg of nicotinic acid should carry the label advisory statement "[This amount of nicotinic acid] may case skin flushes in sensitive individuals"			1,184

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook	1) Institute of Medicine (1998) Niacin In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 6, pp 123-149 3) Cervantes-Laurean, D.; McElvaney, N.G. and Moss, J. (1999) Niacin. In Shils, M.E., Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 401-411 4) Kirkland, J.B. and Rawling, J.M. (2001) Niacin In Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 6, pp 213-254 5) 6) Haller, J. (2005) Vitamins and Brain Function. In: Lieberman, H.R.; Kanarek, R.B. and Prasad, C. (eds.) Nutritional Neuroscience. CRC Press, Boca Raton, 207-233	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				studies	Heseker, H.; Kübler, W.; Pudel, V. and Westenhöfer, J (1995) Interaction of vitamins with mental performance. Bibl Nutr Dieta. Basel: Karger 52, 43-55 Carroll, D.; Ring, C.; Suter, M. and Willemsen, G. (2000) The effects of an oral multivitamin combination with calcium, magnesium, and zinc on psychological well-being in healthy young male volunteers: a double-blind placebo-controlled trial. Psychopharmacology (Berl) 150(2), 220-225 Benton, D.; Fordy, J. and Haller, J. (1995a) The impact of long-term vitamin supplementation on cognitive functioning. Psychopharmacol. 117(3), 298-305 Benton, D.; Haller, J. and Fordy, J. (1995a) Vitamin supplementation for 1 year improves mood. Neuropsychobiology 3, 98-105	
		Macronutrient metabolism	Source of 15% of RDA Agency guidance for supplements is that products containing >20mg nicotinic acid should carry the label advisory statement "this amount of nicotinic acid may cause skin flushes in sensitive individuals"	Authoritive guidelines	Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13	750
		Vitamin/mineral supplementation to reduce fatigue and tirednes in situations of	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of			1,163

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		inadequate micronutrient status	mineral/s]," as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >20 mg of nicotinic acid should carry the label advisory statement "This amount of Nicotinic acid] * may cause skin flushes in sensitive individuals"	textbook; studies	Institute of Medicine (1998) Dietary reference intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin and choline. Institute of medicine. National Academic Press, Washington D.C. Driskell, J. A. (1999a) Vitamins, in Sports Nutrition, pp 49-83, Wolinsky I. ed, CRC Press Marcus, R. and Coulston, A.M. (1996b) Water-soluble vitamins. In: Hardman, J.G.; Limbird, L.E.; Molinoff, P.B.; Ruddon, R.W. and Goodman Gilman, A. eds. Goodman and Gilman's: The pharmacological basis of therapeutics, ninth edition. McGraw-Hill Inc., pp 1555-1572 Depeint, F.; Bruce, W.R.; Shangari, N.; Mehta, R. and O'Brien, P.J. (2006a) Mitochondrial function and toxicity: role of the B-vitamin family on mitochondrial energy metabolism. Chemico-Biol. Inter. (in press) Lukaski, H.C. (2004) Vitamin and mineral status: effects on physical performance. Nutrition 20, 632-644	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Niacin (nicotinic acid)					
		Blood lipids	Adults: Typical starting dose = 10-100 mg three times daily, which can be increased to 1000 mg three times daily, or to tolerance. There is no evidence that low doses (<50 mg daily) have a significant effect on controlling blood lipid levels. Sustained-release formulations of niacin exhibit a significantly lower rate of adverse reactions (notably cutaneous flushing) at equivalent dosages compared with immediate-release forms. Label warning should include: “Product should be taken with food and used under the supervision of a qualified healthcare provider. Some individuals may experience minor adverse reactions such as cutaneous flushing or gastrointestinal upset on starting supplementation with niacin at such doses, but tolerance in	RCTs (low-dose niacin)	Wink J, Giacoppe G, King J. Effect of very-low-dose niacin on high-density lipoprotein in patients undergoing long-term statin therapy. Am Heart J. 2002;143(3):514-8.	1,090
				Meta-analysis (high-dose niacin)	Goldberg, A. C. A meta-analysis of randomized controlled studies on the effects of extended-release niacin in women. Am.J Cardiol. 7-1-2004;94(1):121-124.	
				Systematic review (high dose niacin)	Schectman, G. and Hiatt, J. Dose-response characteristics of cholesterol-lowering drug therapies: implications for treatment. Ann Intern Med 1996; 125(12): 990-1000.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			most is acquired after 1-2 weeks of supplementation." Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >20 mg nicotinic acid should carry the label advisory statement "this amount of nicotinic acid may cause skin flushes in sensitive individuals"	RCTs (high dose niacin)	Elam, M. B., Hunninghake, D. B., Davis, K. B., Garg, R., Johnson, C., Egan, D., Kostis, J. B., Sheps, D. S., and Brinton, E. A. Effect of niacin on lipid and lipoprotein levels and glycemic control in patients with diabetes and peripheral arterial disease: the ADMIT study: A randomized trial. Arterial Disease Multiple Intervention Trial. JAMA 9-13-2000;284(10):1263-1270. Keenan, J. M., Fontaine, P. L., Wenz, J. B., Myers, S., Huang, Z. Q., and Ripsin, C. M. Niacin revisited. A randomized, controlled trial of wax-matrix sustained-release niacin in hypercholesterolemia. Arch Intern Med 1991;151(7):1424-1432. Aronov, D. M., Keenan, J. M., Akhmedzhanov, N. M., Perova, N. V., Oganov, R. Y., and Kiseleva, N. Y. Clinical trial of wax-matrix sustained-release niacin in a Russian population with hypercholesterolemia. Arch Fam.Med 1996;5(10):567-575. Morgan, J. M., Capuzzi, D. M., Guyton, J. R., Centor, R. M., Goldberg, R., Robbins, D. C., DiPette, D., Jenkins, S., and Marcovina, S. Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial. J Cardiovasc.Pharmacol Ther 1996;1(3):195-202. Davignon, J., Roederer, G., Montigny, M., Hayden, M. R., Tan, M. H., Connelly, P. W., Hegele, R., McPherson, R., Lupien, P. J., Gagne, C., and . Comparative efficacy and safety of pravastatin, nicotinic acid and the two combined in patients with hypercholesterolemia. Am J Cardiol 2-15-1994;73(5):339-345. View Abstract Hunninghake, D. B., McGovern, M. E., Koren,	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					M., Brazg, R., Murdock, D., Weiss, S., and Pearson, T. A dose-ranging study of a new, once-daily, dual-component drug product containing niacin extended-release and lovastatin. Clin.Cardiol. 2003;26(3):112-118. Goldberg, A. C. Clinical trial experience with extended-release niacin (Niaspan): dose-escalation study. Am J Cardiol 12-17-1998;82(12A):35U-38U. Goldberg, A., Alagona, P., Jr., Capuzzi, D. M., Guyton, J., Morgan, J. M., Rodgers, J., Sachson, R., and Samuel, P. Multiple-dose efficacy and safety of an extended-release form of niacin in the management of hyperlipidemia. Am J Cardiol 5-1-2000;85(9):1100-1105. Vacek, J. L., Dittmeier, G., Chiarelli, T., White, J., and Bell, H. H. Comparison of lovastatin (20 mg) and nicotinic acid (1.2 g) with either drug alone for type II hyperlipoproteinemia. Am J Cardiol 7-15-1995;76(3):182-184.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Niacin (Vitamin B3)					
		Neurological systems	Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC Agency guidance for supplements is that products containing >20 mg of Nicotinic acid should carry the label advisory statement "This amount of Nicotinic acid] * may cause skin flushes in sensitive individuals"	JHCI IOM DRV report SCF report EVM report Nutrition Text book	JHCI, Final technical report http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf 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 2000. Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Levels of Nicotinic Acid and Nicotinamide (Niacin) April 2002. http://www.europa.eu.int/comm/food/fs/sc/scf/out80j_en.pdf Review of Niacin – Revised Version. Expert Group on Vitamins and Minerals. August 2002. http://www.food.gov.uk/multimedia/pdfs/evm-01-11r.pdf Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	2,387
		Skin and mucous membranes	Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC Agency guidance for supplements is that products containing >20			2,386

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			mg of Nicotinic acid should carry the label advisory statement "This amount of Nicotinic acid] * may cause skin flushes in sensitive individuals"	JHCI IOM DRV report SCF report EVM report Nutrition Text book	JHCI, Final technical report http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf 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 2000. Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Levels of Nicotinic Acid and Nicotinamide (Niacin) April 2002. http://www.europa.eu.int/comm/food/fs/sc/scf/out80j_en.pdf Review of Niacin – Revised Version. Expert Group on Vitamins and Minerals. August 2002. http://www.food.gov.uk/multimedia/pdfs/evm-01-11r.pdf Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego: Academic Press, c1999.	
	Nicotinamide (Niacin)					
		Energy metabolism Neurological system	Minimum 15% RDA per daily dosage as per 90/496/EC .	Authoritative Body	Safe upper levels for vitamins and minerals. Expert Group on Vitamins and Minerals. May 2003 (http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf)	1,117

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Panthothenic acid					
		Metabolism of fat	The product must contain at least 15% of the RDA Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.	IOM DRV Expert Report Encyclopaedia of Human Nutrition SCF Expert Opinion EVM Expert Report	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 2000 Encyclopaedia of Human Nutrition 2E. Editor-in-chief Michele J. Sadler, editors J.J. Strain, Benjamin Caballero. San Diego: Academic Press c.1999 Opinion of the Scientific Committee of Food (SCF) on the Tolerable Upper Intake Levels of Panthothenic Acid, April 2002 (http://www.europa.eu.int/comm/food/fs/sc/scf/out80k_en.pdf). Review of Panthothenic Acid; Expert Group on Vitamins and Minerals, August 2002 (http://www.food.gov.uk/multimedia/pdfs/panto.pdf).	2,338

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Pantothenic Acid					
		The role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)	Only for products with at least 100 % RDA of vitamins	textbook	1) Institute of Medicine (1998) Pantothenic Acid In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 10, pp 357-373 3) 8649.Plesofsky-Vig, N. (1999) Pantothenic acid In Shils, M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 423-432 4) Plesofsky N.S. (2001) Pantothenic Acid In Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 9, pp 317-337 5) Miller, J.W.; Rogers, L.M. and Rucker, R.B. (2001) Panthotenic Acid In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 24, pp 253-260	1,188
				Studies	Carroll, D.; Ring, C.; Suter, M. and Willemsen, G. (2000) The effects of an oral multivitamin combination with calcium, magnesium, and zinc on psychological well-being in healthy young male volunteers: a double-blind placebo-controlled trial. Psychopharmacology (Berl) 150(2), 220-225	
		Vitamin/mineral supplementation to reduce fatigue and tirednes in situations of	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of			1,167

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		inadequate micronutrient status	mineral/s]," as per Annex to Regulation 1924/2006.	textbook	Institute of Medicine (1998) Dietary reference intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin and choline. Institute of medicine. National Academic Press, Washington D.C. Driskell, J. A. (1999a) Vitamins, in Sports Nutrition, pp 49-83, Wolinsky I. ed, CRC Press Marcus, R. and Coulston, A.M. (1996b) Water-soluble vitamins. In: Hardman, J.G.; Limbird, L.E.; Molinoff, P.B.; Ruddon, R.W. and Goodman Gilman, A. eds. Goodman and Gilman's: The pharmacological basis of therapeutics, ninth edition. McGraw-Hill Inc., pp 1555-1572 Depeint, F.; Bruce, W.R.; Shangari, N.; Mehta, R. and O'Brien, P.J. (2006a) Mitochondrial function and toxicity: role of the B-vitamin family on mitochondrial energy metabolism. Chemico-Biol. Inter. (in press)	
		Macronutrient metabolism	Source of 15% of RDA per 100g	Authoritive guidelines	Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13	751
		Carbohydrate and amino-acid metabolism	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.	Textbook	Biesalski et al. 'Vitamins', 1997	1,565

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Pantothenic acid (B-5)					
		Adrenal function	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.	Animal study Review	Tarasov IuA, She bak VM, Mo seenok AG. Adrenal cortex functional activity in pantohtenate deficiency and the administration of the vitamin or it's derivatives. Vopr Pitan.1985 Jul-Aug; (4):51-4. Wirtschafter ZT, Walsh JR. Adrenocorticol alterations induced by deficiency and excess of pantothenic acid. Endocrinology. 1963 May;72:725-34. Hurley LS, MacKenzie JB. Adrenal function in the pantothenic acid defcient rat; liver glycogen, blood glucose, adrenal cholesterol and adrenal ascorbic acid levels. J Nutr.1954 Nov 10;54(3):403-15. Perry WF, Hawkins WW, Cumming GR. Adrenal function in pantothenic acid deficiency. Am J Physiol.1953 Feb; 172(2):259-64.	1,077

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Pyridoxine (B6)					
		Vitamin/mineral supplementation to reduce fatigue and tirednes in situations of inadequate micronutrient status	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >10 mg of Vitamin B6 should carry the label advisory statement "'Long term intakes [of this amount of vitamin B6]* may lead to mild tingling and numbness"	textbook; studies	Institute of Medicine (1998) Dietary reference intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin and choline. Institute of medicine. National Academic Press, Washington D.C. Driskell, J. A. (1999a) Vitamins, in Sports Nutrition, pp 49-83, Wolinsky I. ed, CRC Press Marcus, R. and Coulston, A.M. (1996b) Water-soluble vitamins. In: Hardman, J.G.; Limbird, L.E.; Molinoff, P.B.; Ruddon, R.W. and Goodman Gilman, A. eds. Goodman and Gilman's: The pharmacological basis of therapeutics, ninth edition. McGraw-Hill Inc., pp 1555-1572 Depeint, F.; Bruce, W.R.; Shangari, N.; Mehta, R. and O'Brien, P.J. (2006b) Mitochondrial function and toxicity: role of B vitamins on the one-carbon transfer pathways. Chemico-Biol. Inter. (in press) Lukaski, H.C. (2004) Vitamin and mineral status: effects on physical performance. Nutrition 20, 632-644 Manore, M.M. (2000) Effects of physical activity on thiamine, riboflavine, and vitamin B-6 requirements. Am. J. Clin. Nutr. 72 (suppl), 598S-606S	1,164
		The role of vitamins and minerals in mental performance (where mental	Only for products with at least 100 % RDA of vitamins Agency guidance for			1,185

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)	supplements is that products containing >10 mg of vitamin B6 should carry the label advisory statement "Long term intakes [of this amount of vitamin B6] may lead to mild tingling and numbness"	textbook	1) Institute of Medicine (1998) Vitamin B6 In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 7, pp 150-195 3) Leklem, J.E. (1999) Vitamin B6 In: Shils, M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 413-421 4) Leklem, J.E. (2001) Vitamin B6 in Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 10, pp 339-396 5) McCormick, D.B. (2001) Vitamin B-6 In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 20, pp 207-213 6) Haller, J. (2005) Vitamins and Brain Function. In: Lieberman, H.R.; Kanarek, R.B. and Prasad, C. (eds.) Nutritional Neuroscience. CRC Press, Boca Raton, 207-233	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				studies	Heseker, H.; Kübler, W.; Pudel, V. and Westenhöfer, J (1995) Interaction of vitamins with mental performance. Bibl Nutr Dieta. Basel: Karger 52, 43-55 Carroll, D.; Ring, C.; Suter, M. and Willemsen, G. (2000) The effects of an oral multivitamin combination with calcium, magnesium, and zinc on psychological well-being in healthy young male volunteers: a double-blind placebo-controlled trial. Psychopharmacology (Berl) 150(2), 220-225 Benton, D.; Fordy, J. and Haller, J. (1995a) The impact of long-term vitamin supplementation on cognitive functioning. Psychopharmacol. 117(3), 298-305 Benton, D.; Haller, J. and Fordy, J. (1995a) Vitamin supplementation for 1 year improves mood. Neuropsychobiology 3, 98-105	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Riboflavin					
		Riboflavin participates in oxidation-reduction reactions in numerous metabolic pathways and in energy production via respiratory chain	0.85mg/day (equal to 50% of ADI (Acceptable Daily Intake Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.	Textbook Textbook Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Churchill Livingstone, 2000. Nordic Nutrition Recommendations (NNR) -Integrating nutrition and physical activity. Nordic Council of Ministers, Norden, 2004. Shils ME, Olson JA, Shike M, Ross AC. Modern Nutrition in Health and Disease. Lippincott Williams & Wilkins, 1999	1,876
		Antioxidant properties	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.	Textbook	Biesalski et al. 'Nutritional medicine', 2004	1,562

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Riboflavin (B2)					
		Vitamin/mineral supplementation to reduce fatigue and tirednes in situations of inadequate micronutrient status	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006.			1,162

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook; studies	Institute of Medicine (1998) Dietary reference intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin and choline. Institute of medicine. National Academic Press, Washington D.C. Driskell, J. A. (1999a) Vitamins, in Sports Nutrition, pp 49-83, Wolinsky I. ed, CRC Press Marcus, R. and Coulston, A.M. (1996b) Water-soluble vitamins. In: Hardman, J.G.; Limbird, L.E.; Molinoff, P.B.; Ruddon, R.W. and Goodman Gilman, A. eds. Goodman and Gilman's: The pharmacological basis of therapeutics, ninth edition. McGraw-Hill Inc., pp 1555-1572 Depeint, F.; Bruce, W.R.; Shangari, N.; Mehta, R. and O'Brien, P.J. (2006a) Mitochondrial function and toxicity: role of the B-vitamin family on mitochondrial energy metabolism. Chemico-Biol. Inter. (in press) Lukaski, H.C. (2004) Vitamin and mineral status: effects on physical performance. Nutrition 20, 632-644 Manore, M.M. (2000) Effects of physical activity on thiamine, riboflavine, and vitamin B-6 requirements. Am. J. Clin. Nutr. 72 (suppl), 598S-606S Belko, A.Z.; Obarzanek, E.; Kalkwarf, H.J.; Rotter, M.A.; Bogusz, S.; Miller, D.; Haas, J.D. and Roe, D.A. (1983) Effects of exercise on riboflavin requirements of young women. Am. J. Clin. Nutr. 37(4), 509-517 Winters, L.R.; Yoon, J.S.; Kalkwarf, H.J.;Davies, J.C.; Berkowitz, M.G.; Haas, J.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					and Roe, D.A. (1992) Riboflavin requirements and exercise adaptation in older women. Am. J. Clin. Nutr. 56(3), 526-532	
		"The role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning) "	Only for products with at least 100 % RDA of vitamins	textbook	1) Institute of Medicine (1998) Riboflavin In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 5, pp 87-122 3) McCormick, D.B. (1999) Riboflavin In Shils, M.E.; Olson, J.A.; Shike, M. and Ross, AC. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 391-399 4) RIvlin, R.S. and Pinto, J.T. (2001) Riboflavin (Vitamin B2) In Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 7, pp 255-273 5) Rivlin, R.S. (2001) Riboflavin In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 18, pp 191-198	1,183

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				studies	Haller, J. (2005) Vitamins and Brain Function. In: Lieberman, H.R.; Kanarek, R.B. and Prasad, C. (eds.) Nutritional Neuroscience. CRC Press, Boca Raton, 207-233 Heseker, H.; Kübler, W.; Pudel, V. and Westenhöfer, J (1995) Interaction of vitamins with mental performance. Bibl Nutr Dieta. Basel: Karger 52, 43-55 Carroll, D.; Ring, C.; Suter, M. and Willemsen, G. (2000) The effects of an oral multivitamin combination with calcium, magnesium, and zinc on psychological well-being in healthy young male volunteers: a double-blind placebo-controlled trial. Psychopharmacology (Berl) 150(2), 220-225 Benton, D.; Fordy, J. and Haller, J. (1995a) The impact of long-term vitamin supplementation on cognitive functioning. Psychopharmacol. 117(3), 298-305 Benton, D.; Haller, J. and Fordy, J. (1995a) Vitamin supplementation for 1 year improves mood. Neuropsychobiology 3, 98-105	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Riboflavin (Vitamin B2)					
		Fetal Growth	Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC	Authoritative Body	JHCI:http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf	887
		Healthy iron status	Source of 15% of RDA per 100g.	Authoritive guidelines. Scientific review.	Fishman SM. The role of vitamins in the prevention and control of anaemia. Public Health Nutrition. 2000 3(2):125-150.	753
		Energy metabolism Structure of mucous membranes Defence against oxidative stress (glutathione reductase)	Minimum 15% RDA per daily dosage as per 90/496/EC 0.85mg/day (equal to 50% of ADI (Acceptable Daily Intake)	Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Churchill Livingstone, 2000. Nordic Nutrition Recommendations (NNR) -Integrating nutrition and physical activity. Nordic Council of Ministers, Norden, 2004. Shils ME, Olson JA, Shike M, Ross AC. Modern Nutrition in Health and Disease. Lippincott Williams & Wilkins, 1999	1,114
		Red blood cells	Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC	Authoritative Body	JHCI:http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf	889
		Macronutrient metabolism	Source of 15% of RDA per 100g	Authoritive guidelines	Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13	752
		Eyes	Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC	Authoritative Body	JHCI:http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf	888

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Riboflavin (vitamin B2)					
		Release of energy from food	Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC	JHCI IOM DRV report SCF report Nutrition text book Nutrition text book	JHCI, Final technical report http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf 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 2000. Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B2. November 2000. http://www.europa.eu.int/comm/food/fs/sc/scf/out80i_en.pdf Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Human Nutrition and Dietetics. 10th edition. JS Garrow, WPT James, A Ralph. Churchill Livingstone 2000.	2,384

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Thiamin					
		Thiamin participates as a coenzyme in the carbohydrate metabolism	0,7mg/day (equal to 50% of ADI (Acceptable Daily Intake) The product must contain at least 15% of the RDA	Textbook Textbook Textbook IOM DRV Expert Report Encyclopaedia of Human Nutrition SCF Expert Opinion EVM Expert Report	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Churchill Livingstone, 2000. Nordic Nutrition Recommendations (NNR) -Integrating nutrition and physical activity. Nordic Council of Ministers, Norden, 2004. Shils ME, Olson JA, Shike M, Ross AC. Modern Nutrition in Health and Disease. Lippincott Williams & Wilkins, 1999. 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 2000 Encyclopaedia of Human Nutrition 2E. Editor-in-chief Michele J. Sadler, editors J.J. Strain, Benjamin Caballero. San Diego: Academic Press c.1999 Opinion of the Scientific Committee of Food (SCF) on the Tolerable Upper Intake Levels of Vitamin B1, July 2001 (http://www.europa.eu.int/comm/food/fs/sc/scf/out93_en.pdf). Revised Review of Thiamin; Expert Group on Vitamins and Minerals, August 2002 (http://www.food.gov.uk/multimedia/pdfs/evm0014p.pdf).	1,875
		Cardiac Function	The product must contain at least 15% of the RDA			2,340

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				IOM DRV Expert Report	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 2000	
				Encyclopaedia of Human Nutrition	Encyclopaedia of Human Nutrition 2E. Editor-in-chief Michele J. Sadler, editors J.J. Strain, Benjamin Caballero. San Diego: Academic Press c.1999	
				EVM Expert Report	Revised Review of Thiamin; Expert Group on Vitamins and Minerals, August 2002 (http://www.food.gov.uk/multimedia/pdfs/evm0014p.pdf).	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Thiamin (B1)					
		"The role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning) "	Only for products with at least 100 % RDA of vitamins x	textbook	1) Institute of Medicine (1998) Thiamin In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 4, pp 58-86 3) Tanphaichitr, V. (1999) Thiamin In Shils M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 381-389 4) Tanphaichitr, V. (2001) Thiamine In Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 8, pp 275-316 5) Bates, C.J. (2001) Thiamine In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 17, pp 184-190 6) Haller, J. (2005) Vitamins and Brain Function. In: Lieberman, H.R.; Kanarek, R.B. and Prasad, C. (eds.) Nutritional Neuroscience. CRC Press, Boca Raton, 207-233	1,182

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				studies	Heseker, H.; Kübler, W.; Pudel, V. and Westenhöfer, J (1995) Interaction of vitamins with mental performance. Bibl Nutr Dieta. Basel: Karger 52, 43-55 Carroll, D.; Ring, C.; Suter, M. and Willemsen, G. (2000) The effects of an oral multivitamin combination with calcium, magnesium, and zinc on psychological well-being in healthy young male volunteers: a double-blind placebo-controlled trial. Psychopharmacology (Berl) 150(2), 220-225 Benton, D.; Fordy, J. and Haller, J. (1995a) The impact of long-term vitamin supplementation on cognitive functioning. Psychopharmacol. 117(3), 298-305 Benton, D.; Haller, J. and Fordy, J. (1995a) Vitamin supplementation for 1 year improves mood. Neuropsychobiology 3, 98-105	
		Vitamin/mineral supplementation to reduce fatigue and tirednes in situations of inadequate micronutrient status	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006.			1,161

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook; studies	Institute of Medicine (1998) Dietary reference intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin and choline. Institute of medicine. National Academic Press, Washington D.C. Driskell, J. A. (1999a) Vitamins, in Sports Nutrition, pp 49-83, Wolinsky I. ed, CRC Press Marcus, R. and Coulston, A.M. (1996b) Water-soluble vitamins. In: Hardman, J.G.; Limbird, L.E.; Molinoff, P.B.; Ruddon, R.W. and Goodman Gilman, A. eds. Goodman and Gilman's: The pharmacological basis of therapeutics, ninth edition. McGraw-Hill Inc., pp 1555-1572 Depeint, F.; Bruce, W.R.; Shangari, N.; Mehta, R. and O'Brien, P.J. (2006a) Mitochondrial function and toxicity: role of the B-vitamin family on mitochondrial energy metabolism. Chemico-Biol. Inter. (in press) Lukaski, H.C. (2004) Vitamin and mineral status: effects on physical performance. Nutrition 20, 632-644 Manore, M.M. (2000) Effects of physical activity on thiamine, riboflavine, and vitamin B-6 requirements. Am. J. Clin. Nutr. 72 (suppl), 598S-606S	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Thiamin (vitamin B1)					
		Neurological and cardiac systems	Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC	JHCI	JHCI, Final technical report http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf	2,383
				IOM DRV report	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 2000.	
				SCF report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B1. July 2001. http://www.europa.eu.int/comm/food/fs/sc/scf/out93_en.pdf	
				EVM report	Revised Review of Thiamin. Expert Group on Vitamins and Minerals .August 2002. http://www.food.gov.uk/multimedia/pdfs/evm0014p.pdf	
				Nutrition text book	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				Nutrition text book	Human Nutrition and Dietetics. 10th edition. JS Garrow, WPT James, A Ralph. Churchill Livingstone 2000.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Thiamine (Vitamin B1)					
		Energy metabolism Carbohydrate metabolism Neurological system	Minimum 15% RDA per daily dosage as per 90/496/EC	Authoritative Body Textbook	Shils, Shike, et al. (2006). Modern Nutrition In Health and Disease. Baltimore, Philadelphia, Lippincott Williams & Williams.	1,113

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin A					
		Vision	MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006	Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000.	5
				Authoritative Body	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	
			Agency guidance for supplements is that Products containing beta-carotene should carry the label advisory statement: '[Beta-carotene] should not be taken by heavy smokers"	Authoritative Body	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	
			Beta-carotene can be converted to Vitamin A. Where beta-carotene is the main source the following statements could be preceded by: Beta-carotene can be converted to Vitamin A. Vitamin A is necessary for / contributes to	Authoritative Body	CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	
			15% RDA of vitamin A is equivalent to 720 micrograms beta-carotene Applicable to both children and adults	Authoritative Body	CEDAP. Avis de la commission interministerielle d'etude des produits destines a une alimentation particuliere (CEDAP) en date du 18 decembre 1996 sur les recommandations relatives au caractere non trompeur des seuils des allegations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Repression des fraudes) du 7 octobre 1997	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative Body	FNFC/FOSHU Japan http://www.mhlw.go.jp/english/topics/foodsafety/fhc/index.html	
				Authoritative Body	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	
				Textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Preformed Vitamin A (retinol and retinyl esters). September 2002.	
				EVM report	Revised Review of Vitamin A. Expert Group on Vitamins and Minerals. April 2002.	
				Textbook	Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002.	
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13 Vitamins In: Manual of Dietetic Practice 3rd Edition [Thomas B, editor] Blackwell Science, London.	
		Structure and function of the skin and mucous membranes (such as in the lung, intestines, nose, eyes and female reproductive tract)	MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006	Authoritative Body	CH - Switzerland - Ordonnance du March 1995 sur les dennrees 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	4
			Agency guidance for supplements is that Products containing beta-carotene should carry the label advisory statement: '[Beta-carotene] should not be taken by heavy smokers"	Authoritative Body	CEDAP. Avis de la commission interministerielle d'etude des produits destines a une alimentation particuliere (CEDAP) en date du 18 decembre 1996 sur les recommandations relatives au caractere non trompeur des seuils des allegations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Repression des fraudes) du 7 octobre 1997	
			Beta-carotene can be converted to Vitamin A. Where beta-carotene is the main source the following statements could be preceded by: Beta-carotene can be converted to Vitamin A. Vitamin A is necessary for / contributes to 15% RDA of vitamin A is equivalent to 720	Authoritative Body	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	
				Authoritative Body	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	
				Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			micrograms beta-carotene Applicable to both children and adults	Authoritative Body	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	
				Textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Preformed Vitamin A (retinol and retinyl esters). September 2002.	
				Evm report	Revised Review of Vitamin A. Expert Group on Vitamins and Minerals. April 2002.	
				Textbook	Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002.	
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				JHCI	Revised Review of Vitamin A. Expert Group on Vitamins and Minerals. April 2002.	
				EVM Report IOM DRV report	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.	
		Cell differentiation including immune system	MUST AT LEAST BE A SOURCE OF VITAMINS/S AS PER ANNEX TO REGULATION 1924/2006 15% RDA of vitamin A is equivalent to 720 micrograms beta-carotene Beta-carotene can be converted to Vitamin A. Where beta-carotene is the main source the following statements could be preceded by:Beta-carotene can be converted to Vitamin A. Vitamin A is necessary for / contributes to Agency guidance for supplements is that products containing beta-carotene should	Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000.	3
				Scientific Body	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	
				Authoritative Body	CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	
				Authoritative Body	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 JHCI, Final technical report by the Joint Health Claims Initiative to the Food Standards Agency, 2003 p27 and Annex 4.1 p73-74 http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			carry the label advisory statement: '[Beta-carotene] should not be taken by heavy smokers' Applicable to both children and adults	Scientific Body	WHO, Vitamin A supplementation http://www.who.int/vaccines/en/vitamina.shtml - issues	
				Reviews and Individual Studies	Cantorna et al. In vitamin A deficiency multiple mechanism establish a regulatory T helper cell imbalance with excess Th1 and insufficient Th2 function. J immunol. 1994 Feb;152 (4): 1515-22.	
				Reviews and Individual Studies	Chew BP et al. Carotenoid action to immune response. J Nutr. 2004; 134(1): 98-101.	
				Reviews and Individual Studies	Elitsur Y et al. Vitamin A and retinoic acids immunomodulation on human gut lymphocytes. Immunopharmacology. 1997 Jan; 35(3): 247-53.	
				Reviews and Individual Studies	Iwata M et al. Retinoic acids exert direct effects on T cells to suppress Thl development and enhance Th2 development via retinoic acid receptors. Int Immunol. 2003 Aug;15(8) :1017-25.	
				Reviews and Individual Studies	Semba RD. Vitamin A and immunity to viral, bacterial and protozoan infections. Proc Nutr Soc. 1999 Aug; 58 (3): 719-27	
				Textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				EVM report	Revised Review of Vitamin A. Expert Group on Vitamins and Minerals. April 2002.	
				Textbook	Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				SCF report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Preformed Vitamin A (retinol and retinyl esters). September 2002.	
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000.	
					Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002.	
					Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
					Villamor E & Fawzi WW. Effects of vitamin A supplementation on immune responses and correlation with clinical outcomes. Clin Microbiol Rev 2005 Jul;18(3):446-64.	
					Reifen R. Vitamin A as an anti-inflammatory agent. Proc Nutr Soc 2002 Aug;61(3):397-400. Stephensen CB. Vitamin A, infection, and immune function. Annu Rev Nutr;2001:167-92.	
				Vitamins and Minerals Expert Group Report	Expert Group on Vitamins and Minerals (May 2003) Safe Upper Levels for Vitamins and Minerals. (http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf)	
				Textbooks	Vitamins In: Manual of Dietetic Practice 3rd Edition [Thomas B, editor] Blackwell Science, London. Fat Soluble Vitamins In: Human Nutrition and Dietetics 10th edition. [Garrow JS, James WPT & Ralph A]. London, Churchill Livingstone	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook, studies	Field CJ, Johnson IR, Schley PD: Nutrients and their role to host resistance to infection. J Leukoc Biol 2002;71:16-32	
					Olson JA: Vitamin A, in Rucker RB, Suttie JW, McCormick DB, Machlin LJ (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 1, 2001, pp 1-50	
				JHCI	Revised Review of Vitamin A. Expert Group on Vitamins and Minerals. April 2002.	
				EVM Report	Institute of Medicine Dietary Reference Intakes for vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon,	
				IOM DRV report	vanadium and zinc. Washington D.C. National Academy Press, 2001.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Preformed Vitamin A (retinol and retinyl esters). September 2002.	
				Nutrition text book	Encyclopedia of Human Nutrition. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin	
				Nutrition text book	Caballero. San Diego : Academic Press, c1999.	
					Human Nutrition and Dietetics. 10th edition. JS Garrow, WPT James, A Ralph. Churchill Livingstone 2000.	
		Bone growth and development of teeth	MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO			2

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			REGULATION 1924/2006 Agency guidance for supplements is that products containing beta-carotene should carry the label advisory statement: '[Beta-carotene] should not be taken by heavy smokers" 15% RDA of vitamin A is equivalent to 720 micrograms beta-carotene .	Scientific Body	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	
				Authoritative Body Text Book	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	
				Textbooks	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
				Nutrition Textbook SCF Reports EVM Reports	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Metabolism of iron	Agency guidance for supplements is that products containing >7mg of Beta-carotene should carry the label advisory statement "'[Beta-carotene]* should not be taken by heavy smokers." Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.	Textbook	Biesalski et al. 'Vitamins', 1997	1,558
		Bone/Teeth/Hair/Skin and Nail health	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing beta-carotene should carry the label advisory statement "[Beta-carotene] should not be taken by heavy smokers."			959

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	
		Energy and Vitality	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing beta-carotene should carry the label advisory			960

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			statement "[Beta-carotene] should not be taken by heavy smokers."	OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	
		OXIDATIVE STRESS. Acts as antioxidant and helps protect the body tissues against the potentially damaging effects of free radicals.	Claim to be only used for Foods for sports people under the Dir. 89/398/EEC For athletes who have inadequate food intakes in particular. Condition for use: 2000 IU (600 mcg RE) retinol daily. Agency guidance for supplements is that products containing	textbook	Sports Nutrition by Jeukendrup A and Gleeson M, Chap 9, The micronutrients: vitamins and minerals, p199, 228, ed 2004.	1,596

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			>7mg of Beta-carotene should carry the label advisory statement "'[Beta-carotene]* should not be taken by heavy smokers." Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.			

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin B1					
		Macronutrient metabolism	Source of 15% of RDA per 100g	Authoritive guidelines	Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13	754
		Bone/Teeth/ Hair / Skin and Nail health	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006.	OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	961
		Energy and Vitality	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of			962

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			mineral/s}" as per Annex to Regulation 1924/2006.	OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin B1 (Thiamin)					
		Cardiac function	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults	Authoritative Body	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	14
				Scientific Body	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	
				Individual study	Bender DA. Optimum nutrition: thiamin, biotin and pantothenate. Proceedings of the Nutrition Society 1999;58:427-433.	
				Individual study	Blanc P. et al. Severe metabolic acidosis and heart failure due to thiamine deficiency. Nutrition 2002;18(1):118.	
				Individual study	Several specific metabolic deficiencies have been found in the failing myocardium: a reduction in L-carnitine, coenzyme Q10, creatine, and thiamine nutrient co-factors important for myorcardial energy production.	
				Individual study	Sole MJ. et al Conditioned nutritional requirements: Therapeutic relevance to heart failure. Herz 2002;27(2):174-178.	
				Nutrition Textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B1. July 2001. (http://www.europa.eu.int/comm/food/fs/sc/scf/out93_en.pdf).	
				EVM Report	Revised Review of Thiamin. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/evm0014p.pdf).	
				Nutrition Textbook	Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002.	
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Neurological function	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults	Authoritative Body	-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	15
				Authoritative Body	-CH - Switzerland - Ordonnance du March 1995 sur les dennrees 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	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				IOM DRV Report	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	
				Nutrition Textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B1. July 2001. (http://www.europa.eu.int/comm/food/fs/sc/scf/out93_en.pdf).	
				EVM Report	Revised Review of Thiamin. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/evm0014p.pdf).	
				Nutrition textbook	Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002.	
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Energy and Carbohydrate metabolism	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults 0,7mg/day (equal to 50% of ADI (Acceptable Daily Intake)	Authoritative Body	-CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	13
				Authoritative Body	-CEDAP. Avis de la commission interministerielle d'etude des produits destines a une alimentation particuliere (CEDAP) en date du 18 decembre 1996 sur les recommandations relatives au caractere non trompeur des seuils des allegations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Repression des fraudes) du 7 octobre 1997	
				Authoritative Body	-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	
				Authoritative Body	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	
				Authoritative Body	-FNFC/FOSHU Japan http://www.mhlw.go.jp/english/topics/foodsafety/fhc/index.html	
				IOM DRV Report	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 2000.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Nutrition Textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B1. July 2001. (http://www.europa.eu.int/comm/food/fs/sc/scf/out93_en.pdf).	
				EVM Report	Revised Review of Thiamin. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/evm0014p.pdf).	
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
				textbook and studies	BCC claim documentation existing	
				Textbook	Nordic Nutrition Recommendations (NNR) -Integrating nutrition and physical activity. Nordic Council of Ministers, Norden, 2004. Shils ME, Olson JA, Shike M, Ross AC. Modern Nutrition in Health and Disease. Lippincott Williams & Wilkins, 1999.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				JHCI	JHCI, Final technical report http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf	
				IOM DRV report	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 2000.	
				SCF report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B1. July 2001. http://www.europa.eu.int/comm/food/fs/sc/scf/out93_en.pdf	
				EVM report	Revised Review of Thiamin. Expert Group on Vitamins and Minerals .August 2002. http://www.food.gov.uk/multimedia/pdfs/evm0014p.pdf	
				Nutrition text book	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				Nutrition text book	Human Nutrition and Dietetics. 10th edition. JS Garrow, WPT James, A Ralph. Churchill Livingstone 2000.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin B12					
		The role of vitamins and minerals in immunity	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.	textbook, studies	Dietary Reference Intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin, and choline. A report of the Panel on Folate, other B Vitamins, and Choline, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes; Food and Nutrition Board, Institute of Medicine, National Academy Press, Washington, D.C., 1998; chapter 9: Vitamin B12, pp 306-356 Field CJ, Johnson IR, Schley PD: Nutrients and their role to host resistance to infection. J Leukoc Biol 2002;71:16-32 Tamura J, Kubota K, Murakami H, Sawamura M, Matsushima T, Tamura T, Saitoh T, Kurabayshi H, Naruse T: Immunomodulation by vitamin B12: augmentation of CD8+ T lymphocytes and natural killer (NK) cell activity in vitamin B12-deficient patients by methyl-B12 treatment. Clin Exp Immunol 1999;116:28-32 Animal data: Funada U, Wada M, Kawata T, Mori K, Tamai H, Kawanishi T, Kunou A, Tanaka N, Tadokoro T, Maekawa A: Changes in CD4+CD8-/CD4-CD8+ ratio and humoral immune functions in vitamin B12 deficient rats. Int J Vitam Nutr Res 2000;70:167-171 Funada U, Wada M, Kawata T, Mori K, Tamai H, Isshiki T, Onoda J, Tanaka N, Tadokoro T, Maekawa A: Vitamin B12-deficiency affects immunoglobulin production and cytokine levels in mice. Int J Vitam Nutr Res 2001;71:60-65.	1,218

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Structure and function of the neurological system	The product must contain at least 15% of the RDA X	IOM DRV Expert Report Encyclopaedia of Human Nutrition SCF Expert Opinion	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 2000 Encyclopaedia of Human Nutrition 2E. Editor-in-chief Michele J. Sadler, editors J.J. Strain, Benjamin Caballero. San Diego: Academic Press c.1999 Opinion of the Scientific Committee of Food (SCF) on the Tolerable Upper Intake Levels of Vitamin B12, Oct 2000 (http://www.europa.eu.int/comm/food/fs/sc/scf/out80d_en.pdf).	2,339
		Blood function	Source of / 15% of RDA per 100 g	Authoritative guidelines Scientific review	Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride (1997); Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid,Biotin, and Choline (1998); Food and Nutrition Board, Institute of Medicine, National Academies. Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13 JHCI -A report by the Joint Health Claims Initiative to the Food Standards Agency 2003 PART 2:A list of Well-Established Nutrient Function Statements.JHCI Ref: JHCI/76/03	758
		Nerve system and cognitive function	Source of / 15% of RDA per 100 g			759

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative guidelines Scientific review	Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride (1997); Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid,Biotin, and Choline (1998); Food and Nutrition Board, Institute of Medicine, National Academies. JHCI -A report by the Joint Health Claims Initiative to the Food Standards Agency 2003 PART 2:A list of Well-Established Nutrient 35Function Statements.JHCI Ref: JHCI/76/03	
		Homocysteine levels	Source of / 15% of RDA per 100 g	Authoritative guidelines Scientific review	Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride (1997); Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline (1998); Food and Nutrition Board, Institute of Medicine, National Academies. JHCI -A report by the Joint Health Claims Initiative to the Food Standards Agency 2003 PART 2:A list of Well-Established Nutrient Function Statements.JHCI Ref: JHCI/76/03	760
		Neural Tube Development	MINIMUM 15% RDA			1,025

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Human Intervention Study In Vitro Study Systematic Review Textbook	(1) K.R. Gaber , M.K. Farag, S.E.T. Soliman, H.T. El-Bassyouni and G. El-Kamah, Maternal vitamin B12 and the risk of fetal neural tube defects in Egyptian patients, Clin Lab, 2007; 53(1-2): 69-75. (2) P.N. Kirke et al, Maternal plasma folate and vitamin B12 are independent risk factors for neural tube defects. Quarterly Journal of Medicine 1993; 86 : 703-708 (3) Steen MT, Boddie AM, Fisher AJ, Macmahon W, Saxe D, Sullivan KM, Dembure PP, Elsas LJ. Neural-tube defects are associated with low concentrations of cobalamin (vitamin B12) in amniotic fluid, Prenat Diagn 1998 Jun; 18(6):545-55 (4) Thorand B, Pietrzik K, Prinz-Langenohl R, Hages M, Holzgreve W, Maternal and fetal serum and red blood cell folate and vitamin B12 concentrations in pregnancies affected by neural tube defects., Z Geburtshilfe Neonatol. 1996 Sep-Oct;200(5):176-80 (5) M.M. Elmazar, R. Thiel and H. Nau, Effect of Supplementation with Folinic Acid, Vitamin B6 and Vitamin B12 on Val-proic Acid-Induced Teratogenesis in Mice, Fundam Appl Toxical 1992 Apr;18(3):389-94 (6) P. Gerdiki-Kouidou, and M.J. Seller, Amniotic Fluid Folate, Vitamin B12 and Transcobalamins in Neural Tube Defects, Clin Genet 1988 Jun;33(6):441-8 (7) Wald NJ, Hackshaw AD, Stone R, Sourial NA. Blood folic acid and vitamin B12 in relation to neural tube defects Br J Obstet Gynaecol.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					1996 Apr;103(4):319-24	
		Heart Health	Only for products with at least 100 % RDA	OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	974

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				studies	"B-Vitamin Treatment Trialists' Collaboration Oxford, United Kingdom, Homocysteine-lowering trials for prevention of cardiovascular events: A review of the design and power of the large randomized trials Am Heart J 2006;151:282-7/ Homocysteine lowering trialsist's Collaboration. Lowering blood homocysteine with folic acid based supplements: meta-analysis of randomized trials. BMJ 1998, 316-8 Schnyder G, Roffi M, Flammer Y, Pin R, Hess OM. Effect of homocysteine-lowering therapy with folic acid, vitamin B12, and vitamin B6 on clinical outcome after percutaneous coronary intervention. The Swiss Heart Study: A Randomized Controlled Trial. JAMA: 288(8): 973-979, 2002. Schnyder G, Roffi M, Flammer Y, Pin R, Eberli FR, et al. Effect of homocysteine-lowering therapy on restenosis after percutanous coronary intervention for narrowings in small coronary arteries. Am J Cardiol. 91:1265-9 Peterson JC, Spence JD. Vitamins and progression of atherosclerosis in hyper-homocyst(e)inaemia. Lancet: 351: 263, 1998. Hackam DG, Peterson JC, Spence JD. What level of plasma homocyst(e)ine should be treated? Effects of vitamin therapy on progression of carotid atherosclerosis in patients with homocyst(e)ine levels above and	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					below 14 µmol/L. Am J Hypertens: 13: 105-110, 2000 Woo KS, Chook P, Chan LLT, Cheung ASP, Fung WH et al. Long-term improvement in homocysteine levels and endothelial function after 1-year folic acid supplementation. Am J Med:112: 535-539, 2002. Title LM, Cummings PM, Giddens K, Genest JJ, Nassar BA. Effect of folic acid and antioxidant vitamins on endothelial dysfunction in patients with coronary artery disease. J Am Coll Cardiol: 36(3): 758-765, 2000. Willems FF, Aengevaeren WRM, Boers GHJ, Blom HJ, Verheugt FWA. Coronary endothelial function in hyperhomocysteinemia. Improvement after treatment with folic acid and cobalamin in patients with coronary artery disease. J Am Coll Cardiov: 40(4): 766-772, 2002."	
		Energy and Vitality	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006.			973

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	
		Bone/Teeth/ Hair / Skin and Nail health	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006.			971

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	
		Vitamin/mineral supplementation to reduce fatigue and tirednes in situations of inadequate micronutrient status	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006.			1,165

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook	Institute of Medicine (1998) Vitamin B12 In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 9, pp 306-356 Driskell, J. A. (1999a) Vitamins, in Sports Nutrition, pp 49-83, Wolinsky I. ed, CRC Press Marcus, R. and Coulston, A.M. (1996b) Water-soluble vitamins. In: Hardman, J.G.; Limbird, L.E.; Molinoff, P.B.; Ruddon, R.W. and Goodman Gilman, A. eds. Goodman and Gilman's: The pharmacological basis of therapeutics, ninth edition. McGraw-Hill Inc., pp 1555-1572 Depeint, F.; Bruce, W.R.; Shangari, N.; Mehta, R. and O'Brien, P.J. (2006b) Mitochondrial function and toxicity: role of B vitamins on the one-carbon transfer pathways. Chemico-Biol. Inter. (in press) Lukaski, H.C. (2004) Vitamin and mineral status: effects on physical performance. Nutrition 20, 632-644	
		The role of vitamins and minerals in mental performance (where mental performance stands for those aspects of brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)	Only for products with at least 100 % RDA of vitamins			1,186

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbook	1) Institute of Medicine (1998) Vitamin B12 In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 9, pp 306-356 3) Weir, D.G. and Scott, J.M. (1999) Vitamin B12 “cobalamin”. In: Shils M.E.; Olson, J.A.; Shike, M. and Ross, A.C (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 447-458 4) Beck, W.S. (2001) Cobalamin (Vitamin B12) in Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 13, pp 463-512 5) Stabler, S.P. (2001) Vitamin B-12 In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 22, pp 230-240 6) Haller, J. (2005) Vitamins and Brain Function. In: Lieberman, H.R.; Kanarek, R.B. and Prasad, C. (eds.) Nutritional Neuroscience. CRC Press, Boca Raton, 207-233	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				studies	Heseker, H.; Kübler, W.; Pudel, V. and Westenhöfer, J (1995) Interaction of vitamins with mental performance. Bibl Nutr Dieta. Basel: Karger 52, 43-55 Carroll, D.; Ring, C.; Suter, M. and Willemsen, G. (2000) The effects of an oral multivitamin combination with calcium, magnesium, and zinc on psychological well-being in healthy young male volunteers: a double-blind placebo-controlled trial. Psychopharmacology (Berl) 150(2), 220-225 Benton, D.; Fordy, J. and Haller, J. (1995a) The impact of long-term vitamin supplementation on cognitive functioning. Psychopharmacol. 117(3), 298-305 6) Benton, D.; Haller, J. and Fordy, J. (1995a) Vitamin supplementation for 1 year improves mood. Neuropsychobiology 3, 98-105	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin B12 (Cyanocobalamin)					
		Cognitive function in aging	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006	Authoritative/Scientific Body	Institute of Medicine (1998) Vitamin B12 In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 9, pp 306-356	36
				Authoritative/Scientific Body	JHCI Final technical report 2003 p31 Annex 4.11p142-143 http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf	
				Review	Selhub J, Bagley LC, Miller J, Rosenberg IH. B vitamins, homocysteine, and neurocognitive function in the elderly. Am J Clin Nutr. 2000 Feb;71(2):614S-620S. Review.	
				Review	Wolters, M, Strohle, A and Hahn, A, (2004) Cobalamin: a critical vitamin in the elderly, Journal/Prev Med, 39, 1256-66 (Review)	
				Textbook	Gruber, U. Orthomolekulare Medizin. 2. Ed. Wissenschaftl. Verlagsgesellschaft Stuttgart 2002. (textbook)	
				Textbook	Haller, J. (2005) Vitamins and Brain Function. In: Lieberman, H.R.; Kanarek, R.B. and Prasad, C. (eds.) Nutritional Neuroscience. CRC Press, Boca Raton, 207-233	
				Textbook	Stabler, S.P. (2001) Vitamin B-12 In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 22, pp 230-240	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbook	Weir, D.G. and Scott, J.M. (1999) Vitamin B12 cobalamin. In: Shils M.E.; Olson, J.A.; Shike, M. and Ross, A.C (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 447-458	
				Individual study	Beck, W.S. (2001) Cobalamin (Vitamin B12) in Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 13, pp 463-512	
				Individual study	Bryan, J, Calvaresi, E and Hughes, D, (2002) Short-term folate, vitamin B-12 or vitamin B-6 supplementation slightly affects memory performance but not mood in women of various ages, Journal/J Nutr, 132, 1345-56	
				Individual study	Bryan J., Associations between dietary intake of folate and vitamins B-12 and B-6 and self-reported cognitive function and psychological well-being in Australian, J Nutr Health Aging 2004; 8 (4) : 226-32. Cf Annex 2	
				Individual study	Clarke, R, Harrison, G and Richards, S, (2003) Effect of vitamins and aspirin on markers of platelet activation, oxidative stress and homocysteine in people at high risk of dementia, Journal/J Intern Med, 254, 67-75 (interventional study)	
				Individual study	Louwman, MWJ, van Dusseldorp, M, van de Vijver, FJR, Thomas, CMG, Schneede, J, Ueland, PM, Refsum, H & van Staveren, WA (2000) Signs of impaired cognitive function in adolescents with marginal cobalamin status. American Journal of Clinical Nutrition, 72, 762-9	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual study	Nilsson, K, Gustafson, L and Hultberg, B, (2001) Improvement of cognitive functions after cobalamin/folate supplementation in elderly patients with dementia and elevated plasma homocysteine, Journal/Int J Geriatr Psychiatry, 16, 609-14 (interventional study)	
				Individual study	Selhub, J, Bagley, LC, Miller, J & Rosenberg, IH (2000) B vitamins, homocysteine, and neurocognitive function in the elderly. American Journal of Clinical Nutrition, 71, 614S-20S	
				Individual study	Tucker KL., High homocysteine and low B vitamins predict cognitive decline in aging men : the Veterans Affairs Normative Aging Study, Am J Clin Nutr 2005; 82 :627-35. Cf. Annex 3	
				Individual study	Van Asselt, DZ, Pasman, JW, van Lier, HJ, Vingerhoets, DM, Poels, PJ, Kuin, Y, Blom, HJ & Hoefnagels, WH (2001) Cobalamin supplementation improves cognitive and cerebral function in older, cobalamin deficient persons. Journal of Gerontology: Medical Sciences, 56A, M775-M779	
				Individual study	Wang HX et al. Vitamin (B12) and folate in relation to the development of Alzheimer's disease. Neurology. 2001 May 8; 56(9): 1188-94.	
				Individual study	Wolters, M, Strohle, A & Hahn, A (2004) Cobalamin: a critical vitamin in the elderly. Preventive Medecine, 39, 1256-1266	
		Neurological system, structure and function	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults	Authoritative Body	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	35

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Scientific Body	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	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B12. October 2000. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80d_en.pdf).	
				EVM Report	Revised review of Vitamin B12. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/EVM/00/20/P).	
				Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Homocysteine metabolism	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO			34

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			REGULATION 1924/2006 Only for products with at least 100 % RDA	Authoritative Body	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	
				Meta-analysis	Homocysteine Lowering Trialists' Collaboration (2005) Dose-dependent effects of folic acid on blood concentrations of homocysteine: a meta-analysis of the randomized trials. American Journal of Clinical Nutrition, 82: 806-12.	
				Meta-analysis	Lowering blood homocysteine with folic acid based supplements: meta-analysis of randomised trials. Homocysteine Lowering Trialists' Collaboration. BMJ. 1998 Mar 21; 316 (7135): 894-8. Texte integral : http://bmj.com/cgi/content/full/316/7135/894	
				Individual study	Koebnick, C, Hoffmann, I, Dagnelie, PC, Heins, UA, Wickramasinghe, SN, Ratnayaka, ID, Gruendel, S, Lindemans, J & Leitzmann, C (2004) Long-term ovo-lacto vegetarian diets impairs vitamin B12 status in pregnant women. Journal of Nutrition, 134, 3319-26.	
				Individual study	Marcucci R et al. Vitamin supplementation reduces the progression of atherosclerosis in hyperhomocysteinemic renal-transplant recipients. Transplantation. 2003 May 15; 75(9): 1551-5.	
				Individual study	Schnyder G et al. Effect of homocysteine-lowering therapy with folic acid, vitamin B12, and vitamin B6 on clinical outcome after percutaneous coronary intervention: the Swiss Heart Study: a randomized controlled trial. JAMA. 2002 Aug 28; 288(8): 973-9.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual study	Schnyder G et al. Decreased rate of coronary restenosis after lowering of plasma homocysteine levels. N Engl J Med. 2001 Nov 29; 345(22): 1593-600.	
				Individual study	Van Asselt, DZ, Pasman, JW, van Lier, HJ, Vingerhoets, DM, Poels, PJ, Kuin, Y, Blom, HJ & Hoefnagels, WH (2001) Cobalamin supplementation improves cognitive and cerebral function in older, cobalamin deficient persons. Journal of Gerontology: Medical Sciences, 56A, M775-M779	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook	"B-Vitamin Treatment Trialists' Collaboration Oxford, United Kingdom, Homocysteine-lowering trials for prevention of cardiovascular events: A review of the design and power of the large randomized trials Am Heart J 2006;151:282-7/ Homocysteine lowering trialsist's Collaboration. Lowering blood homocysteine with folic acid based supplements: meta-analysis of randomized trials. BMJ 1998, 316-8 Schnyder G, Roffi M, Flammer Y, Pin R, Hess OM. Effect of homocysteine-lowering therapy with folic acid, vitamin B12, and vitamin B6 on clinical outcome after percutaneous coronary intervention. The Swiss Heart Study: A Randomized Controlled Trial. JAMA: 288(8): 973-979, 2002. Schnyder G, Roffi M, Flammer Y, Pin R, Eberli FR, et al. Effect of homocysteine-lowering therapy on restenosis after percutanous coronary intervention for narrowings in small coronary arteries. Am J Cardiol. 91:1265-9 Peterson JC, Spence JD. Vitamins and progression of atherosclerosis in hyper-homocyst(e)inaemia. Lancet: 351: 263, 1998. Hackam DG, Peterson JC, Spence JD. What level of plasma homocyst(e)ine should be treated? Effects of vitamin therapy on progression of carotid atherosclerosis in patients with homocyst(e)ine levels above and below 14 µmol/L. Am J Hypertens: 13:	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					105-110, 2000 Woo KS, Chook P, Chan LLT, Cheung ASP, Fung WH et al. Long-term improvement in homocysteine levels and endothelial function after 1-year folic acid supplementation. Am J Med:112: 535-539, 2002. Title LM, Cummings PM, Giddens K, Genest JJ, Nassar BA. Effect of folic acid and antioxidant vitamins on endothelial dysfunction in patients with coronary artery disease. J Am Coll Cardiol: 36(3): 758-765, 2000. Willems FF, Aengevaeren WRM, Boers GHJ, Blom HJ, Verheugt FWA. Coronary endothelial function in hyperhomocysteinemia. Improvement after treatment with folic acid and cobalamin in patients with coronary artery disease. J Am Coll Cardiov: 40(4): 766-772, 2002."	
		Blood formation	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults	Authoritative Body	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	33
				Authoritative Body	CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	
				Authoritative Body	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	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				IOM DRV Report	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 2000.	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B12. October 2000. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80d_en.pdf).	
				Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Cell division (such as in the gastrointestinal tract)	Must meet minimum requirements for use of the claim "source of Vitamin B12 (Cyanocobalamin) " as per Annex to Regulation 1924/2006. Applicable to both children and adults	Authoritative Body	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	32

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				IOM DRV Report	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 2000.	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B12. October 2000. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80d_en.pdf).	
				EVM Report	Revised review of Vitamin B12. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/EVM/00/20/P).	
				Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Energy metabolism: propionate and amino acids	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION			37

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			1924/2006	Authoritative/Scientific Body	Institute of Medicine (1998) Vitamin B12 In Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington D.C, chapter 9, pp 306-356	
				Individual study	Beck, W.S. (2001) Cobalamin (Vitamin B12) in Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 13, pp 463-512	
				Individual study	Driskell, J. A. (1999a) Vitamins, in Sports Nutrition, pp 49-83, Wolinsky I. ed, CRC Press	
				Individual study	Stabler, S.P. (2001) Vitamin B-12 In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 22, pp 230-240	
				Individual study	Weir, D.G. and Scott, J.M. (1999) Vitamin B12 cobalamin. In: Shils M.E.; Olson, J.A.; Shike, M. and Ross, A.C (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 447-458	
					AR *Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.*	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin B12 and folate					
		Strong healthy bones:	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.	Textbook	Herrmann, M, Widmann, T and Herrmann, W, (2005) Homocysteine – a newly recognised risk factor for osteoporosis, Journal/Clin Chem Lab Med, 43, 1111-7 Van Meurs, JB, Dhonukshe-Rutten, RA, Pluijm, SM, van der aklift, M, de Jonge, R, Lindermans, J, de Groot, LC, Hofman, A, Witterman, JC, van Leeuwen, JP, Breteler, MM, Lips, P, Pols, HA and Uitterlinden, AG, (2004) Homocysteine levels and the risk of osteoporotic fracture, Journal/N Engl J Med, 350, 2003-41 McLean, RR, Jacques, PF, Selhub, J, Tucker, KL, Samelson, EJ, Broe KE, Hannan, MT, Cupples, LA and Kiel, DP, (2004) Homocysteine as a predictive factor for hip fracture in older persons, Journal/N Engl J Med, 350, 2042-9. Dhonukshe-Rutten, RA, Pluijm, SM, de Groot, LC, Lips, P, Smit, JH and van Staveren, WA, (2005) Homocysteine and vitamin B12 status relate to bone turnover markers, broadband ultrasound attenuation, and fracture in healthy elderly people, Journal/J Bone Miner Res, 20, 921-9.	1,571

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin B2					
		Energy and Vitality	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006.	OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	964
		Bone/Teeth/ Hair / Skin and Nail health	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006.			963

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin B2 (Riboflavin)					
		Required for the normal structure of mucous membranes (such as the surface of the tongue, the mouth, eyes and intestines).	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults	Authoritative Body	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	18
				IOM DRV Report	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 2000.	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B2. November 2000. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80i_en.pdf).	
				Nutrition textbook	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.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Transport and metabolism of iron	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC	Authoritative Body	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	17
				Authoritative Body	-CH - Switzerland - Ordonnance du March 1995 sur les dennrees 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	
				IOM DRV Report	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	
				Nutrition Textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B2. November 2000. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80i_en.pdf).	
				Nutrition Textbook	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.	
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				JHCI	JHCI, Final technical report http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf	
				IOM DRV report	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 2000.	
					Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B2. November 2000. http://www.europa.eu.int/comm/food/fs/sc/scf/out80i_en.pdf	
					Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
		Energy metabolism	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults	Authoritative Body	-CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	16
				Authoritative Body	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	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative Body	-CEDAP. Avis de la commission interministerielle d'etude des produits destines a une alimentation particuliere (CEDAP) en date du 18 decembre 1996 sur les recommandations relatives au caractere non trompeur des seuils des allegations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Repression des fraudes) du 7 octobre 1997	
				Authoritative Body	-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	
				IOM DRV Report	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	
				Nutrition Textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B2. November 2000. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80i_en.pdf).	
				EVM Report	Revised Review of Riboflavin. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/reviewriboflavin).	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin B3					
		Bone/Teeth/ Hair / Skin and Nail health	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >20mg of nicotinic acid carry the label statement "may cause skin flushes in sensitive individuals."	OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	965
		Energy and Vitality	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006. Agency guidance for			966

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			supplements is that products containing >20mg of nicotinic acid carry the label statement "may cause skin flushes in sensitive individuals."	OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin B3 (Niacin)					
		Energy metabolism Nutrient utilisation	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006	Authoritative Body	-CH - Switzerland - Ordonnance du March 1995 sur les dennrees 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	19
			Agency guidance for supplements is that products containing >20mg Nicotinic acid should carry the label statement: '[This amount of Nicotinic acid] may cause skin flushes in sensitive individuals'. Applicable to both children and adults	Authoritative Body	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	
				Authoritative Body	-CEDAP. Avis de la commission interministerielle d'etude des produits destines a une alimentation particuliere (CEDAP) en date du 18 decembre 1996 sur les recommandations relatives au caractere non trompeur des seuils des allegations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Repression des fraudes) du 7 octobre 1997	
				Authoritative Body	-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	
				IOM DRV Report	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 2000.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Levels of Nicotinic Acid and Nicotinamide (Niacin) April 2002. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80j_en.pdf).	
				EVM Report	Review of Niacin Revised Version. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/evm-01-11r.pdf).	
				Nutrition Textbook	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.	
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Neurological functions	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006	Authoritative Body	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	20

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			supplements is that products containing >20mg Nicotinic acid should carry the label statement: '[This amount of Nicotinic acid] may cause skin flushes in sensitive individuals'. Applicable to both children and adults	Authoritative Body	-CH - Switzerland - Ordonnance du March 1995 sur les dennrees 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	
				Scientific Body	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	
				Authoritative Body	-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	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Levels of Nicotinic Acid and Nicotinamide (Niacin) April 2002. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80j_en.pdf).	
				EVM Report	Review of Niacin Revised Version. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/evm-01-11r.pdf).	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				COMA Report	Dietary Reference Values for Food Energy and Nutrients for the United Kingdom. Report of the Panel on Dietary Reference Values. Report on Health and Social Subjects No. 41. DH: The Stationery Office, 1991.	
				Nutrition textbook	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.	
				Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Normal structure and function of skin and mucous membranes (such as the intestines)	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing >20mg Nicotinic acid should carry the label statement: '[This amount of Nicotinic acid] may cause skin flushes in sensitive individuals'. Applicable to both children and adults	Authoritative Body	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	21
				Authoritative Body	-CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				IOM DRV Report	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 2000.	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Levels of Nicotinic Acid and Nicotinamide (Niacin) April 2002. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80j_en.pdf).	
				EVM Report	Review of Niacin – Revised Version. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/evm-01-11r.pdf).	
				COMA Report	Dietary Reference Values for Food Energy and Nutrients for the United Kingdom. Report of the Panel on Dietary Reference Values. Report on Health and Social Subjects No. 41. DH: The Stationery Office, 1991.	
				Nutrition textbook	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.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin B5					
		Bone/Teeth/Hair/Skin and Nail health	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006.	OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	967
		Energy and Vitality	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006.			968

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin B5 (Pantothenic acid)					
		Fat and carbohydrate metabolism	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults	Authoritative Body	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	22
				Authoritative Body	-CH - Switzerland - Ordonnance du March 1995 sur les dennrees 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	
			At least a significant amount as defined in the Annex to Directive 90/496/EEC for Pantothenic acid (being Dexpanthenol the alcoholic analogue of D-pantothenic acid)	IOM DRV Report	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 2000.	
			At least a significant amount as defined in the Annex to Directive 90/496/EEC for Pantothenic acid (being Dexpanthenol the alcoholic analogue of D-pantothenic acid)	Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Pantothenic Acid. April 2002. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80k_en.pdf).	
				EVM Report	Review of Pantothenic Acid. Expert Group on Vitamins and Minerals. August 2002. (www.food.gov.uk/multimedia/pdfs/panto.pdf)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Energy metabolism	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults	IOM DRV Report	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 2000.	64
				SCF Reports	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Pantothenic Acid. April 2002. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80k_en.pdf).	
				EVM Reports	Review of Pantothenic Acid. Expert Group on Vitamins and Minerals. August 2002. (www.food.gov.uk/multimedia/pdfs/panto.pdf	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				Nutrition textbook	/	
				EVM Report	Review of Pantothenic Acid. Expert Group on Vitamins and Minerals. August 2002. (www.food.gov.uk/multimedia/pdfs/panto.pdf)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin B6					
		An essential co-factor in fatty acid metabolism that impacts upon hormonal health	The product must contain no less than 15% RDA Long term intakes of over 10mg of vitamin B6 per day may lead to mild tingling and numbness.			674

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Text Books Expert Review Human Intervention Studies Animal Studies	Ref 1 - MacKey AD, Davis SR, Gregory III JF. Vitamin B6. . In: ME Shils, M Shike, AC Ross, B Caballero, RJ Cousins (eds). Modern Nutrition in Health and Disease. Philadelphia: Lippincott, Williams and Wilkins, 10th edition, 2006, p452-461. Ref 2 – Leklem JE. Vitamin B6. In: PM Coates, MR Blackman, GM Cragg, M Levine, J Moss, JD White.(eds). Encyclopaedia of Dietary Supplements. New York: Mercel Dekker, 2006, p. 715-734. Ref 3 - Expert Group on Vitamins and Minerals. Vitamin B6 (Pyridoxine) In: Safe Upper Levels for Vitamins and Minerals. Food Standards Agency, May 2003, p. 81-93. Ref 4 - Brush MG. Vitamins, essential fatty acids and minerals in relation to the aetiology and management of premenstrual syndrome. In: Brush MG and Gouldsmit EM. Functional Disorders of the Menstrual Cycle. John Wiley & Sons Ltd. 1988, p. 69-85. Ref 5 - McCormick DB. Vitamin B6. In: Bowman BA and Russell RM. Present Knowledge in Nutrition, 8th Edition. ILSI Press, Washington, DC. 2001, p. 207-213. Ref 6 - Sherman H. Pyridoxine and fat metabolism. Vitam Horm 1950;8:55-68. Ref 7 - Bender DA. Novel functions of vitamin B6. Proceedings of the Nutrition Society. 1994;53:625-630 Ref 8 - Wyatt KM, Dimmock PW, Jones PW, O' Brien PMS. Efficacy of vitamin B6 in the	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					treatment of premenstrual syndrome: systematic review. BMJ 1999;318:1375-81 Ref 9 – De Souza MC, Walker AF, Robinson PA, Bolland K. A synergistic effect of a daily supplement for 1 month of 200 mg magnesium plus 50 mg vitamin B6 for the relief of anxiety related premenstrual symptoms: a randomized, double-blind, crossover study. J Women's Health Gend Based Med 2000 Mar;9(2):131-9 Ref 10 - Doll H, Brown S, Thurston A, Vessey M. Pyridoxine (vitamin B6) and the premenstrual syndrome: a randomized crossover trial. Journal of the Royal College of General Practitioners. 1989;39:364-368 Ref 11 - Cunnane SC, Manku MS, Horrobin DF. Accumulation of linoleic and gamma-linolenic acids in tissue lipids of pyridoxine-deficient rats. J Nutr 1984;114:1754-1761 Ref 12 - Witten PW, Holman RT. Polyethenoid fatty acid metabolism. VI. Effects of pyridoxine on essential fatty acid conversions. Arch Biochem Biophys 1952;41:266-273. Ref 13 - Sato Y. A possible role of pyridoxine in lipid metabolism. Nagoya J Med Sci 1970;33:105-130	
		B vitamins and heart health	Only for products with at least 100 % RDA Agency guidance for supplements is that products containing >10 mg of vitamin B6 should carry the label advisory statement "Long term			1,231

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			intakes [of this amount of vitamin B6] may lead to mild tingling and numbness"	studies	"B-Vitamin Treatment Trialists' Collaboration Oxford, United Kingdom, Homocysteine-lowering trials for prevention of cardiovascular events: A review of the design and power of the large randomized trials Am Heart J 2006;151:282-7/ Homocysteine lowering trialsist's Collaboration. Lowering blood homocysteine with folic acid based supplements: meta-analysis of randomized trials. BMJ 1998, 316-8 Schnyder G, Roffi M, Flammer Y, Pin R, Hess OM. Effect of homocysteine-lowering therapy with folic acid, vitamin B12, and vitamin B6 on clinical outcome after percutaneous coronary intervention. The Swiss Heart Study: A Randomized Controlled Trial. JAMA: 288(8): 973-979, 2002. Schnyder G, Roffi M, Flammer Y, Pin R, Eberli FR, et al. Effect of homocysteine-lowering therapy on restenosis after percutanous coronary intervention for narrowings in small coronary arteries. Am J Cardiol. 91:1265-9 Peterson JC, Spence JD. Vitamins and progression of atherosclerosis in hyper-homocyst(e)inaemia. Lancet: 351: 263, 1998. Hackam DG, Peterson JC, Spence JD. What level of plasma homocyst(e)ine should be treated? Effects of vitamin therapy on progression of carotid atherosclerosis in patients with homocyst(e)ine levels above and below 14 µmol/L. Am J Hypertens: 13:	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					105-110, 2000 Woo KS, Chook P, Chan LLT, Cheung ASP, Fung WH et al. Long-term improvement in homocysteine levels and endothelial function after 1-year folic acid supplementation. Am J Med:112: 535-539, 2002. Title LM, Cummings PM, Giddens K, Genest JJ, Nassar BA. Effect of folic acid and antioxidant vitamins on endothelial dysfunction in patients with coronary artery disease. J Am Coll Cardiol: 36(3): 758-765, 2000. Willems FF, Aengevaeren WRM, Boers GHJ, Blom HJ, Verheugt FWA. Coronary endothelial function in hyperhomocysteinemia. Improvement after treatment with folic acid and cobalamin in patients with coronary artery disease. J Am Coll Cardiov: 40(4): 766-772, 2002."	
		Energy and Vitality	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >10 mg of Vitamin B6 should carry the label advisory statement "Long term intakes may lead to mild			970

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			tingling and numbness" Encourages reformulation to lower daily amount.	OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	
		Bone/Teeth/ Hair / Skin and Nail health	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >10 mg of Vitamin B6 should carry the label advisory			969

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			statement "Long term intakes may lead to mild tingling and numbness" Encourages reformulation to lower daily amount.	OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	
		Heart Health	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >10 mg of Vitamin B6 should carry the label advisory			972

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			statement "Long term intakes may lead to mild tingling and numbness" Encourages reformulation to lower daily amount.	OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	
		Blood health	Source of / 15% of RDA per 100 g Agency guidance for supplements is that products containing >10mg of vitamin B6 should carry the label advisory statement "long term intakes of this amount of vitamin B6 may lead to mild tingling and numbness"	Authoritative guidelines	Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13	756

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Macronutrient metabolism	Source of 15% of RDA per 100g Agency guidance for supplements is that products containing >10mg of vitamin B6 should carry the label advisory statement "long term intakes of this amount of vitamin B6 may lead to mild tingling and numbness"	Authoritive guidelines	Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13	755
		Glucose Metabolism	MINIMUM 15% RDA Agency guidance for supplements is that products containing >10mg of vitamin B6 should carry the label advisory statement "long term intakes of this amount of vitamin B6 may lead to mild tingling and numbness"			1,026

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				In Vitro Study Review	(1) Adrover M, Vilanova B, Munoz F, Donoso JChem Biodivers. Inhibition of Glycosylation Processes; The Reaction Between Pyridoxamine and Glucose, Chemistry & Biodiversity, 2005 Jul; 2(7):964-75. (2) Voziyan PA, Hudson BG. Pyridoxamine as a multifunctional pharmaceutical: targeting pathogenic glycation and oxidative damage. Cell Mol Life Sci. 2005 Aug; 62(15):1671-81. (3) Voziyan PA, Hudson BG. Pyridoxamine: the many virtues of a maillard reaction inhibitor. Ann N Y Acad Sci. 2005 Jun;1043:807-16 (4) Booth AA, Khalifah RG, Todd P, Hudson BG. In vitro kinetic studies of formation of antigenic advanced glycation end products (AGEs). Novel inhibition of post-Amadori glycation pathways. J Biol Chem. 1997 Feb 28; 272(9):5430-7. (5) Jain SK, Lim G. Pyridoxine and pyridoxamine inhibits superoxide radicals and prevents lipid peroxidation, protein glycosylation, and (Na+ + K+)-ATPase activity reduction in high glucose-treated human erythrocytes. Free Radic Biol Med. 2001 Feb 1; 30(3):232-7.	
		Homocysteine levels	15% RDA per 100 Source of / 15% of RDA per 100 g Agency guidance for supplements is that products containing >10mg of vitamin B6 should carry the label advisory statement "long term intakes of this	Authoritative guidelines Scientific review	Spinneher A et al. Vitamin B6 status, deficiency and its consequences - an overview. Nutr Hosp 2007Jan-Feb;22(1):7-24. Selhub J. The many facets of hyperhomocysteinemia: studies from the Framingham cohorts. J Nutr 2006 Jun;136(6suppl):1726S-1730S.	757

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			amount of vitamin B6 may lead to mild tingling and numbness"			

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin B6 (Pyridoxine)					
		Immune system function	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing >10 mg mg of Vitamin B6 (Pyridoxine) should carry the label advisory statement "Long term in takes of this amount of Vitamin B6 may lead to mild tingling and numbness"- - Applicable to both children and adults	Scientific Body	-Deutsche Gesellschaft fur Ernahrung(German Society of Nutrition).	27
				Textbook	-Biesalski et al. 'Nutritional medicine', 2004	
				Reviews and individual studies	-Frisco, S.; Girelli, D.; Martinelli, N.; Olivieri, O.; Lotto, V.; Bozzini, C.; Pizzolo, F.; Faccini, G.; Beltrame, F. and Corrocher, R. (2004) Low plasma vitamin B6 concentrations and modulation of coronary artery disease risk. Am. J. Clin. Nutr. 79, 992-998	
				Reviews and individual studies	-Kwak, H.K.; Hansen, C.M.; Leklem, J.E.; Hardin, K. and Shultz, T.D. (2002) Improved vitamin B-6 status is positively related to lymphocyte proliferation in young women consuming a controlled diet. J. Nutr. 132, 3308-3313	
				Reviews and individual studies	-Long, .KZ. and Santos, J.L. (1999) Vitamins and the regulation of the immune response. Ped. Inf. Dis. J. 18, 283-290	
				Reviews and individual studies	-Meydani, S.N. and Han, S.N. (2001) Nutrition regulation of the immune response: the case of vitamin E; in Bowman, B.A. and Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 41, pp 449-462	
				Reviews and individual studies	-Meydani, S.N.; Ribaya-Mercado, J.D.; Russel,l R.M.; Sahyoun. N.; Morrow, F.D. and Gershoff, S.N. (1991) Vitamin B-6 deficiency impairs interleukin 2 production and lymphocyte proliferation in elderly adults. Am. J. Cli.n Nutr. 53, 1275-1280	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Reviews and individual studies	-Miller, L.T. and Kerkvliet, N.T. (1990) Effect of vitamin B6 on immune competence in the elderly. Ann. N.Y. Acad. Sc. 587, 49-54	
				Reviews and individual studies	-Namazi, M.R. (2003) Pyridoxal 5´-phosphate as a novel weapon against autoimmunity and transplant rejection. FASEB J 1, :2184-2186	
				Reviews and individual studies	-Rall, L.C. and Meydani, S.N. (1993) Vitamin B6 and immune competence. Nutr. Rev.51, 217-225	
				Reviews and individual studies	-Trakatellis, A.; Dimitriadou, A. and Trakadelli, M. (1997) Pyridoxine deficicency: new approaches in immunosuppression and chemotherapy. Postgr. Med. J. 73, 617-622	
				Reviews and individual studies	-Van den Berg, H.; Mulder, J.; Spanhaak, S.; Dokkum, W.V. and Oickhuizen, T. (1988) The influence of marginal vitamin B-6 status on immunological indices; in Leklem, J.E. and Reynolds, R.D. (eds): Clinical and physiological applications of vitamin B-6. New York, N.Y., Alan R Liss, pp 147-155	
				EVM Report	Review of Pantothenic Acid. Expert Group on Vitamins and Minerals. August 2002. (www.food.gov.uk/multimedia/pdfs/panto.pdf)	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook, studies	Dietary Reference Intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin, and choline. A report of the Panel on Folate, other B Vitamins, and Choline, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes; Food and Nutrition Board, Institute of Medicine, National Academy Press, Washington, D.C., 1998; chapter 7: Vitamin B6, pp 150-195 Field CJ, Johnson IR, Schley PD: Nutrients and their role to host resistance to infection. J Leukoc Biol 2002;71:16-32	
		Nervous system function	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing >10 mg mg of Vitamin B6 (Pyridoxine) should carry the label advisory statement "Long term in takes of this amount of Vitamin B6 may lead to mild tingling and numbness"- - Applicable to both children and adults	EVM Report	Review of Pantothenic Acid. Expert Group on Vitamins and Minerals. August 2002. (www.food.gov.uk/multimedia/pdfs/panto.pdf)	26
				Scientific Body	Opinion of the Scientific Committee on Food (SCF) on the Tolerable upper Intake Level of Vitamin B6 October 2000. -Biesalski et al. 'Nutritional medicine', 2004	
				Textbook	-Biesalski et al. 'Nutritional medicine', 2004 Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Transport and metabolism of iron	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing >10 mg mg of Vitamin B6 (Pyridoxine) should carry the label advisory statement "Long term in takes of this amount of Vitamin B6 may lead to mild tingling and numbness" - Applicable to both children and adults	Authoritative Body	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	25
				Authoritative Body	-CEDAP. Avis de la commission interministerielle d'etude des produits destines a une alimentation particuliere (CEDAP) en date du 18 decembre 1996 sur les recommandations relatives au caractere non trompeur des seuils des allegations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Repression des fraudes) du 7 octobre 1997	
				IOM DRV Report	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 2000.	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B6. October 2000. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80c_en.pdf).	
				EVM Report	Revised review of Vitamin B6. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/EVM/00/19/P.pdf).	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Protein metabolism	MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that Products containing >10mg Vitamin B6 should carry the label statement: 'Long term intakes [of this amount of Vitamin B6] may lead to mild tingling and numbness'. Applicable to both children and adults	IOM DRV Report	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 2000.	80
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin B6. October 2000. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80c_en.pdf).	
				EVM Report	Revised review of Vitamin B6. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/EVM/00/19/P.pdf).	
		Protein and Glycogen/ stored carbohydrate metabolism	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing >10 mg mg of Vitamin B6 (Pyridoxine) should carry the label advisory statement "Long term in takes of this amount of Vitamin B6 may lead to mild tingling and	Authoritative Body	-CEDAP. Avis de la commission interministerielle d'etude des produits destines a une alimentation particuliere (CEDAP) en date du 18 decembre 1996 sur les recommandations relatives au caractere non trompeur des seuils des allegations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Repression des fraudes) du 7 octobre 1997	23
				Authoritative Body	-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	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			numbness"	Authoritative Body	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	
				Authoritative Body	-CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	
				Authoritative Body	-FNFC/FOSHU Japan http://www.mhlw.go.jp/english/topics/foodsafety/fhc/index.html	
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Homocysteine metabolism	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing >10mg Vitamin B6 should carry the label statement: 'Long term intakes [of this amount of Vitamin B6] may lead	Authoritative Body	-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	24
				Meta-analysis	Clarke R. Lowering blood homocysteine with folic acid based supplements: meta-analysis of randomised trials. Homocysteine Lowering Trialists' Collaboration. BMJ 1998;316:894-898.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			to mild tingling and numbness'. Only for products with at least 100 % RDA	Meta-analysis	-Homocysteine Lowering Trialists' Collaboration (2005) Dose-dependent effects of folic acid on blood concentrations of homocysteine: a meta-analysis of the randomized trials. American Journal of Clinical Nutrition, 82: 806-12.	
				Individual study	-Bates CJ, Pentieva KD, Prentice A, Mansoor MA, Finch S. Plasma pyridoxal phosphate and pyridoxic acid and their relationship to plasma homocysteine in a representative sample of British men and women aged 65 years and over. Br J Nutr 1999;81:191-201.	
				Individual study	-Boushey CJ, Beresford SA, Omenn GS, Motulsky AG. A quantitative assessment of plasma homocysteine as a risk factor for vascular disease. Probable benefits of increasing folic acid intakes [see comments]. JAMA 1995;274:1049-1057.	
				Individual study	-Dakshinamurti K, Lal KJ, Ganguly PK. Hypertension, calcium channel and pyridoxine (vitamin B6). Mol.Cell Biochem. 1998;188:137-148.	
				Individual study	-De Deckere EAM. Cardiovascular disease and plasma homocysteine: role of folate/folic acid, vitamin B6, and vitamin B12. VD 00 0334 (2000).	
				Individual study	-Folsom AR, Nieto FJ, McGovern PG et al. Prospective study of coronary heart disease incidence in relation to fasting total homocysteine, related genetic polymorphisms, and B vitamins: the Atherosclerosis Risk in Communities (ARIC) study. Circulation 1998;98:204-210.	
				Individual study	-Haller J. The vitamin status and its adequacy in the elderly: an international overview. Int J Vitam Nutr Res 1999;69:160-168.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual study	-Leklem JE. In: Present Knowledge in Nutrition, Ziegler EE, Filer LJ, eds. ILSI Press, Washington DC 1996, pp 176-178.	
				Individual study	-McKinley MC, McNulty H, McPartlin J et al. Low-dose vitamin B-6 effectively lowers fasting plasma homocysteine in healthy elderly persons who are folate and riboflavin replete. Am J Clin.Nutr. 2001;73:759-764.	
				Individual study	-Rimm EB, Willett WC, Hu FB et al. Folate and vitamin B6 from diet and supplements in relation to risk of coronary heart disease among women. JAMA 1998;279:359-364.	
				Individual study	-Robinson K, Mayer EL, Miller DP et al. Hyperhomocysteinemia and low pyridoxal phosphate. Common and independent reversible risk factors for coronary artery disease. Circulation 1995;92:2825-2830.	
				Individual study	-Robinson K, Arheart K, Refsum H et al. Low circulating folate and vitamin B6 concentrations: risk factors for stroke, peripheral vascular disease, and coronary artery disease. European COMAC Group. Circulation 1998;97:437-443.	
				Individual study	-Selhub J, Jacques PF, Bostom AG et al. Association between plasma homocysteine concentrations and extracranial carotid-artery stenosis. N Engl J Med 1995;332:286-291.	
				Individual study	-Tsuge H, Hotta N, Hayakawa T. Effects of vitamin B-6 on (n-3) polyunsaturated fatty acid metabolism. J Nutr. 2000;130:S333-S334.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual study	-van Dijk RA, Rauwerda JA, Steyn M, Twisk JW, Stehouwer CD. Long-term homocysteine-lowering treatment with folic acid plus pyridoxine is associated with decreased blood pressure but not with improved brachial artery endothelium-dependent vasodilation or carotid artery stiffness: a 2-year, randomized, placebo-controlled trial. Arterioscler.Thromb.Vasc.Biol. 2001;21:2072-2079.	
				Individual study	-VERA Schriftenreihe. Kubler W, Anders HJ, Heeschen W, Kohlmeier M, eds. Band III Lebensmittel- und Nahrstoffaufname Erwachsener in der Bundesrepublik Deutschland. Die Wissenschaftlicher Fachverlag Dr. Fleck. Niederkleen, Germany, 1992.	
				Individual study	-VERA Schriftenreihe. Kubler W, Anders HJ, Heeschen W, Kohlmeier M, eds. Band IV Vitaminversorgung Erwachsener in der Bundesrepublik Deutschland. Die Wissenschaftlicher Fachverlag Dr. Fleck. Niederkleen, Germany, 1992.	
				Individual study	-Verhoef P, Meleady R, Daly LE, Graham IM, Robinson K, Boers GH. Homocysteine, vitamin status and risk of vascular disease; effects of gender and menopausal status. European COMAC Group. Eur Heart J 1999;20:1234-1244.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook	"B-Vitamin Treatment Trialists' Collaboration Oxford, United Kingdom, Homocysteine-lowering trials for prevention of cardiovascular events: A review of the design and power of the large randomized trials Am Heart J 2006;151:282-7/ Homocysteine lowering trialsist's Collaboration. Lowering blood homocysteine with folic acid based supplements: meta-analysis of randomized trials. BMJ 1998, 316-8 Schnyder G, Roffi M, Flammer Y, Pin R, Hess OM. Effect of homocysteine-lowering therapy with folic acid, vitamin B12, and vitamin B6 on clinical outcome after percutaneous coronary intervention. The Swiss Heart Study: A Randomized Controlled Trial. JAMA: 288(8): 973-979, 2002. Schnyder G, Roffi M, Flammer Y, Pin R, Eberli FR, et al. Effect of homocysteine-lowering therapy on restenosis after percutanous coronary intervention for narrowings in small coronary arteries. Am J Cardiol. 91:1265-9 Peterson JC, Spence JD. Vitamins and progression of atherosclerosis in hyper-homocyst(e)inaemia. Lancet: 351: 263, 1998. Hackam DG, Peterson JC, Spence JD. What level of plasma homocyst(e)ine should be treated? Effects of vitamin therapy on progression of carotid atherosclerosis in patients with homocyst(e)ine levels above and	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					below 14 µmol/L. Am J Hypertens: 13: 105-110, 2000 Woo KS, Chook P, Chan LLT, Cheung ASP, Fung WH et al. Long-term improvement in homocysteine levels and endothelial function after 1-year folic acid supplementation. Am J Med:112: 535-539, 2002. Title LM, Cummings PM, Giddens K, Genest JJ, Nassar BA. Effect of folic acid and antioxidant vitamins on endothelial dysfunction in patients with coronary artery disease. J Am Coll Cardiol: 36(3): 758-765, 2000. Willems FF, Aengevaeren WRM, Boers GHJ, Blom HJ, Verheugt FWA. Coronary endothelial function in hyperhomocysteinemia. Improvement after treatment with folic acid and cobalamin in patients with coronary artery disease. J Am Coll Cardiov: 40(4): 766-772, 2002."	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin B9 (Folate/Folic acid)					
		Cell division/multiplication (such as in the gastrointestinal tract): Nucleic acids and amino acids synthesis	Must meet minimum requirements for use of the claim source of Vitamin B9 (Folate/Folic acid) as per Annex to Regulation 1924/2006 Applicable to both children and adults	Authoritative Body	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	28
				IOM DRV Report	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 2000.	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Folate. October 2000. (http://www.europa.eu.int/comm/food/fs/sc/scf/out80e_en.pdf).	
				EVM Report	Review of Folic Acid. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/evm0018p.pdf).	
				COMA Report	Folic Acid and the Prevention of Disease. Report of the Committee on Medical Aspects of Food and Nutrition Policy. Report on Health and Social Subjects No. 50. DH: The Stationery Office, 2000.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Vascular function / Cardiovascular health	Must meet minimum requirements for ise of the claim source of Vitamin B9 (Folate/Folic acid) as per Annex to Regulation 1924/2006 400 microgram/ day Only for products with at least 100 % RDA	Authoritative/Scientfic Bodies	Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs, document: 390L0496. Official Journal L276, 06/10/1990 P. 0040-0044.	31
				Authoritative/Scientfic Bodies	Holland B, Welch AA, Unwin ID, Buss DH, Paul AA, Southgate DAT. McCance and Widdowson's The composition of foods, 5th edn. UK: Royal Society of Chemistry and Ministry of Agriculture, Fisheries and Food, 1991.	
				Authoritative/Scientfic Bodies	Malinow MR, Bostom AG, Krauss RM, Homocysteine, diet and cardiovascular diseases. A statement for Healthcare Professionals from the Nutrition Committee American heart Association. Circulation. 1999; 99:178-182.	
				Authoritative/Scientfic Bodies	UK Committee on Medical Aspects of Food and Nutrition Policy. Folic acid and the prevention of disease. London, Stationery Office, 2000.	
				Review	-Bergen C, Compher C. Total homocysteine concentration and associated cardiovascular and renal implications in adults. J Cardiovasc Nurs. 2006 Jan-Feb;21(1):40-6.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Review	-Eikelboom JW, Lonn E, Genest JJ, Hankey G, Yusuf S. Homocyst(e)ine and cardiovascular disease: a critical review of the epidemiologic evidence. Ann Intern Med 1999;131:363-375.	
				Meta-analysis	-Angelika de Bree, Linda A. van Mierlo, Richard Draijer; Folic acid improves vascular reactivity in humans: a meta-analysis of randomized controlled trials. Accepted for publication in the American Journal of Clinical Nutrition.	
				Individual study	-Bates CJ, Mansoor MA, van der Pols J, Prentice A, Cole TJ, Finch S. Plasma total homocysteine in a representative sample of 972 British men and women aged 65 and over. Eur J Clin Nutr . 1997;51:691-697.	
				Individual study	-Bazzano LA, He J, Ogden LG et al. Dietary intake of folate and risk of stroke in US men and women: NHANES I Epidemiologic Follow-up Study. National Health and Nutrition Examination Survey. Stroke 2002;33:1183-1189.	
				Individual study	-Beresford SA, Boushey CJ. Homocysteine, folic acid, and cardiovascular diseases risk. In: Bendich A, Deckelbaum RJ, eds. Preventive Nutrition. Totowa NJ, USA: Humana Press 1997:193-224.	
				Individual study	-Boushey CJ, Beresford SA, Omenn GS, Motulsky AG. A quantitative assessment of plasma homocysteine as a risk factor for vascular disease. Probable benefits of increasing folic acid intakes. JAMA 1995;274:1049-1057.	
				Individual study	-Cesari M., Rossi GP, Sticchi D, Pessina AC. Is homocysteine as risk factor for coronary heart disease? Nutr Metab Cardiovasc Dis. 2005 Apr; 15(2):140-7	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual study	-Cheerag Shirodaria, Charalambos Antoniades, Justin Lee, Clare E. Jackson, Matthew D. Robson, Jane M. Francis, Stuart J. Moat, Chandi Ratnatunga, Ravi Pillai, Helga Refsum, Stefan Neubauer, and Keith M. Channon; Global Improvement of Vascular Function and Redox State With Low-Dose Folic Acid: Implications for Folate Therapy in Patients With Coronary Artery Disease; Circulation 2007 115: 2262 - 2270; published online before print April 9 2007, doi:10.1161/CIRCULATIONAHA.106.679084	
				Individual study	-Christen WG, Ajani UA, Glynn RJ, Hennekens CH. Blood levels of homocysteine and increased risks of cardiovascular disease: causal or casual? Arch Intern Med 2000;160:422-434.	
				Individual study	-Eichholzer M, Luthy J, Gutzwiller F, Stahelin HB. The role of folate, antioxidant vitamins and other constituents in fruit and vegetables in the prevention of cardiovascular disease: the epidemiological evidence. Int J Vitam Nutr Res. 2001 Jan;71(1):5-17	
				Individual study	-Finch S, Doyle W, et al. National Diet and Nutrition Survey: people aged 65 years and over. Volume 1: Report of the diet and nutrition survey. London, The Stationary Office, 1998	
				Individual study	-Guthikonda S., Haynes WG. Homocysteine: role and implications in atherosclerosis. Curr Atheroscler Rep. 2006 Mar; 8(2):100-6.	
				Individual study	-Homocysteine Lowering Trialists' Collaboration. Lowering blood homocysteine with folic acid based supplements: meta-analysis of randomised trials. BMJ. 1998 Mar 21; 316 (7135): 894-8.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual study	-Jacques PF, Bostom AG, Williams RR et al. Relation between folate status, a common mutation in methylenetetrahydrofolate reductase, and plasma homocysteine concentrations. Circulation 1996;93:7-9.	
				Individual study	-Jacques PF, Rosenberg IH, Rogers G et al. Serum total homocysteine concentrations in adolescent and adult Americans: results from the third National Health and Nutrition Examination Survey. Am J Clin Nutr 1999b;69:482-489.	
				Individual study	-Jacques PF, Selhub J, Bostom AG, Wilson PW, Rosenberg IH. The effect of folic acid fortification on plasma folate and total homocysteine concentrations. N Engl J Med 1999a;340:1449-1454.	
				Individual study	-Joosten E, van den Berg A, Riezler R et al. Metabolic evidence that deficiencies of vitamin B-12 (cobalamin), folate, and vitamin B-6 occur commonly in elderly people. Am J Clin Nutr 1993;58:468-476.	
				Individual study	-Klevay LM. The homocysteine theory of arteriosclerosis. Nutr Rev. 1992 May;50(5):155.	
				Individual study	-Mayer EL, Jacobsen D, Robinson K. Homocysteine and coronary atherosclerosis. J Am Coll Cardiol. 1996;27:517-527.	
				Individual study	-Nygard O, Vollset SE, Refsum H, Brattstrom L, Ueland PM. Total homocysteine and cardiovascular disease. J Intern Med 1999;246:425-454.	
				Individual study	-Refsum H, Ueland PM. Recent data are not in conflict with homocysteine as a cardiovascular risk factor. Curr Opin Lipidol 1998;9:533-539.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual study	-Rimm EB, Willett WC, Hu FB et al. Folate and vitamin B6 from diet and supplements in relation to risk of coronary heart disease among women. JAMA 1998;279:359-364.	
				Individual study	-Ueland PM, Refsum H, Beresford SA, Vollset SE. The controversy over homocysteine and cardiovascular risk. Am J Clin Nutr 2000;72:324-332.	
				Individual study	-VERA Schriftenreihe. Kubler W, Anders HJ, Heeschen W, Kohlmeier M, eds. Band III Lebensmittel- und Nahrstoffaufname Erwachsener in der Bundesrepublik Deutschland. Die Wissenschaftlicher Fachverlag Dr. Fleck. Niederkleen, Germany, 1992.	
				Individual study	-VERA Schriftenreihe. Kubler W, Anders HJ, Heeschen W, Kohlmeier M, eds. Band IV Vitaminversorgung Erwachsener in der Bundesrepublik Deutschland. Die Wissenschaftlicher Fachverlag Dr. Fleck. Niederkleen, Germany, 1992.	
				Individual study	-Verhoef P, Kok FJ, Kluijtmans LA et al. The 677C-->T mutation in the methylenetetrahydrofolate reductase gene: associations with plasma total homocysteine levels and risk of coronary atherosclerotic disease. Atherosclerosis 1997;132:105-113.	
				Individual study	-Verhoef P, Stampfer MJ, Buring JE et al. Homocysteine metabolism and risk of myocardial infarction: relation with vitamins B6, B12, and folate. Am J Epidemiol 1996;143:845-859.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual study	-Villa P., Suriano R., Costantini B., Macri F., Ricciardi L., Campagna G., Lanzone A. Hyperhomocysteinemia and cardiovascular risk in postmenopausal women : the role of folate supplementation. Clin Chem Lab Med. 2007;45(2):130-5.	
				Individual study	-Wilmink HW, Stroes ES, Erkelens WD, et al. Influence of folic acid on postprandial dysfunction. Artherioscler. Thromb. Vasc. Biol. 2000;20:185-188.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				studies	B-Vitamin Treatment Trialists' Collaboration Oxford, United Kingdom, Homocysteine-lowering trials for prevention of cardiovascular events: A review of the design and power of the large randomized trials Am Heart J 2006;151:282-7 Schnyder G, Roffi M, Flammer Y, Pin R, Hess OM. Effect of homocysteine-lowering therapy with folic acid, vitamin B12, and vitamin B6 on clinical outcome after percutaneous coronary intervention. The Swiss Heart Study: A Randomized Controlled Trial. JAMA: 288(8): 973-979, 2002. Schnyder G, Roffi M, Flammer Y, Pin R, Eberli FR, et al. Effect of homocysteine-lowering therapy on restenosis after percutanous coronary intervention for narrowings in small coronary arteries. Am J Cardiol. 91:1265-9 Peterson JC, Spence JD. Vitamins and progression of atherosclerosis in hyper-homocyst(e)inaemia. Lancet: 351: 263, 1998. Hackam DG, Peterson JC, Spence JD. What level of plasma homocyst(e)ine should be treated? Effects of vitamin therapy on progression of carotid atherosclerosis in patients with homocyst(e)ine levels above and below 14 µmol/L. Am J Hypertens: 13: 105-110, 2000 Woo KS, Chook P, Chan LLT, Cheung ASP, Fung WH et al. Long-term improvement in homocysteine levels and endothelial function after 1-year folic acid supplementation. Am J Med:112: 535-539, 2002. Title LM, Cummings PM, Giddens K, Genest JJ, Nassar BA. Effect of folic acid and antioxidant vitamins on endothelial dysfunction in patients with coronary artery disease. J Am Coll Cardiol: 36(3): 758-765, 2000.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Willems FF, Aengevaeren WRM, Boers GHJ, Blom HJ, Verheugt FWA. Coronary endothelial function in hyperhomocysteinemia. Improvement after treatment with folic acid and cobalamin in patients with coronary artery disease. J Am Coll Cardiov: 40(4): 766-772, 2002.	
		Homocysteine metabolism	MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Only for products with at least 100 % RDA	Authoritative Body	-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	30
				Meta-analysis	Homocysteine Lowering Trialists' Collaboration (2005) Dose-dependent effects of folic acid on blood concentrations of homocysteine: a meta-analysis of the randomized trials. American Journal of Clinical Nutrition, 82: 806-12.	
				Meta-analysis	-Klerk M, Verhoef P, Clarke R, Blom HJ, Kok FJ, Schouten EG; MTHFR Studies Collaboration Group. MTHFR 677C-->T polymorphism and risk of coronary heart disease: a meta-analysis. JAMA. 2002 Oct 23-30;288(16):2023-31.	
				Review	-Verhoef P, de Groot LC. Dietary determinants of plasma homocysteine concentrations. Semin Vasc Med. 2005 May;5(2):110-23.	
				Individual study	-Appel, LJ, Miller ER, Jee, SH, Stolzenberg-Solomon, R et al. (2000) Effect of dietary patterns on serum homocysteine. Results of a randomized, controlled feeding study. Circulation, 102, 852-7.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual study	-Brevik, A, Vollset, SE, Tell, GS, Refsum, H et al. (2005) Plasma concentration of folate as a biomarker for the intake of fruit and vegetables: the Hordaland Homocysteine Study. The American Journal of Clinical Nutrition, 81, 434-9.	
				Individual study	-Brouwer, IA, van Dusseldorp, M, West, CE, Meyboom, S et al. Dietary folate from vegetables and citrus fruit decreases plasma homocysteine concentrations in humans in a dietary controlled trial. Journal of Nutrition, 129, 1135-9.	
				Individual study	-Brouwer, IA, van Dusseldorp, M, Thomas, CMG, Duran, M et al. Low-dose folic acid supplementation decreases plasma homocysteine concentrations: a randomized trial. The American Journal of Clinical Nutrition, 69, 99-104.	
				Individual study	-Durga J, Bots ML, Schouten EG, Kok FJ, Verhoef P. Low concentrations of folate, not hyperhomocysteinemia, are associated with carotid intima-media thickness. Atherosclerosis. 2005 Apr;179(2):285-92.	
				Individual study	-Ganji, V & Kafai, MR (2004) Frequent consumption of milk, yogurt, cold breakfast cereals, peppers and cruciferous vegetables and intakes of dietary folate and riboflavin but not vitamins B-12 and B-6 are inversely associated with serum total homocysteine concentrations in the US population. The American Journal of Clinical Nutrition, 80, 1500-7.	
				Individual study	-Gao, X, Yao, M, McCrory, MA, Ma, G et al. (2003) Dietary pattern is associated with homocysteine and B vitamin status in an urban Chinese population. Journal of Nutrition, 133, 3636-42.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual study	-Picciano, MF, West, SG, Ruch, AL, Kris-Etherton, PM et al. (2004) Effect of cow milk on food folate bioavailability in young women. The American Journal of Clinical Nutrition, 80, 1565-9.	
				Individual study	-Van Oort, FVA, Melse-Boonstra, A, Brouwer, IA, Clarke, R et al. (2003) Folic acid and reduction of plasma homocysteine concentrations in older adults: a dose-response study. The American Journal of Clinical Nutrition, 77, 1318-23.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook	"B-Vitamin Treatment Trialists' Collaboration Oxford, United Kingdom, Homocysteine-lowering trials for prevention of cardiovascular events: A review of the design and power of the large randomized trials Am Heart J 2006;151:282-7/ Homocysteine lowering trialsist's Collaboration. Lowering blood homocysteine with folic acid based supplements: meta-analysis of randomized trials. BMJ 1998, 316-8 Schnyder G, Roffi M, Flammer Y, Pin R, Hess OM. Effect of homocysteine-lowering therapy with folic acid, vitamin B12, and vitamin B6 on clinical outcome after percutaneous coronary intervention. The Swiss Heart Study: A Randomized Controlled Trial. JAMA: 288(8): 973-979, 2002. Schnyder G, Roffi M, Flammer Y, Pin R, Eberli FR, et al. Effect of homocysteine-lowering therapy on restenosis after percutanous coronary intervention for narrowings in small coronary arteries. Am J Cardiol. 91:1265-9 Peterson JC, Spence JD. Vitamins and progression of atherosclerosis in hyper-homocyst(e)inaemia. Lancet: 351: 263, 1998. Hackam DG, Peterson JC, Spence JD. What level of plasma homocyst(e)ine should be treated? Effects of vitamin therapy on progression of carotid atherosclerosis in patients with homocyst(e)ine levels above and	

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					below 14 µmol/L. Am J Hypertens: 13: 105-110, 2000 Woo KS, Chook P, Chan LLT, Cheung ASP, Fung WH et al. Long-term improvement in homocysteine levels and endothelial function after 1-year folic acid supplementation. Am J Med:112: 535-539, 2002. Title LM, Cummings PM, Giddens K, Genest JJ, Nassar BA. Effect of folic acid and antioxidant vitamins on endothelial dysfunction in patients with coronary artery disease. J Am Coll Cardiol: 36(3): 758-765, 2000. Willems FF, Aengevaeren WRM, Boers GHJ, Blom HJ, Verheugt FWA. Coronary endothelial function in hyperhomocysteinemia. Improvement after treatment with folic acid and cobalamin in patients with coronary artery disease. J Am Coll Cardiov: 40(4): 766-772, 2002."	
		Blood formation	Must meet minimum requirements for use of the claim source of Vitamin B9 (Folate/Folic acid) as per Annex to Regulation 1924/2006 Applicable to both children and adults	Authoritative Body	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	29
				Authoritative Body	-CH - Switzerland - Ordonnance du March 1995 sur les dennrees 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	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative Body	-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	
				IOM DRV Report	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 2000.	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				EVM Report	Review of Folic Acid. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/evm0018p.pdf).	
				COMA Report	Folic Acid and the Prevention of Disease. Report of the Committee on Medical Aspects of Food and Nutrition Policy. Report on Health and Social Subjects No. 50. DH: The Stationery Office, 2000.	
				Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritive guidelines	Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride (1997); Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid,Biotin, and Choline (1998); Food and Nutrition Board, Institute of Medicine, National Academies. Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13	
				SCF report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Folate. October 2000. http://www.europa.eu.int/comm/food/fs/sc/scf/out80e_en.pdf	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin C					
		Healthy blood vessels	Guidance level is 1000mg/day or less. Agency guidance for supplements is that products containing >1000mg of clacium should carry the label advisory statement "may cause mild stomach upset in sensitive individuals." Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], as per Annex to Regulation 1924/2006.	EVM Expert Report JHCI Expert Report FAO/WHO Expert Report Institute of Medicine (USA) Food and Nutrition Board Expert Report	Review of Vitamin C. Expert Group on Vitamins and minerals (2002). Final Technical Report. Joint Health Claims Initiative (2003). Human vitamin and mineral requirements (2002). Dietary reference intakes for vitamin C, vitamin E selenium and carotenoids (2000)	1,108
		Eye health	> 135 mg/day ingestion of vitamin C is associated with reduced cataract risk Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >1000mg vitamin C	Study	* Jacques P.F. et al., Am J Clin Nutr 66 (4) 911-6 (1997), Long term vitamin c supplement use and prevalence of early age related lens opacities Lindstrom-R-L, Ocul-Surg-News (Int-Ed), 1 - 15 , August (2003):Vitamin therapy use in age related ,macular degeneration;	605

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			should carry the label advisory statement "this amount of vitamin C may cause mild stomach upset in sensitive individuals"	Textbooks, studies	* Takano et al.Curr Eye Res 16 (6) 589-594 (1997):Determination of acsorbic acid in human vitreous humour by HPLC with Uv detection; * Zhang X.M. et al.: Exp Eye Res 73 (3) 303-309 (2001): Microdialysis measurement of ascorbic acid in rabbit vitreous after photodynamic reaction; *Jacques P.F. et al. Arch Ophthalmol 119 (7) 1009-19 (2001):Long term nutrient intake and early age related nuclear lens opacities; *Kuzniarz M. et al. (Blue Montain Eye St.) Am J Ophthal. Jul 132(1):19-26 (2001); Use of vitamin supplements and cataract * Zhang X.M. et al.: Exp Eye Res 73 (3) 303-309 (2001): Microdyalysis measurement of ascorbic acid in rabbit vitreous after photodynamic reaction; * van der Pols JC Proc Nutr Soc 58 (2) 295-301 (1999):A possible role for vitamin c in age related cataract;	
				Textbooks, studies (Beaver Dam, Nurses Health Cohort)	*Taylor A. et al. Am J Clin Nutr 75 (3) 540-9 (2002) :Long term intake of vitamins and caertenoids and odds of early age related cortical and postural subcapsular lens opacities; *Valero MP et al. J Nutr 132 (6) 1299-306 (2002):Vitamin C is associated with reduced risk of cataract in a mediterranean population; *Kottler UB et al. Ophthalmologe 100 (3) 190-196 (2003):Current status with special emphasis on the pathophysiology of oxidative lens damage, nutritional factors, and the SRED stsudy; *Tessier F. et al. Int J Vitam Nutr Res. 68 (5):309-15 (1998):Decrease in Viramin C concentration in human lenses during cataract progression	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				In Vitro Study	C.A. Paterson and M.C. O'Rouke, Vitamin C Levels in Human Tears, Arch Ophthalmol 1987 Mar;105(3):376-7 R. Gogia, S.P. Richer and R.C. Rose, Tear Fluid Content of Electrochemically Active Components Including Water Soluble Antioxidants. Curr Eye Res 1998 Mar;17(3):257-63 S.D. Varma, and R.D. Richards, Ascorbic Acid and the Eye Lens, Ophthalmic Res 1988;20(3):164-73 T.K. Koskela, G.R. Reiss, R.F. Brubaker and R.D. Ellefson, Is the High Concentration of Ascorbic Acid in the Eye an Adaptation to Intense Solar Irradiation? Invest Ophthalmol Vis Sci 1989 Oct;30(10):2265-7 F. Tessier, V. Moreaux, I. Birlouez-Aragon, P. Junes and H. Mondon, Decrease in Vitamin C Concentration in Human Lenses During Cataract Progression .1998. Int J Vitam Nutr Res; 68 (5): 309-315. D.A. Stoyanovsky, R. Goldman, R. Darrow, D. Organisciak, and V. Kagan, Endogenous Ascorbate regenerates Vitamin E in the retina directly and in combination with exogenous dihydrolipoic acid. Curr Eye Res 1995 Mar;14(3):181-9 Malik A., Kojima M, and Sasaki K, Morphological and Biochemical Changes in Lenses in Guinea-pigs after Vitamin C Deficient Diet and UV-B Radiation.1995 Opthalm Res ; 27 (4) : 189-196 Chandra DB; Varma R; Ahrmed S.Varma SD.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Vitamin C in the Human Aqueous Humor and Cataracts, 1986 Int J Vitam Nutr Res; 56 (2) : 165-168 J. Berger, D. Shepard, F. Morrow and A. Taylor. Relationship Between Dietary Intake and Tissue Levels of Reduced and Total Vitamin C in the Nonscorbutic Guinea Pig. 1989. J Nutr.May;119(5) : 734-740 M. Goralska, J. Harned, L.N. Fleisher and M.C. McGahan, The Effect of Ascorbic Acid and Ferric Ammonium Citrate on Iron Uptake and Storage in Lens Epithelial Cells, Exp Eye Res 1998 Jun;66(6):687-97	
				Review	Brown NA; Bron AJ; Harding JJ; Dewer HM Nutrition Supplements and the Eye. 1998.Eye,12,(pt 1) : 127- 133	
		Anitoxidants and aging	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >1000 mg of Vitamin C should carry the label advisory statement "[This amount of Vitamin C] may cause mild stomach upset in sensitive individuals"	textbook	1) Engelhart, M.J.; Geerlings, M.J.; Ruitenberg, A.; van Swieten, J.C.; Hofman, A.; Witteman, J.C.M. and Breteler, M.M.B. (2002) Dietary intake of antioxidants and risk of Alzheimer disease. JAMA 287, 3223-3229 2) Grundman, M. and Delaney, P. (2002) Antioxidant strategies for Alzheimer's disease. Proc. Nutr. Soc. 61, 191-202 3) Ortega, R.M.; Requejo, A.M.; Andrés, P.; Lopez-Sobaler, A.M.; Quintas, M.E.; Redondo, M.R.; Navia, B. and Rivas, T. (1997) Dietary intake and cognitive function in a group of elderly people. Am. J. Clin. Nutr. 66, 803-809	1,211
		Eye health, free radical scavenger	Must meet minimum requirements for use of			603

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >1000mg vitamin C should carry the label advisory statement "this amount of vitamin C may cause mild stomach upset in sensitive individuals"	Study Textbook	Cao G, J Nutr. 1998 Dec;128(12):2383-90; Vitamine: Physiologie, Pathophysiologie, Therapie, H. K. Biesalski et al. ISBN:3-13-118401-9:Serum Antioxidant Capacity is increased by consumption of strawberries, Spinach and Red wine or vitamin C in elderley women;	
		Promotes the antioxidative function of lutein	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s)" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >1000mg vitamin C should carry the label advisory statement "this amount of vitamin C may cause mild stomach upset in sensitive individuals"	Study	* Tanumihardjo S.A. et al., J Am Diet Assoc 105 (1) 114-8 (2005):Lutein absorption is facilitated with cosupplementation of ascorbic acid in young adults	607
		Antioxidant activity. Protection of body	MUST AT LEAST BE A SOURCE OF			45

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		tissues and cells from oxidative damage. Antioxidant.	MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing >1000 mg of Vitamin C should carry the label advisory statement "[This amount of Vitamin C]* may cause mild stomach upset in sensitive individuals.." Applicable to both children and adults 30 mg /day equal to 50% of ADI (Acceptable Daily Intake)	Authoritative body	CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	
				Authoritative body	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	
				Authoritative body	FNFC/FOSHU - Japan http://www.mhlw.go.jp/english/topics/foodsafety/fhc/index.html	
				Authoritative body	SNF - Swedish Nutrition Foundation http://www.snf.ideon.se/snf/en/rh/Healh_claims_FF.htm	
				Authoritative/Scientific Bodies	VITAMIN C and Antioxidant Action -National Research Council. Recommended Dietary Allowances 10th Edition. Washington DC: National Academy Press, 1989.	
				Authoritative/Scientific Bodies	Scientific Committee for Food. Reports of The Scientific Committee for Food (31st Series), Nutrient and Energy Intakes for the European Community (Opinion Expressed on 11 December, 1992). Directorate - General Industry. The Commission of the European Communities, 1993. Chapter 15.	
				Reviews and Individual Studies	Carr AC & Frei B. Toward a New Recommended Dietary Allowance for Vitamin C Based on Antioxidant and Health Effects in Humans. American Journal of Clinical Nutrition 1999; 69: 1086-1107	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Reviews and Individual Studies	Hallberg L, Sandstrom B, Ralph A, Arthur J. Iron, Zinc and Other Trace Elements. In: Garrow JS, James WPT, Ralph A eds. Human Nutrition and Dietetics, 10th Edition. Edinburgh: Churchill Livingstone, 2000: 177-209.	
				Reviews and Individual Studies	Kallner AB, Hartmann D, Hornig DH. On the Requirements of Ascorbic Acid in Man: Steady-State Turnover and Body Pool in Smokers. American Journal of Clinical Nutrition 1981; 34: 1347-1355.	
				Reviews and Individual Studies	Riemersma RA. Epidemiology and the Role of Antioxidants in Preventing Coronary Heart Disease: a Brief Overview. Proceedings of the Nutrition Society 1994; 53: 59-65.	
				Reviews and Individual Studies	Rock CL, Jacob RA, Bowen PE. Update on the Biological Characteristics of Antioxidant Micronutrients: Vitamin C, Vitamin E and the Carotenoids. Journal of the American Dietetic Association 1996; 96: 693-702.	
				Reviews and Individual Studies	Southgate DAT. Food processing. In: Garrow JS, James WPT, Ralph A eds. Human Nutrition and Dietetics, 10th Edition. Edinburgh: Churchill Livingstone, 2000: 397-409.	
				IOM DRV Report	Institute of Medicine Dietary Reference Intakes for Vitamin C, Vitamin E, selenium and carotenoids. Washington D.C. National Academy Press, 2000.	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				EVM Report	Revised review of Vitamin C. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/vitaminc.pdf).	
				Study	* Richer S., Int Ophthalmol Clin 40 (4) 1-16 (2000):no title	
				Authoritive guidellines.	Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13	
				Published research study	Frei B, England L, Ames BN (1989) Ascorbate is an outstanding antioxidant in human blood plasma. Proc Natl Acad Sci; 86: 6377-6381.	
				Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Churchill Livingstone, 2000. Bender D.A. Nutritional Biochemistry of the Vitamins. Cambridge, 2003.	
		Regeneration of vitamin E, have synergistic effects	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >1000mg vitamin C should carry the label advisory statement "this amount of vitamin C may cause mild stomach	Textbooks, studies	*Janisch KM et al. (Buch) Augustin A (ed):Nutrition and the Eye. Dev Ophthalmol Basel, Karger, 2005, vol 38, pp59-69 Vitamin C, E and Flavonoids (2005);	606

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			upset in sensitive individuals"			
		Immune system function	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing >1000mg of Vitamin C should carry the label advisory statement may cause mild stomach upset in sensitive individuals Agency guidance for supplements is that products containing >1000mg Vitamin C should carry the label statement '[This amount of Vitamin C] may cause mild stomach upset in sensitive individuals.' Only for at least 0.5 g vitamin C, 10 mg zinc	Authoritative/Scientific Bodies	Department of Health. Dietary Reference Values for Food Energy and Nutrients for the United Kingdom, Report on Health and Social Subjects 41. London: HMSO, 1991.	50
				Authoritative/Scientific Bodies	EGVM: Expert Group of Vitamins and Minerals, Safe upper levels for vitamins and Minerals - Mai 2003.	
				Authoritative/Scientific Bodies	Institute of Medicine, F.N.B., Vitamin C, in Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium and Carotenoids. National Academy Press: Washington DC. 2000. 95-185.	
				Authoritative/Scientific Bodies	JHCI: Joint Health Claims Initiative (UK), List of Well-Established Nutrient Function Statements, A report by the Joint Health Claims Initiative to the Food Standards Agency. Prepared by JHCI Executive Director. 17th Dec 2003.	
				Authoritative/Scientific Bodies	SCF, Request N° EFSA-Q-2003-018: Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Vitamin C (L-Ascorbic acid, its calcium, potassium and sodium salts and L-ascorbyl-6-palmitate). Adopted on 28 April 2004, Scientific Committee on Food SCF/CS/NUT/UPPLEV/ 54. Final, 11 October 2001 (expressed on 26 September 2001).	
				Textbooks and Monographs	Courtand M, Sagaut P. Acide ascorbique (Vitamine C). In Les Vitamines - Aspects metaboliques, genetiques, nutritionnels et therapeutiques. A. Munich (Ed.), Masson, Paris, 1987, pp.326-346.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbooks and Monographs	Guilland JC, Lequeu B., Vitamine C et grippe, - Les Vitamines du nutriment au medicament. Ed. Medicales Internationales 1992. pp.293-295.	
				Textbooks and Monographs	Moser U., Bendich A. Vitamin C. In Handbook of vitamins, Edited by L.J. Machlin, 2nd edition, revised and expanded Marcel Dekker Inc, 1991, 5, 195-232. (and ANDERSON R. The immunostimulatory, anti-inflammatory and anti-allergic properties of ascorbate. In Advances in Nutritional Research, vol.6, H.H. Draper (Ed.). Plenum Press, New York 1984, pp. 19-45.)	
				Reviews	Hemila H., Does vitamin C alleviate the symptoms of the common cold? A review of current evidence, Scand J Infect Dis. 1994, 26 (1) : 1-6.	
				Reviews	Hemila H: Vitamin C and common cold incidence: a review of studies with subjects under heavy physical stress. Int J Sports Med 1996;17:379-383.	
				Clinical Trials	Bucca C, Rolla G, Arossa W, Caria E, Elia C, Nebiolo F, Baldi S, Effect of ascorbic acid on increased bronchial responsiveness during upper airway infection, Respiration. 1989;55(4):214-9.	
				Clinical Trials	Bucca C, Rolla G, Oliva A, Farina JC, Effect of vitamin C on histamine bronchial responsiveness of patients with allergic rhinitis, Ann Allergy. 1990 Oct;65(4):311-4	
				Clinical Trials	Du W.D., Yuan Z.R., Sun J., Tang J.X., Cheng A.Q., Shen D.M., Huang C.J., Song X.H., Yu X.F., Zheng S.B., Therapeutic efficacy of high-dose vitamin C on acute pancreatitis and its potential mechanisms, d. J. Gastroenterol., 2003, 9 (11), 2565-2569.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Clinical Trials	Lenton KJ, Sane AT, Therriault H, Cantin AM, Payette H, Wagner JR., Vitamin C augments lymphocyte glutathione in subjects with ascorbate deficiency, Am J Clin Nutr. 2003;77(1):189-195	
				Clinical Trials	Nieman D.C., Peters .E.M., Henson D.A., Nevines E.I., Thompson M.M., Influence of vitamin C supplementation on cytokine changes following an ultramarathon, J. Interferon Cytokine Res., 2000, 20 (11), 1029-1035.	
				Clinical Trials	Sasazuki S, Sasaki S, Tsubono Y, Okubo S, Hayashi M, Tsugane S., Effect of vitamin C on common cold: randomized controlled trial, Eur J Clin Nutr. 2006;60(1):9-17.	
				Clinical Trials	Tauler P., Aguilo A., Gimeno I., Noguera A., Agusti A., Tur J.A., Pons A., Differential response of lymphocytes and neutrophils to high intensity physical activity and to vitamin C diet supplementation, Free Radic. Res., 2003, 37 (9), 931-938.	
				Clinical Trials	Thompson D., Williams C., McGregor S.J., Nicholas C.W., McArdle F., Jackson M.J., Powell J.R., Prolonged vitamin C supplementation and recovery from demanding exercise, Int. J. Sport Nutr. Exerc. Metab., 2001, 11 (4), 466-481.	
				Clinical Trials	Van Straten M, Josling P., Preventing the common cold with a vitamin C supplement: a double-blind, placebo-controlled survey, Adv Ther. 2002;19(3):151-9	
				Individual Studies	Anderson R: Vitamin C; in Hughes DA, Darlington LG, Bendich A (eds): Diet and human immune function. Humana Press, Totowa, NJ, chapter 7; 2004, pp 133-148	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Studies	Anderson, R., Oosthuizen, R., Maritz, R., Theron, A.,Van Rensburg, A.J., The effects of increasing weekly doses of ascorbate on certain cellular and humoral immune functions in normal volunteers. Am J Clin Nutr, 1980. 33(1): 71-76.	
				Individual Studies	Anderson TW, Beaton GH, Corey PN, Spero L: Winter illness and vitamin C: The effect of relatively low doses. Can Med Assoc J 1975;112:823-826.	
				Individual Studies	Brenner, G., [Enteral absoprtion of ascorbic acid in man after application of a micro-encapsulated retard preparation (author's transl)]. Med Klin, 1975. 70(28-29): 1219-1222.	
				Individual Studies	Campbell J.D., Cole M., Bunditrutavorn B., Vella A.T., Ascorbic acid is a potent inhibitor of various forms of T cell apoptosis, Cell. Immunol., 1999, 194 (1), 1-5.	
				Individual Studies	Carr, A.C. and Frei, B., Toward a new recommended dietary allowance for vitamin C based on antioxidant and health effects in humans. Am J Clin Nutr, 1999. 69(6): 1086-1107.	
				Individual Studies	Chandra R: Influence of multinutrient supplement on immune responses and infection-related illness in 50-65 year old individuals. Nutr Res 2002a;22:5-11.	
				Individual Studies	Chandra RK: Nutrition and the immune system from birth to old age. Eur J Clin Nutr 2002b;56:S73-S76.	
				Individual Studies	Delafuente JC. Prendergast JM. Modigh A., Immunologic modulation by vitamin C in the elderly, Int J Immunopharmacol. 1986; 8(2): 205-211.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Studies	Douglas, R., Hemila, H., D'Souza, R., Chalker, E.,Treacy, B., Vitamin C for preventing and treating the common cold. Cochrane Database Syst Rev, 2004(4): CD000980.	
				Individual Studies	Douglas RM, Chalker EB, Treacy B: Vitamin C for preventing and treating the common cold. Cochrane Database Syst Rev 2000;2.	
				Individual Studies	Dwenger A., Funck M., Lueken B., Schweitzer G., Lehmann U., Effect of ascorbic acid on neutrophil functions and hypoxanthine/xanthine oxidase-generated, oxygen-derived radicals, Eur. J. Clin. Chem. Clin. Biochem., 1992, 30 (4), 187-191.	
				Individual Studies	Field, C.J., Johnson, I.R.,Schley, P.D., Nutrients and their role in host resistance to infection. J Leukoc Biol, 2002. 71(1): 16-32.	
				Individual Studies	Fraker PJ, Lill-Elghanian DA: The many roles of apoptosis in immunity as modified by aging and nutritional status. J Nutr Health Aging 2004;8: 56-63.	
				Individual Studies	Galli F., Vitamin C, vitamin E and immune response, J Nutr Biochem. 2005, 16 (4) : 257.	
				Individual Studies	Hemila H., Vitamin C, respiratory infections and the immune system, Trends Immunol. 2003, 24 (11) : 579-80.	
				Individual Studies	Hemila H. Vitamin C and the Common Cold. British Journal of Nutrition 1992; 67(1): 3-16.	
				Individual Studies	Hemila H. Vitamin C Intake and Susceptibility to the Common Cold. British Journal of Nutrition. 1997, 77(1): 59-72.	
				Individual Studies	Hemila H, Chalker E, D´Souza RRD, Douglas RM, Treacy B: Vitamin C for preventing and treating the common cold. The Cochrane Database of Systematic Reviews 2004, issue 4.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Studies	Hemila H, Douglas RM: Vitamin C and acute respiratory infections. Int J Tuberc Lung Dis 1999;3:756-761.	
				Individual Studies	Hemila H: Vitamin C intake and susceptibility to the common cold - Invited commentary - Reply. Br J Nutr 1997c;78:861-866.	
				Individual Studies	Hemila H: Vitamin C supplementation and the common cold was Linus Pauling right or wrong? Int J Vitam Nutr Res 1997a;67:329-335.	
					-	
				Individual Studies	Heuser G, Vojdani A: Enhancement of natural killer cell activity and T and B cell function by buffered vitamin C in patients exposed to toxic chemicals; the role of protein kinase-C. Immunopharmacol Immunotoxicol 1997;19:291-312	
				Individual Studies	Higdon, J.V. and Frei, B., Vitamin C: An Introduction, in The Antioxidant Vitamins C and E, Packer, L., et al., Editors. AOCS Press: Champaign, Illinois. 2002. 1-16.	
				Individual Studies	Hughes DA: Antioxidant vitamins and immune function; in Calder PC, Field CJ, Gill HS (eds): Nutrition and immune function. CABI 2002, pp 171-191	
				Individual Studies	Hume R and Weyers E. Changes in Leucocyte Ascorbic Acid During the Common Cold. Scottish Medical Journal. 1973. 18: 3 7	
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Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Studies	-Jacob, R.A., Kelley, D.S., Pianalto, F.S., Swendseid, M.E., Henning, S.M., Zhang, J.Z., Ames, B.N., Fraga, C.G.,Peters, J.H., Immunocompetence and oxidant defense during ascorbate depletion of healthy men. Am J Clin Nutr, 1991. 54(6 Suppl): 1302S-1309S.	
				Individual Studies	Jacob, R.A., Vitamin C, in Modern Nutrition in Health and Disease, Shils, M.E., et al., Editors. Williams & Wilkins: Baltimore. 1999. 467-483.	
				Individual Studies	Johnston CS: Complement component C1q unaltered by ascorbate supplementation in healthy men and women. J Nutr Biochem 1991;2:499-501	
				Individual Studies	Kelley, D.S. and Bendich, A., Essential nutrients and immunologic functions. Am J Clin Nutr, 1996. 63(6): 994S-996S.	
				Individual Studies	Kennes B, Dumont I, Brohee D, Hubert C, Neve P: Effect of vitamin C supplements on cell-mediated immunity in older people. Gerontology 1983;29:305-310.	
				Individual Studies	Levine M, Conry-Cantilena C, Wang Y, Welch RW, Washko PW, Dhariwal KR, Park JB, Lazarev A, Graumlich JF, King J, Cantilena LR: Vitamin C pharmacokinetics in healthy volunteers: evidence for a recommended dietary allowance. Proc Natl Acad Sci USA 1996;93:3704-3709	
				Individual Studies	Levy R, Shriker O, Porath A, Riesenberg K, Schlaeffer F: Vitamin C for the treatment of recurrent furunculosis in patients with impaired neutrophil functions. J Infect Dis 1996;173:1502-1505	
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Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Studies	Muggli R: Vitamin C and phagocytes; in Cunningham-Rundles S (ed): Nutrient modulation of the immune response. New York, Basel, Hongkong, Marcel Dekker Inc, 1992, pp 75-90	
				Individual Studies	Panush RS, Delafuente JC, Katz P, Johnson J. Modulation of certain immunologic responses by vitamin C. III. Potentiation of in vitro and in vivo lymphocyte response. Int J Vitam Nutr Res Suppl 1982;23:35-47	
				Individual Studies	Peters, E.M., Goetzsche, J.M., Grobbelaar, B.,Noakes, T.D., Vitamin C supplementation reduces the incidence of postrace symptoms of upper-respiratory-tract infection in ultramarathon runners. Am J Clin Nutr, 1993. 57(2): 170-174.	
				Individual Studies	Schwager J., Schulze J., Modulation of interleukin production by ascorbic acid, Vet. Immunol. Immunopathol., 1998, 64 (1), 45-57.	
				Individual Studies	Schwartz AR, Togo Y, Hornick RB, Tominaga S and Gleckman RA. Evaluation of the Efficacy of Ascorbic Acid in Prophylaxis of Induced Rhinovirus 44 Infection in Man. The Journal of Infectious Diseases. 1973, 128 (4): 500 505.	
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				Individual Studies	Shankar AH: Nutritional modulation of malaria morbidity and mortality. J Infect Dis 2000;182:S37-S53.	
				Individual Studies	Shils ME, Olson JA, Shike M, Ross AK: Modern Nutrition in Health and Disease, 9th Ed. Philadelphia, Baltimore, New York, London, Buenos Aires, Hong Kong, Sydney, Tokyo, Lippincott Williams & Wilkins, 1999, pp223-240 & pp467-484.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Studies	Siegel BV, Morton JI., Vitamin C and immunity: natural killer (NK) cell factor, Int J Vitam Nutr Res. 1983 ; 53(2) : 179-183.	
				Individual Studies	Siegel BV: Vitamin C and the immune response in health and disease; in Klurfeld DM (ed) Nutrition and immunology. Plenum Press, New York, 1993, pp 167-196	
				Individual Studies	Washko P., Rotrosen D., Levine M., Ascorbic acid in human neutrophils, Am. J. Clin. Nutr., 1991, 54 (6 Suppl), 1221S-1227S.	
				Individual Studies	Wilson CWM and Loh HS. Common Cold and Vitamin C. The Lancet. 1973, 1: 638 641.	
				Individual Studies	Wintergerst, E.S., Maggini, S.,Hornig, D.H., Immune-enhancing role of vitamin C and zinc and effect on clinical conditions. Ann Nutr Metab, 2006. 50(2): 85-94.	
				Individual Studies	Wolf G., Uptake of ascorbic acid by human neutrophils, Nutr. Rev., 1993, 51 (11), 337-8.	
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
				Individual Studies	Webb R., Vitamin C. Give a boost to your immune system, Diabetes Forecast. 2004, 57 (1) : 17-9.	
		OXIDATIVE STRESS. Acts as antioxidant and helps protect	Claim to be only used for Foods for sport people under the Dir. 89/398/EEC. The DRA			1,598

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		the body tissues against the potentially damaging effects of free radicals	for vit C is 90 mg (M) and 75 mg (F). CEDAP recommendations for sports people: vit C is 1000 mg. Agency guidance for supplements is that products containing >1000 mg of Vitamin C should carry the label advisory statement "This amount of Vitamin C may cause mild stomach upset in sensitive individuals"	Textbook RCT French legislation	Sports Nutrition by Jeukendrup A and Gleeson M, Chap 9, The micronutrients: vitamins and minerals, p199, 228, ed 2004; Effects of vitamin C and E on in vivo lipid peroxidation: results of a randomized controlled trial. Huang HY et al. Am J Clin Nutr 76, 549-555, 2002 Produits diététiques de l'effort. Order 1977-07-20, Articles 49-54	
		Immune system.	Sports foods and food supplements containing vitamin C and targeted at sports people Agency guidance for supplements is that products containing >1000 mg of Vitamin C should carry the label advisory statement "This amount of Vitamin C may cause mild stomach upset in sensitive individuals" Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006.			1,597

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Review paper	Biological Significance of Ascorbic Acid (Vitamin C) in Human Health – A Review Iqbal K, Khan A, Ali Khan Khattak MM Pakistan Journal of Nutrition 3(1): 5-13, 2004 White paper on inflammation and associated diseases – Beneficial role of citrus. Cancalon P	
				Textbook Human study Randomised clinical trial (RCT)	Vitamin Intake and Health: A Scientific Review, 1991; p 96, 105, 120 Gaby SK, Bendich A, Singh VN, Machlin LJ. Ascorbate is an outstanding antioxidant in human blood plasma - Frei B, England L, Ames BN Proc. Nati. Acad. Sci. USA, 86: 6377-6381, 1989. Vitamin C supplementation reduces the incidence of postrace symptoms of upper-respiratory-tract infection in ultramarathon runners. Peters EM, Goetzsche JM, Grobbelaar B, Noakes TD Am J Clin Nutr 57: 170-4, 1993	
		Healthy skin	Guidance level is 1000mg/day or less. Agency guidance for supplements is that products containing >1000mg of clacium should carry the label advisory statement "may cause mild stomach upset in sensitive individuals." Must meet minimum requirements for use of	EVM Expert Report JHCI Expert Report FAO/WHO Expert Report Institute of Medicine (USA) Food and Nutrition Board Expert Report	Review of Vitamin C. Expert Group on Vitamins and minerals (2002). Final Technical Report. Joint Health Claims Initiative (2003). Human vitamin and mineral requirements (2002). Dietary reference intakes for vitamin C, vitamin E selenium and carotenoids (2000)	1,107

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			the claim "source of [name of vitamin/s] and/or [name of mineral/s], as per Annex to Regulation 1924/2006.			
		Connective tissue - structure and function: bones, teeth, gums, skin/Normal collagen formation	MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing > 1000 mg mg of Vitamin C should carry the label advisory statement "may cause mild stomach upset in senistive individuals" - Applicable to both children and adults 30 mg /day equal to 50% of ADI (Acceptable Daily Intake)	Authoritative body Authoritative body Authoritative body Authoritative body VITAMIN C and Connective Tissue Textbook Reviews	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 -CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr 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 CEDAP. Avis de la commission interministerielle d'etude des produits destines a une alimentation particuliere (CEDAP) en date du 18 decembre 1996 sur les recommandations relatives au caractere non trompeur des seuils des allegations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Repression des fraudes) du 7 octobre 1997 Hahn, Strohle, Wolters: Ernehrung. Physiologische Grundlagen, Prevention, Therapie. WVG. 2005. -Asplund K. Antioxidant vitamins in the prevention of cardiovascular disease: a systematic review. J. Int. Med. 2002;251:372-392.	47

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Clinical Trials	-A randomized, placebo-controlled, clinical trial of high-dose supplementation with vitamins C and E, beta carotene, and zinc for age-related macular degeneration and vision loss: AREDS report no. 8. Arch. Ophthalmol. 2001;119(10):1417-1436.	
				Clinical Trials	-A randomized, placebo-controlled, clinical trial of high-dose supplementation with vitamins C and E and beta carotene for age-related cataract and vision loss: AREDS report no. 9. Arch. Ophthalmol. 2001;119(10):1439-1452.	
				IOM DRV Report	Institute of Medicine Dietary Reference Intakes for Vitamin C, Vitamin E, selenium and carotenoids. Washington D.C. National Academy Press, 2000.	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				EVM Report	Revised review of Vitamin C. Expert Group on Vitamins and Minerals. August 2002. (www.food.gov.uk/multimedia/pdfs/vitaminc.pdf).	
				Authoritive guidelines	Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13	
				FAO/WHO Expert Report	Human vitamin and mineral requirements (2002).	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Churchill Livingstone, 2000. Bender D.A. Nutritional Biochemistry of the Vitamins. Cambridge, 2003.	
		Healthy gums	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], as per Annex to Regulation 1924/2006. Guidance level is 1000mg/day or less. Agency guidance for supplements is that products containing >1000mg of clacium should carry the label advisory statement "may cause mild stomach upset in sensitive individuals."	EVM Expert Report JHCI Expert Report FAO/WHO Expert Report Institute of Medicine (USA) Food and Nutrition Board Expert Report	Review of Vitamin C. Expert Group on Vitamins and minerals (2002). Final Technical Report. Joint Health Claims Initiative (2003). Human vitamin and mineral requirements (2002). Dietary reference intakes for vitamin C, vitamin E selenium and carotenoids (2000)	1,106
		Neurological system function	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing > 1000 mg of Vitamin C should carry the label advisory statement "may	Authoritative body IOM DRV Report	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 Institute of Medicine Dietary Reference Intakes for Vitamin C, Vitamin E, selenium and carotenoids. Washington D.C. National Academy Press, 2000.	49

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			cause mild stomach upset in senistive individuals" -	Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
			Applicable to both children and adults The product must contain at least 15% of the RDA	EVM Report	Revised review of Vitamin C. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/vitaminc.pdf).	
				IOM DRV Expert Report	Institute of Medicine Dietary Reference Intakes for Vitamin C, Vitamin E, selenium and carotenoids. Washington D.C. National Academy Press 2000	
				Encyclopaedia of Human Nutrition	Encyclopaedia of Human Nutrition 2E. Editor-in-chief Michele J. Sadler, editors J.J. Strain, Benjamin Caballero. San Diego: Academic Press c.1999	
				EVM Expert Report	Revised Review of Vitamin C; Expert Group on Vitamins and Minerals, Aug 2002 (http://www.food.gov.uk/multimedia/pdfs/vitaminc.pdf).	
		Energy and Vitality	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >1000 mg of Vitamin C should carry the label advisory statement "This			977

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			amount of Vitamin C may cause mild stomach upset in sensitive individuals"	OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	
		Antioxidant activity Blood vessels Neurological system	Minimum 15% RDA per daily dosage as per 90/496/EC Agency guidance for supplements is that products containing >1000 mg of Vitamin C should carry the label advisory statement "[This amount of Vitamin C]* may cause mild stomach upset in sensitive individuals."	Authoritative Body Reference book	Safe upper levels for vitamins and minerals. Expert Group on Vitamins and Minerals. May 2003 (http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf)	1,116

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Structure and function of blood vessels	Must meet minimum requirements for use of the claim "Vitamin C" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing > 1000 mg mg of Vitamin C should carry the label advisory statement "may cause mild stomach upset in senistive individuals" - Applicable to both children and adults	Authoritative body IOM DRV Report Nutrition textbook EVM Report	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 Institute of Medicine Dietary Reference Intakes for Vitamin C, Vitamin E, selenium and carotenoids. Washington D.C. National Academy Press, 2000. Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Revised review of Vitamin C. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/vitaminc.pdf). Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	46
		The role of vitamins and minerals in mental performance (where mental performance stands for those aspects of	Only for products with at least 100 % RDA of vitamins Agency guidance for supplements is that products containing			1,189

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		brain and nerve functions which determine aspects like concentration, learning, memory and reasoning)	>1000 mg of Vitamin C should carry the label advisory statement "[This amount of Vitamin C] may cause mild stomach upset in sensitive individuals"	textbook	1) Institute of Medicine (2000) Vitamin C In Dietary reference intakes for vitamin C, vitamin E, selenium and carotenoids. National Academic Press, Washington D.C, chapter 5, pp 95-185 2) 3) Jacob, R.A. (1999) Vitamin C In Shils, M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 467-483 4) Johnston, C.S.; Steinberg, F.M. and Rucker, R.B. (2001) Vitamin C In Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 15, pp 529-554 5) Johnston, C.S. (2001) Vitamin C In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 16, pp 175-183 6) Haller, J. (2005) Vitamins and Brain Function. In: Lieberman, H.R.; Kanarek, R.B. and Prasad, C. (eds.) Nutritional Neuroscience. CRC Press, Boca Raton, 207-233	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				studies	Heseker, H.; Kübler, W.; Pudel, V. and Westenhöfer, J (1995) Interaction of vitamins with mental performance. Bibl Nutr Dieta. Basel: Karger 52, 43-55 Carroll, D.; Ring, C.; Suter, M. and Willemsen, G. (2000) The effects of an oral multivitamin combination with calcium, magnesium, and zinc on psychological well-being in healthy young male volunteers: a double-blind placebo-controlled trial. Psychopharmacology (Berl) 150(2), 220-225 Benton, D.; Fordy, J. and Haller, J. (1995a) The impact of long-term vitamin supplementation on cognitive functioning. Psychopharmacol. 117(3), 298-305 Benton, D.; Haller, J. and Fordy, J. (1995a) Vitamin supplementation for 1 year improves mood. Neuropsychobiology 3, 98-105	
		Vitamin/mineral supplementation to reduce fatigue and tirednes in situations of inadequate micronutrient status	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >1000 mg of Vitamin C should carry the label advisory statement "[This amount of Vitamin C]* may cause mild stomach upset in sensitive individuals"			1,168

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook; studies	Institute of Medicine (2000) Vitamin C In Dietary reference intakes for vitamin C, vitamin E, selenium and carotenoids. National Academic Press, Washington D.C, chapter 5, pp 95-185 Jacob, R.A. (1999) Vitamin C In Shils, M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 467-483 Johnston, C.S.; Steinberg, F.M. and Rucker, R.B. (2001) Vitamin C In Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 15, pp 529-554 Johnston, C.S. (2001) Vitamin C In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 16, pp 175-183 5) Driskell, J. A. (1999a) Vitamins, in Sports Nutrition, pp 49-83, Wolinsky I. ed, CRC Press; Tsao C.S. An overview of ascorbic acid chemistry and biochemistry. In: Vitamin C in Health and Disease (Packer L., Fuchs J., eds) Marcel Dekker, New York (1997) pp 25-58 Lukaski, H.C. (2004) Vitamin and mineral status: effects on physical performance. Nutrition 20, 632-644 Johnston, C.S.; Swan, P.D.; Corte, C. (1999) Substrate utilization and work efficiency during submaximal exercise in vitamin C depleted-repleted adults. Internat. J. Vit. Nutr.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Res. 69, 41-44	
		Energy metabolism: camitine biosynthesis	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Agency guidance for supplements is that products containing > 1000 mg of Vitamin C should carry the label advisory statement "may cause mild stomach upset in senistive individuals" -	VITAMIN C and Energy Metabolism Individual Studies	-Driskell, J. A. (1999) Vitamins, in Sports Nutrition, pp 49-83, Wolinsky I. ed, CRC Press	52
				Individual Studies	Institute of Medicine (2000) Vitamin C In Dietary reference intakes for vitamin C, vitamin E, selenium and carotenoids. National Academic Press, Washington D.C, chapter 5, pp 95-185	
				Individual Studies	-Institute of Medicine (2001) Iron In Dietary Reference Intakes for vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc. National Academic Press, Washington D.C, chapter 9, pp 290-393	
				Individual Studies	-Jacob, R.A. (1999) Vitamin C In Shils, M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): Modern Nutrition in Health and Disease, 9th edition. Baltimore; Williams & Wilkins, pp 467-483;	
				Individual Studies	-Johnston, C.S.; Steinberg, F.M. and Rucker, R.B. (2001) Vitamin C In Rucker, R.B.; Suttie, J.W.; McCormick, D.B., Machlin, L.J. (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 15, pp 529-554;	
				Individual Studies	-Johnston, C.S. (2001) Vitamin C In Bowman, B.A., Russel, R.M. (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, chapter 16, pp 175-183	
				Individual Studies	-Tsao C.S. An overview of ascorbic acid chemistry and biochemistry. In: Vitamin C in Health and Disease (Packer L., Fuchs J., eds) Marcel Dekker, New York (1997) pp 25-58	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
		Cell protection from free radical damage	The product must contain at least 15% of the RDA Agency guidance for supplements is that products containing > 1000 mg of Vitamin C should carry the label advisory statement "[This amount of Vitamin C]* may cause mild stomach upset in sensitive individuals. "	IOM DRV Expert Report Encyclopaedia of Human Nutrition EVM Expert Opinion	Institute of Medicine Dietary Reference Intakes for Vitamin C, Vitamin E, selenium and carotenoids. Washington D.C. National Academy Press 2000 Encyclopaedia of Human Nutrition 2E. Editor-in-chief Michele J. Sadler, editors J.J. Strain, Benjamin Caballero. San Diego: Academic Press c.1999 Revised Review of Vitamin C; Expert Group on Vitamins and Minerals, Aug 2002	2,343
		Iron absorption	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing > 1000 mg mg of Vitamin C should carry the label advisory statement may cause mild upset in	Authoritative body Authoritative body	CH - Switzerland - Ordonnance du March 1995 sur les dennrees 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 SNF - Swedish Nutrition Foundation http://www.snf.ideon.se/snf/en/rh/Healh_claims_FF.htm	48

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			senistive individuals" when consumed with iron- containing foods x	Authoritative body	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	
			Applicable to both children and adults 30mg /day equal to 50% of ADI (Acceptable Daily Intake)	Authoritative body	CEDAP. Avis de la commission interministerielle d'etude des produits destines a une alimentation particuliere (CEDAP) en date du 18 decembre 1996 sur les recommandations relatives au caractere non trompeur des seuils des allegations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Repression des fraudes) du 7 octobre 1997	
				IOM DRV Report	Institute of Medicine Dietary Reference Intakes for Vitamin C, Vitamin E, selenium and carotenoids. Washington D.C. National Academy Press, 2000.	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				EVM Report	Revised review of Vitamin C. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/vitaminc.pdf).	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Expert Textbook RCT	Nordic Nutrition Recommendations (NNR) -Integrating nutrition and physical activity. Nordic Council of Ministers, Norden, 2004. Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Churchill Livingstone, 2000. Tetens I, Larsen TM, Kristensen MB et al. The importance of dietary composition for efficacy of iron absorption measured in a whole diet that includes rye bread fortified with ferrous fumerate: a radioisotope study in young women. Br J Nutr 2005;94:720-6.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin D					
		Encocrine / thyroid metabolism	Typical adults dosages 5 – 50 mcg daily for vitamin D2, (ergocalciferol, and up to 100 mcg daily for vitamin D3 (cholecalciferol). Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.	Human studies / RCTs	Martin KJ, Gonzalez E, Lindberg JS, et al. Paricalcitol dosing according to body weight or severity of hyperparathyroidism: a double-blind, multicenter, randomized study. Am J Kidney Dis 2001;38(5 Suppl 5):S57-S63. Roh JL, Park CI. Routine oral calcium and vitamin D supplements for prevention of hypocalcemia after total thyroidectomy. Am J Surg. 2006 Nov;192(5):675-8. Trang HM, Cole DE, Rubin LA, et al. Evidence that vitamin D3 increases serum 25-hydroxyvitamin D more efficiently than does vitamin D2. Am J Clin Nutr 1998;68(4):854-858.	1,087
		Muscle growth, development and function	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006	Meta-Analysis	Bischoff-Ferrari HA et al. Effect of vitamin D on falls: a meta-analysis. JAMA. 291: 1999-2006, 2004a.	58
				Reviews	-Boland R. Role of vitamin D in skeletal muscle function. Endocrine Reviews. 7(4): 434-448.	
				Reviews	-Grant WB and Holick MF. Benefits and Requirements of vitamin D for optimal health: a review. Altern Med Rev. 10(2): 94-111, 2005	
				Reviews	-Janssen HCJP et al. Vitamin D deficiency, muscle function, and falls in elderly people. Am J Clin Nutr. 75: 611-615, 2002	
				Reviews	-Zitterman A. Vitamin D in preventive medicine: are we ignoring the evidence? Br J Nutr. 89: 552-572, 2003.	
				Individual Studies Human	-Bischoff HA et al. Effects of vitamin D and calcium supplementation on falls: a randomized controlled trial. J Bone Miner Res. 18: 343-351, 2003.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Studies Human	-Bischoff Ha et al. In situ detection of 1,25-dihydroxyvitamin D3 receptor in human skeletal muscle tissue. Histochemical J. 33: 19-24, 2001.	
				Individual Studies Human	-Bischoff-Ferrari et al. Vitamin D receptor expression in human muscle tissue decreases with age. J Bone Miner Res. 19: 265-9, 2004c.	
				Individual Studies Human	-Bischoff-Ferrari HA et al. Higher 25-hydroxyvitamin D concentrations are associated with better lower-extremity function in both active and inactive persons aged >60y. Am J Clin Nutr. 80: 752-758, 2004b.	
				Individual Studies Human	-Dhesi JK et al. Vitamin D supplementation improves neuromuscular function in older people who fall. Age and Aging. 33: 589-595, 2004.	
				Individual Studies Human	-Fraser D and Scriver CR. Hereditary disorders associated with vitamin D resistance or defective phosphate metabolism. In: DeGroot LJ, ed. Endocrinology, vol 2. New York: Grune & Stratton, 797-807, 1979.	
				Individual Studies Human	-Geusens P et al. Quadriceps and grip strength are related to vitamin D receptor genotype in elderly non-obese women. J Bone Miner Res. 12: 2082-2088, 1997.	
				Individual Studies Human	-Grady D et al. 1,25-dihydroxyvitamin D3 and muscle strength in the elderly: a randomized controlled trial. J Clin Endo Metab. 73(5): 1111-1117, 1991.	
				Individual Studies Human	-Kenny et al. Effects of vitamin D supplementation on strength, physical function, and health perception in older, community-dwelling men. J Am Geriatr Soc. 51: 1762-1767, 2003.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Studies Human	-Latham et al. A randomized, controlled trial of quadriceps resistance exercise and vitamin D in frail older people: the frailty interventions trial in elderly subjects (FITNESS). J Am Geriatr Soc. 51: 291-299, 2003.	
				Individual Studies Human	-Lips et al. Vitamin D supplementation and fracture incidence in elderly persons. Ann Int Med. 124(4): 400-406, 1996.	
				Individual Studies Human	-Lips P et al. A global study of vitamin D status and parathyroid function in post menopausal women with osteoporosis: baseline data from the multiple outcomes of raloxifene evaluation clinical trial. J Clin Endo Metab. 86(3): 1212-1221, 2001.	
				Individual Studies Human	-Ritz E et al. Effects of vitamin D and parathyroid hormone on muscle: potential role in uremic myopathy. Am J Clin Nutr. 33: 1522-1529, 1980.	
				Individual Studies Human	-Schott GD and Willis MR. Muscle weakness in osteomalacia. Lancet. 1: 626-629, 1976.	
				Individual Studies Human	-Simpson RU et al. Identification of 1,25-hydroxyvitamin D3 receptors and activities in muscle. J Biol Chem. 260(15): 8882-8891, 1985.	
				Individual Studies Human	-Sorenson OH et al. Myopathy in bone loss of ageing: improvement by treatment with 1 alpha¬hydroxycholecalciferol and calcium. Clin Sci (Colch). 56: 157-161, 1979.	
				Others	-Holick MF. The vitamin D epidemic and its health consequences. J Nutr. 135: 2739S-2748S, 2005	
				Others	-Weaver CM and Heaney RP. Calcium. In: Modern Nutrition in Health and Disease. ed. Shils ME, Olson JA, Shike M and Ross AC. Williams & Wilkins, Baltimore, 1999.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Absorption and utilisation of Calcium, Phosphorus	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults	Authoritative body	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	55
				Authoritative body	-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	
				Authoritative body	-CEDAP. Avis de la commission interministerielle d'etude des produits destines a une alimentation particuliere (CEDAP) en date du 18 decembre 1996 sur les recommandations relatives au caractere non trompeur des seuils des allegations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Repression des fraudes) du 7 octobre 1997	
				Authoritative body	-CH - Switzerland - Ordonnance du March 1995 sur les dennrees 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	
				IOM DRV Report	Institute of Medicine Dietary Reference Intakes for calcium, phosphorus, magnesium, vitamin D, and fluoride. Washington D.C. National Academy Press, 1997.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of vitamin D. December 2002. (http://www.europa.eu.int/comm/food/fs/sc/scf/out157_en.pdf).	
				EVM Report	Review of Vitamin D Revised Version. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/evm-00-11r.pdf).	
				COMA Report	Nutrition and Bone Health: with particular reference to calcium and vitamin D. Report of the Subgroup on Bone Health, Working Group on the Nutritional Status of the Population of the Committee on Medical Aspects of Food and Nutrition Policy. Report on Health and Social Subjects No. 49. DH: The Stationery Office, 1998.	
		Teeth mineralization	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006	Authoritative body	-CEDAP. Avis de la commission interministerielle d'etude des produits destines a une alimentation particuliere (CEDAP) en date du 18 decembre 1996 sur les recommandations relatives au caractere non trompeur des seuils des allegations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Repression des fraudes) du 7 octobre 1997	54

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative body	-CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	
				Authoritative body	-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	
		Immune system	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006	Clinical Trial	Schulze Schleithoff, S.; Zittermann, A.; Tenderich, G.; Berthold, H.K.; Stehle, P. and Koerfer, R. (2006) Vitamin D supplementation improves cytokine profiles in patients with congestive heart failure: a double-blind, randomized, placebo-controlled trial. Am. J. Clin. Nutr. 83, 754-759	57
				Individual Studies	-Boonstra, A.; Barrat, F.J.; Crain, C.; Heath, V.L.; Savelkoul, H.F. and O´Garra, A (2001) 1a,25-dihydroxyvitamin D3 has a direct effect on naive CD4(+) T cells to enhance the development of Th2 cells. J. Immuno.l 167. 4974-4980	
				Individual Studies	-Cannell, J.J.; Vieth, R.; Umhau, J.C.; Holick, M.F.; Grant, W.B.; Madronich, S.; Garland, C.F. and Giovannucci, E. (2006) Epidemic influenza and vitamin D. Epidemiol Infect. 134(6), 1129-1140	
				Individual Studies	-Cantorna, M.T.; Zhu, Y.; Froicu, M. and Wittke, A. (2004) Vitamin D status, 1,25-dihydroxy- vitamin D3, and the immune system. Am. J. Clin. Nutr. 80, 1717S-1720S	
				Individual Studies	-DeLuca, H.F. and Cantorna, M.T. (2001) Vitamin D: its role and uses in immunology. FASEB J. 15, 2579-2585	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Studies	-Griffin, M.D.; Xing, N. and Kumar, R. (2003) Vitamin D and its analogs as regulators of immune activities and antigen presentation. Ann. Rev. Nutr. 23, 117-145	
				Individual Studies	-Hayes, C.E.; Nashold, F.E.; Spach, K.M. and Pedersen, L.B. (2003) The immunological functions of the vitamin D endocrine system. Cell. Molec. Biol. 49, 277-300	
				Individual Studies	-Hypponen, E.; Laara, E.; Reunanen, A.; Jarvelin, M.R. and Virtanen, S.M. (2001) Intake of vitamin D and risk of type 1 diabetes: a birth-cohort study. Lancet 358, 1500-1503	
				Individual Studies	-Lemire, J.M.; Archer, D.C.; Beck, L. and Spiegelberg, H.L. (1995) Immunosuppressive actions of 1,25(OH)2D3: preferential inhibition of Th1 functions. J. Nutr. 125, 1704S-1708S	
				Individual Studies	-Lips, P. (2006) Vitamin D physiology. Prog. Biophys. Mol. Biol. 92(1), 4-8	
				Individual Studies	-Mahon, B.D.; Gordon, S.A.; Cruz, J.; Cosman, F. and Cantorna, M.T. (2003) Cytokine profile in patients with multiple sclerosis following vitamin D supplementation: J. Neuroimmunol. 134, 128-132	
				Individual Studies	-Penna, G. and Adorini, L (2000) 1a,25-Dihydroxyvitamin D3 inhibits differentiation, maturation, activation and survival of dendritic cells leading to impaired alloreactive T cell activation. J. Immunol. 164, 2405-2411	
				Individual Studies	-Reichel, H.; Koeffler, H.P. and Norman, A.W. (1990) Regulation of immune system 1a,25-dihydroxyvitamin D3 by hematopoietic cells. Prog. Clin. Biol. Res. 332, 81-97	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Studies	-The EURODIAB substudy 2 study group (1999) Vitamin D supplement in early childhood and risk for type I (insulin-dependent) diabetes mellitus. Diabetologia 42, 51-54	
				Individual Studies	-Veldman, C.M.; Cantorna, M.T. and DeLuca, H.F. (2000) Expression of 1,25-dihydroxyvitamin D3 receptor in the immune system. Arch. Biochem. Biophys. 374, 334-338	
				Individual Studies	-Witte, K.K. and Clark, A.L. (2005) Chronic heart failure and multiple micronutrient supplementation: realistic hope or idealistic conjecture? Heart Fail. Monit. 4, 123-129	
				Individual Studies	-Yang, S.; Smith, C.; Prahl, J.M.; Luo, X. and DeLuca, H.F. (1993) Vitamin D deficiency suppresses cell-mediated immunity in vivo. Arch. Biochem. Biophys. 303, 98-106	
				Individual Studies	-Zittermann, A.; Schulze Schleithoff, S.; Tenderich, G.; Berthold, H.K.; Koerfer, R. and Stehle, P. (2003) Low vitamin D status: A contributing factor in the pathogenesis of congestive heart failure? J. Am. Coll.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Published Review Published Research Study	Cantorna MT (2000) Vitamin D and autoimmunity:is vitamin D status an environmental factor affecting autoimmune disease prevalence? Proc Soc Exp Biol Med; 223: 230-233 DeLuca HF, Zierold CF (1998) Mechanisms and functions of vitamin D. Nutr Rev; 56(2): 4-10 Froccu M, Cantorna MT (2007) Vitamin D and vitamin D receptor are critical for control of the innate immune response to colonic injury. BMC Immunol; 8:5 Bemiss CJ, Mahon BD, Henry A et al (2002) Interleukin-2 is one of the targets of 1,25-dihydroxyvitamin D3 in the immune system. Arch Biochem Biophys; 402(2): 249-254. Cantorna MT, Humpal J DeLuca HF (2000) In vivo upregulation of interleukin-4 is one mechanism underlying the immunoregulatory effects of 1,25-dihydroxyvitamin D3. Arch Biochem Biophys; 377(1): 135-138.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook, studies	Collins ED, Norman AW: Vitamin D; in Rucker RB, Suttie JW, McCormick DB, Machlin LJ (eds): Handbook of vitamins; 3rd ed, revised and expanded. Marcel Dekker Inc, New York, chapter 2, 2001, pp 51-113 Dietary Reference Intakes for calcium, phosphorus, magnesium, vitamin D, and fluoride. A report of the Panel on Micronutrients, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes; Food and Nutrition Board, Institute of Medicine, National Academy Press, Washington, D.C., 1997; chapter 7: Vitamin D, pp 250-287 DiMonaco M: Osteoporosis, nutrition and the immune system; in Hughes DA, Darlington LG, Bendich A (eds): Diet and human immune function. Humana Press, Totowa, NJ, chapter 15, 2004, pp 287-301 Field CJ, Johnson IR, Schley PD: Nutrients and their role to host resistance to infection. J Leukoc Biol 2002;71:16-32 Griffin MD, Xing N, Kumar R: Vitamin D and its analogs as regulators of immune activities Hayes CE, Nashold FE, Spach KM, Pedersen LB: The immunological functions of the vitamin D endocrine system. Cell Molec Biol 2003;49:277-300 Mathieu C, van Etten E, Decallonne B, Guilietti A, Gysemans C, Bouillon R, Overbergh L: Vitamin D and 1,25-dihydroxyvitamin D3 as modulators in the immune system. J Steroid Biochem Molec Biol 2004;89-90:449-452.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Pietschmann P, Willhelm M, Peterlik M: Bedeutung von Vitamin D im Immunsystem. J Miner Stoffwechs 2003;10:13-15.	
		Normal blood calcium levels	Guidance level is 25mcg/day or less (FSA)> Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], as per Annex to Regulation 1924/2006.	EVM Expert Report COMA Expert Report JHCI Expert Report Published Review	Review of Vitamin D. Expert Group on Vitamins and Minerals (2002). Nutrition and Bone Health: with particular reference to calcium and vitamin D. Report of the Subgroup on Bone Health, Working Group on the Nutritional Status of the population, committee on Medical Aspects of Food and Nutrition Policy (1998). Final Technical Report. Joint Health Claims Initiative (2003) DeLuca HF (2004) Overview of general physiologic features and functions of vitamin D. Am J Clin Nutr; 80(6S): 1689-1696. DeLuca HF, Zierold CF (1998) Mechanisms and functions of vitamin D. Nutr Rev; 56(2): 4-10.	1,109
		Bone health/bone strength includes bone structure, bone mineralisation, bone density	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults Typical adults dosage: 5 – 100 mcg daily. .	Authoritative body	-CEDAP. Avis de la commission interministerielle d'etude des produits destines a une alimentation particuliere (CEDAP) en date du 18 decembre 1996 sur les recommandations relatives au caractere non trompeur des seuils des allegations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Repression des fraudes) du 7 octobre 1997	53

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative body	-CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	
				Authoritative body	-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	
				IOM DRV Report	Institute of Medicine Dietary Reference Intakes for calcium, phosphorus, magnesium, vitamin D, and fluoride. Washington D.C. National Academy Press, 1997.	
				Scientific Body	-SNF - Swedish Nutrition Foundation http://www.snf.ideon.se/snf/en/rh/Healh_claims_FF.htm	
				Autoritative Body	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	
				Nutrition Textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of vitamin D. December 2002. (http://www.europa.eu.int/comm/food/fs/sc/scf/out157_en.pdf).	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				EVM Report	Review of Vitamin D Revised Version. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/evm-00-11r.pdf).	
				COMA Report	Nutrition and Bone Health: with particular reference to calcium and vitamin D. Report of the Subgroup on Bone Health, Working Group on the Nutritional Status of the Population of the Committee on Medical Aspects of Food and Nutrition Policy. Report on Health and Social Subjects No. 49. DH: The Stationery Office, 1998.	
					Sundhedsanprisninger af levnedsmidler- det faglige grundlag of forslag til vilkår for anvendelsen af sundhedsanprisninger. Ministeriet for fødevarer, landbrug og Fiskeri. Fødevarerapport 2000:24	
					Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13	
				Authoritative body (prepared for Agency for Healthcare Research and Quality, US Dept Health & Human Services)	University of Ottawa Evidence-based Practice Center, Effectiveness and Safety of Vitamin D in Relation to Bone Health, Evidence report 158. http://www.ahrq.gov/downloads/pub/evidence/pdf/vitamind/vitad.pdf	
				Medical body/position statement	Working Group of the Australian and New Zealand Bone and Mineral Society, Endocrine Society of Australia and Osteoporosis Australia. Vitamin D and adult bone health in Australia and New Zealand: a position statement. Medical Journal of Australia 2005; 182 (6): 281-285.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Meta-analysis	Tang BM, Eslick GD, Nowson C, Smith C, Bensoussan A. Use of calcium or calcium in combination with vitamin D supplementation to prevent fractures and bone loss in people aged 50 years and older: a meta-analysis. Lancet. 2007; 370(9588):657-66. Review.	
				textbook	DK S. Boonen, D. Vanderschueren, P. Haentjens, P. Lips. Calcium and vitamin D in the prevention and treatment of osteoporosis - a clinical update. J Int Med 2006; 259; 539-552.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				JHCI	JHCI, Final technical report http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf	
				IOM DRV report	Institute of Medicine Dietary Reference Intakes for calcium, phosphorus, magnesium, vitamin D, and fluoride. Washington D.C. National Academy Press, 1997.	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				EVM report	Review of Vitamin D – Revised Version. Expert Group on Vitamins and Minerals. August 2002. http://www.food.gov.uk/multimedia/pdfs/evm-00-11r.pdf	
				SCF report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of vitamin D. December 2002. http://www.europa.eu.int/comm/food/fs/sc/scf/out157_en.pdf	
				COMA report	Nutrition and Bone Health: with particular reference to calcium and vitamin D. Report of the Subgroup on Bone Health, Working Group on the Nutritional Status of the Population of the Committee on Medical Aspects of Food and Nutrition Policy. Report on Health and Social Subjects No. 49. DH: The Stationery Office, 1998.	
				Nutrition Text book		

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		Normal bone and tooth formation	Guidance level is 25mcg/day or less (FSA)> Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], as per Annex to Regulation 1924/2006.	EVM Expert Report COMA Expert Report JHCI Expert Report Published Review Published Controlled Clinical Trial	Review of Vitamin D. Expert Group on Vitamins and Minerals (2002). Nutrition and Bone Health: with particular reference to calcium and vitamin D. Report of the Subgroup on Bone Health, Working Group on the Nutritional Status of the population, committee on Medical Aspects of Food and Nutrition Policy (1998). Final Technical Report. Joint Health Claims Initiative (2003) DeLuca HF (2004) Overview of general physiologic features and functions of vitamin D. Am J Clin Nutr; 80(6S): 1689-1696. DeLuca HF, Zierold CF (1998) Mechanisms and functions of vitamin D. Nutr Rev; 56(2): 4-10 Dawson-Hughes B, Harris SS, Krall EA et al (1997) Effect of calcium and vitamin D supplementation on bone density in men and women 65 years of age or older. N Engl J Med; 337: 670-676. Honkanen R, Alhava E, Parviainen M et al (1990) The necessity and safety of calcium and vitamin D in the elderly. J Am Geriatr Soc; 38: 862-866.	1,110
		Cell division	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both	Authoritative Body	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	56

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			children and adults	IOM DRV Report	Institute of Medicine Dietary Reference Intakes for calcium, phosphorus, magnesium, vitamin D, and fluoride. Washington D.C. National Academy Press, 1997.	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of vitamin D. December 2002. (http://www.europa.eu.int/comm/food/fs/sc/scf/out157_en.pdf).	
				EVM Report	Review of Vitamin D Revised Version. Expert Group on Vitamins and Minerals. August 2002. (http://www.food.gov.uk/multimedia/pdfs/evm-00-11r.pdf).	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin D3					
		Vitamin D3 has long been known to aid in calcium absorbtion, but new research shows that D3 also plays a role in cardiovascular function and supports healthy inflammatory response	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006. D3 Recommended Daily dosage 200-400iu. D3 Product Dosage 4.5µg: 100% RDA			2,412

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					"Cohen-Lahav M, Douvdevani A, Chaimovitz C, Shany S. The anti-inflammatory activity of 1,25-dihydroxyvitamin D3 in macrophages. J Steroid Biochem Mol Biol. 2007 Mar;103(3-5):558-62. Abstract available at <http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T8X-4MMWHGC-3&_user=10&_coverDate=03%2F31%2F2007&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=7891bd8fa8b8fc80905751f479cbd9cb>. Shoji T, Shinohara K, Kimoto E, Emoto M, Tahara H, Koyama H, Inaba M, Fukumoto S, Ishimura E, Miki T, Tabata T, Nishizawa Y. Lower risk for cardiovascular mortality in oral 1alpha-hydroxy vitamin D3 users in a haemodialysis population. Nephrol Dial Transplant. 2004 Jan;19(1):179-84. Full-text available at <http://ndt.oxfordjournals.org/cgi/reprint/19/1/179>. Patel S, Farragher T, Berry J, Bunn D, Silman A, Symmons D. Association between serum vitamin D metabolite levels and disease activity in patients with early inflammatory polyarthritis. Arthritis Rheum. 2007 Jul;56(7):2143-9. Abstract available at <http://www3.interscience.wiley.com/cgi-bin/abstract/114285166/ABSTRACT?CRETRY=1&SRETRY=0>. " Armas L, Hollis B, Heaney R (2004). "Vitamin D2 is much less effective than vitamin D3 in humans". J Clin Endocrinol Metab 89 (11): 5387–91. PMID 15531486	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin E					
		Protection of body tissues, cells, membranes and lipids from oxidative damage (such as the oxidation of polyunsaturated fatty acids in red blood cell membranes). Antioxidant activity.	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults Guidance level is 540mg/day or less from supplements (FSA).	Authoritative body	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 Safe upper levels for vitamins and minerals. Expert Group on Vitamins and Minerals. May 2003 (http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf)	65
				Authoritative body	-SNF - Swedish Nutrition Foundation http://www.snf.ideon.se/snf/en/rh/Healh_claims_FF.htm	
				Authoritative body	-CH - Switzerland - Ordonnance du March 1995 sur les dennrees 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	
				Authoritative body	-CEDAP. Avis de la commission interministerielle d'etude des produits destines a une alimentation particuliere (CEDAP) en date du 18 decembre 1996 sur les recommandations relatives au caractere non trompeur des seuils des allegations nutritionnelles fonctionnelles. BOCCRF (Bulletin Officiel de la Concurrence, de la Consommation et de la Repression des fraudes) du 7 octobre 1997	
				Authoritative body	-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	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Authoritative body	-FNFC/FOSHU - Japan http://www.mhlw.go.jp/english/topics/foodsafety/fhc/index.html	
				IOM DRV Report	Institute of Medicine Dietary Reference Intakes for Vitamin C, Vitamin E, selenium and carotenoids. Washington D.C. National Academy Press, 2000.	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin E. April 2003. (http://www.europa.eu.int/comm/food/fs/sc/scf/out195_en.pdf).	
				EVM Report	Review of Vitamin E Revised Version. Expert Group on Vitamins and Minerals. July 2002. (http://www.food.gov.uk/multimedia/pdfs/evm-00-13r.pdf).	
					Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Published Review	Brigelius R, Kelly FJ, Salonen JT et al (2002) The European perspective on vitamin E: current knowledge and future research. Am J Clin Nutr; 76(4): 703-716. Herrera E, Barbas C (2001) Vitamin E; action, metabolism and perspectives. J Physiol Biochem; 57(2): 43-56. Wang X, Quinn PJ (1999) Vitamin E and its function in membranes. Prog Lipid Res; 38(4): 309-336. Packer L (1991) Protective role of vitamin E in biological systems. Am J Clin Nutr; 53(S4): 1050-1055. Bisby RH (1990) Interactions of vitamin E with free radicals and membranes. Free Radic Res Commun; 8(4): 299-306. Burton GW, Ingold KU (1989) Vitamin E as an in vitro and in vivo antioxidant. Ann NY Acad Sci; 570: 7-22. Santini B, David O, Miniero R (1988) Vitamin E; physiology and pathology. Pediatr Med Chir; 10(1): 25-30.	
		Normal immune system function	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 100-200 IU per day = approx 70-135mg Guidance level is 540mg/day or less from supplements (FSA).	VITAMIN E and Immune Function References Background References Background	-Albers R, Antoine JM, Bourdet-Sicard R, Calder PC, Gleeson M, Lesourd B, Samartin S, Sanderson IR, Van Loo J, Vas Dias FW, Watzl B. Markers to measure immunomodulation in human nutrition intervention studies. Br J Nutr. 2005;94:452-481 -Chavanne M, Herbert B, Fournier C, Janot C, Vernhes G. Vitamin status, immunity and infections in elderly populations. Eur J Clin Nutr 1989;48:827-835	66

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				References Background	-Meydani SN, Han SN: Nutrient regulation of the immune response: The case of vitamin E. In: Present Knowledge in Nutrition (Bowman BA, Russell RM, eds.) 9th edition, ILSI Press, Washington 2006, pp 585-603	
				Recognised Textbooks and Monographs	-Han SN, Adolfsson O, Meydani SN: Vitamin E and enhancement of the immune response in the aged: Cellular and molecular mechanisms. In: The antioxidant vitamins E and C (Packer L, Traber MG, Kraemer K, Frei B, ed.) AOCS Press, Champaign, Illinois, USA 2002, 216-227	
				Recognised Textbooks and Monographs	High KP Nutritional strategies to boost immunity and prevent infection in elderly individuals. Clin Infect Dis. 2001;33:1892-1900.	
				Recognised Textbooks and Monographs	-Hughes DA: Antioxidant vitamins and immune function. In: Nutrition and Immune Function (Calder PC, Field CJ, Gill HS, eds.) CABI Publishing, Oxon, New York 2002, pp 171-192.	
				Recognised Textbooks and Monographs	-Meydani SN, Tengerdy RP: Vitamin E and immune response. In: Vitamin E in health and disease (Packer L, Fuchs J, eds.) Marcel Dekker, New York 1993, pp 549-562	
				Recognised Textbooks and Monographs	-Serafini M: Dietary vitamin E and T cell-mediated function in the elderly: effectiveness and mechanism of action. Int J Dev Neurosci 2000;18:401-410	
				Reviews	-Han SN, Meydani SN. Vitamin E and infectious diseases in the aged. Proc Nutr Soc. 1999 Aug;58(3):697-705. Review.	
				Reviews	-Kelleher J. Vitamin E and the immune response. Proc Nutr Soc. 1991 Aug;50(2):245-9. Review.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Reviews	-Meydani SN, Han SN, Wu D. Vitamin E and immune response in the aged: molecular mechanisms and clinical implications. Immunol Rev. 2005 Jun;205:269-84. Review.	
				Reviews	-Meydani SN, Beharka AA. Recent developments in vitamin E and immune response. Nutr Rev. 1998 Jan;56 (1 Pt 2):S49-58. Review.	
				Clinical Trials	-Graat JM, Schouten EG, Kok FJ; Effect of Daily vitamin E and Multivitamin-Mineral Supplementation on Acute Respiratory Tract Infections in Elderly Persons A Randomized Controlled Trial. JAMA 2002;288:715-721	
				Clinical Trials	-Meydani SN, Meydani M, Blumberg JB, Leka LS, Siber G, Loszewski R, Thompson C, Pedrosa MC, Diamond RD, Stollar BD; Vitamin E supplementation and In Vivo Immune Response in Healthy Elderly Subjects. JAMA 1997;277:1380-1386	
				Clinical Trials	-Wu D, Han SN, Meydani M, Meydani SN; Effect of Concomitant Consumption of Fish Oil and Vitamin E on T Cell Mediated Function in the Elderly: A Randomized Double-Blind Trial. J Am Coll Nutr 2006;25:300-306	
				Individual Papers	-De la Fuente M, Ferrandez MD, Burgos MS, Soler A, Prieto A, Miquel J; Immune function in aged women is improved by ingestion of vitamins C and E. Can J Physiol Pharmacol (1998); 76:373-380	
				Individual Papers	-De Waart FG, Portengen L, Doekes G, Verwaal CJ, Kok FJ; Effects of 3 month vitamin E supplementation on indices of the cellular and humoral immune response in elderly subjects. Br J Nutr 1997;78:761-774	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Papers	-Hann SN,Adolfosson O,Lee CK, Prolla TA,ORDOVAS J,MEYDANI SN Vitamin E and gene expression in immun cells, ANN N Y ACAD SCI 2004 DEC, 1031:96-101	
				Individual Papers	-Harman D, White Miller R; Effect of Vitamin E on the Immune Response to Influenza Virus Vaccine and the Incidence of Infectious Disease in Man. Age 1986; 9:21-23	
				Individual Papers	-Hemila H, Kaprio J; Albanes D, Heinonen OP; Virtamo J; Vitamin C, Vitamin E, and Beta-carotene in Relation to common Cold Incidence in male Smokers. Epidemiology 2002;13:32-37	
				Individual Papers	-Hemila H, Virtamo J, Albanes D, Kaprio J; Vitamin E and Beta-carotene supplementation and Hospital-treated Pneumonia Incidence in Male Smokers. CHEST 2004;125:557-565	
				Individual Papers	-Hemila H, Virtamo J; Albanes D, Kaprio J; The Effect of vitamin E on Common Cold Incidence Is Modified by Age, Smoking and Residential Neighborhood. J Am Coll Nutr 2006;25:332-339	
				Individual Papers	-Lee C-YJ, Wan JM-F; Vitamin E supplementation Improves Cell-Mediated Immunity and Oxidative Stress of Asian Men and Women. J Nutr 2000;130:2932-2937	
				Individual Papers	-Malkowska-Zwierz W, Garlinski P, Zukowska M, Zabuska K, Wartanowicz M, Kleniewska D, Niemirowska H, Izdebska Z, Roszowski W, Wroblewski T, Ziemlanski S, Radomska D, Skopinska-Rozewska E; The effect of vitamin E on Granulocyte Function in Patients with recurrent Infections. Arch Immunol Ther Exp (Warz.) 1991;39:109-115	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Papers	-Meydani SN, Barklund MP, Liu S, Meydani M, Miller RA, Cannon JG, Morrow FD, Rocklin R, Blumberg JB; Vitamin E supplementation enhances cell-mediated immunity in healthy elderly subjects. Am J Clin Nutr 1990;52:557-63	
				Individual Papers	-Meydani SN, Leka LS, Fine BC, Dallal GE, Keusch GT, Singh MF, Hamer DH; Vitamin E and Respiratory Tract Infections in Elderly Nursing Home Residents. JAMA 2004;292:828-236	
				Individual Papers	-Okano T, Tamai H, Mino M; Superoxide Generation in Leukocytes and Vitamin E. Internat J Vit Nutr Res 1991;61:20-26	
				Individual Papers	-Pallast EG, Schouten EG, de Waart FG, Fonk HC, Doekes F, von Blomberg BM, Kok FJ; Effect of 50- and 100-mg vitamin E supplements on cellular immune function in noninstitutionalized elderly persons. Am J Clin Nutr 1999;69:1273-1281	
				Individual Papers	-Prasad JS; Effect of vitamin E supplementation on leukocyte function. Am J Clin Nutr 1980;33:606-608	
				Individual Papers	-Richards GA, Theron AJ, van Rensburg CEJ, Van Rensburg AJ, Van der Merwe CA, Kuyl JM, Anderson R; Investigation of the Effects of Oral Administration of Vitamin E and Beta-Carotene on the Chemiluminescence Responses and the Frequency of Sister Chromitid Exchanges in Circulating Leukocytes from Cigarette Smokers. Am Rev Respir Dis 1990;142:648-654	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Individual Papers	-van Tits LJ, Demacker PN, de Graaf J, Hak-Lemmers HL, Stalenhoef AF; a-Tocopherol supplementation decreases production of superoxide and cytokines by leukocytes ex vivo in both normolipidemic and hypertriglyceridemic individuals. Am J Clin Nutr 2000; 71:458-464 Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Published Review	Feki M, Souisse M, Mebazaa A (2001) Vitamin E; structure, metabolism and functions. Ann Med Interne; 152(6): 384-391. Moriguchi S, Muraga M (2000) Vitamin E and immunity. Vitam Horm; 59: 305-336. High KP (1999) Micronutrient supplementation and immune function in the elderly. Clin Infect Dis; 28(4): 717-722. Meydani M (1999) Dietary antioxidants modulation of aging and immune-endothelial cell interaction. Mech Ageing Dev; 111(2): 123-132. Hughes DA (1999) Effects of dietary antioxidants on the immune function of middle aged adults. Proc Nutr Soc; 58(1): 79-84. Landmark K (1998) Vitamin E is beneficial for the immune system in the elderly. Tidsskr Nor Laegeforen; 118(28): 4403-4404.	
		Anitoxidants and aging	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.	textbook	1) Engelhart, M.J.; Geerlings, M.J.; Ruitenberg, A.; van Swieten, J.C.; Hofman, A.; Witteman, J.C.M. and Breteler, M.M.B. (2002) Dietary intake of antioxidants and risk of Alzheimer disease. JAMA 287, 3223-3229 2) Grundman, M. and Delaney, P. (2002) Antioxidant strategies for Alzheimer's disease. Proc. Nutr. Soc. 61, 191-202 3) Ortega, R.M.; Requejo, A.M.; Andrés, P.; Lopez-Sobaler, A.M.; Quintas, M.E.; Redondo, M.R.; Navia, B. and Rivas, T. (1997) Dietary intake and cognitive function in a group of elderly people. Am. J. Clin. Nutr. 66, 803-809	1,212

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
		OXIDATIVE STRESS. Acts as antioxidant and helps protect the body tissues against the potentially damaging effects of free radicals	Claim to be only used for Foods for sport people under the Dir. 89/398/EEC. The DRA for vit E is 15 mg alpha-TE. CEDAP recommendations for sports people: vit E is 60 mg alpha-TE. Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006.	Textbook RCT	Sports Nutrition by Jeukendrup A and Gleeson M, Chap 9, The micronutrients: vitamins and minerals, p199, 228, ed 2004; Effects of vitamin C and E on in vivo lipid peroxidation: results of a randomized controlled trial. Huang HY et al. Am J Clin Nutr 76, 549-555, 2002 Antioxidant Supplementation and Tapering Exercise Improve Exercise-Induced Antioxidant Response Margaritis I, Palazzetti S, Rousseau A, Richard M, Favier A. Journal of the American College of Nutrition 22(2): 147-156, 2003.	1,599
		Heart Health	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006.			980

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	
		Energy and Vitality	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006.			979

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	
		Bone/Teeth/ Hair / Skin and Nail health	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s}" as per Annex to Regulation 1924/2006.			978

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				OM DRV Reports Nutrition Textbook SCF Reports EVM Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Reports of the European Scientific Committee on Food Draft reports of the UK Expert Group on Vitamins and Minerals Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002. 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.	
		Antioxidant	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.			608

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				JHCI IOM report SCF report EVM report Nutrition text book Nutrition text book	JHCI, Final technical report http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf Institute of Medicine Dietary Reference Intakes for Vitamin C, Vitamin E, selenium and carotenoids. Washington D.C. National Academy Press, 2000. Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin E. April 2003. http://www.europa.eu.int/comm/food/fs/sc/scf/out195_en.pdf Review of Vitamin E – Revised Version. Expert Group on Vitamins and Minerals. July 2002. http://www.food.gov.uk/multimedia/pdfs/evm-00-13r.pdf Encyclopaedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999. Human Nutrition and Dietetics. 10th edition. JS Garrow, WPT James, A Ralph. Churchill Livingstone 2000.	
		Regeneration of vitamin C, vitamin C and vitamin E have synergistic effects	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation	Textbooks, studies	* Elaine R. Berman: Biochemistry of the Eye ISBN 0-306-43633-7; *Janisch KM et al. (Buch) Augustin A (ed):Nutrition and the Eye. Dev Ophthalmol Basel, Karger, 2005, vol 38, pp59-69 Vitamin C, E and Flavonoids (2005);	610

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
			1924/2006.			
		The role of vitamins and minerals in immunity	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.			1,217

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				textbook, studies	2) Bogden JD, Louria DB: Nutrition and immunity in the elderly; in Hughes DA, Darlington LG, Bendich A (eds): Diet and human immune function. Humana Press, Totowa, NJ, chapter 5, 2004, pp 79-101 3) Dietary Reference Intakes for vitamin C, vitamin E, selenium, and carotenoids. A report of the Panel on Antioxidants and Related compounds, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes; Food and Nutrition Board, Institute of Medicine, National Academy Press, Washington, D.C., 2000; chapter 6: Vitamin E, pp 186-283 4) Field CJ, Johnson IR, Schley PD: Nutrients and their role to host resistance to infection. J Leukoc Biol 2002;71:16-32 5) Han SN, Meydani SN: Vitamin E; in Hughes DA, Darlington LG, Bendich A (eds): Diet and human immune function. Humana Press, Totowa, NJ, chapter 8, 2004, pp 149-164. 6) Meydani SN, Meydani M, Blumberg JB, Leka LS, Siber G, Loszewski R, Thompson C, Pedrosa MC, Diamond RD, Stollar BD: Vitamin E supplementation and in vivo immune response in healthy elderly subjects. A randomized controlled trial: J Am Med Assoc 1997;277:1380-1386 7) Meydani SN, Beharka AA: Recent developments in vitamin E and immune response. Nutr Rev 1998;56:S49-S58 8) Meydani SN, Beharka AA: Vitamin E and immune response in the aged; in Walter P, Hornig D, Moser U (eds): Functions of vitamins	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					beyond recommended dietary allowances. Karger, Basel, Bibl Nutr Dieta, vol 55, 2001, pp 148-158 9) Meydani SN, Han SN: Nutrition regulation of the immune response: the case of vitamin E; in Bowman BA, Russel RM (eds): Present knowledge in Nutrition, 8th edition. Washington, DC, ILSI Press, 2001, chapter 41, pp 449-462 10) Moriguchi S, Muraga M: Vitamin E and immunity. Vitamins Hormones 2000;59:305-336.	
		Eye health; vitamin E, C are found in the lens of the eye; acts jointly with vitamin C	Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.	Study	* Jacques P.F. et al. Arch Ophthalmol 119 (7) 1009-19 (2001):Long term nutrient intake and early age related nuclear lens opacities; *Kuzniarz M. et al. (Blue Montain Eye St.) Am J Ophthal. Jul 132(1):19-26 (2001):Use of vitamin supplements and cataract: the Blue mountain eye study; Mares-Perlman JA et al. Arch Ophthal. Nov, 118 (11): 1556-63 (2000):Vitamin supplement use and incident cataracts in a population based study; *Taylor A. et al. Am J Clin Nutr 75 (3) 540-9 (2002): Lon term intake of vitamins and cartenoids and odds of early age related cortical and posterior subcapsular lens opacities;	611

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin K					
		Blood coagulation	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Guidance level is 1mg/day or less (FSA).	Authoritative body	CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	42
				Authoritative body	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	
					Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	
				EVM Expert report	Review of Vitamin K. Expert Group on Vitamins and Minerals (2002).	
		Bone integrity	Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC			884

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Expert Group Critical review of Expert Workshop Scientific Body Review Intervention studies Randomized, controlled trial Prospective Study Prospective Study Cross-sectional observational study	http://europa.eu.int/comm/food/fs/sc/scf/out196_en.pdf (Scientific Committee Foods, 2003) Vermeer C et al (2004) Beyond deficiency: Potential benefits of increased intakes of vitamin K for bone and vascular health. Eur J Nutr 43; 325-335 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 Adams & Pepping (2005) Vitamin K in the treatment and prevention of osteoporosis and arterial calcification. Am J Health Syst Pharm 62:1574-1581. Berkner (2005) The vitamin K dependent carboxylase. Annu Rev Nutr 25, 127-149. Bolton-Smith et al (2001) Two-year intervention study with phylloquinone (vitamin K1), vitamin D and calcium: effect on bone mineral content. Ann Nutr Metab 45;246. Braam et al (2003) Vitamin K1 supplementation retards bone loss in postmenopausal women between 50 and 60 years of age. Calcif Tissue Int 73; 21-26.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					Booth SL et al (2000) Dietary vitamin K intakes are associated with hip fracture but not with bone mineral density in elderly men and women. Am J Clin Nutr 71; 1201-1208. Feskanich D et al (1999) Vitamin K intake and hip fractures in women: a prospective study. Am J Clin Nutr 69; 74-79. Tsugawa et al (2006) Vitamin K status of healthy Japanese women: age related vitamin K requirement for ?-carboxylation of osteocalcin. Am J Clin Nutr 83; 380-386.	
		Bone Structure	MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults Typical adults dosage: up to 10 mg. No RDA established for Vitamin K. Pregnant and nursing mothers should avoid supplemental intakes. Vitamin K should be avoided by those taking warfarin. Guidance level is 1mg/day or less (FSA).	Authoritative body IOM DRV Report Authoritative/Scientific Bodies Authoritative/Scientific Bodies Meta-analysis	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 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. VITAMIN K and Bone Integrity -http://europa.eu.int/comm/food/fs/sc/scf/out196_en.pdf (Scientific Committe Foods, 2003) -http://www.iom.edu/?id=12703 (Institute of Medicine of the National Academies, 2001) -Adams & Pepping, Am J Health Syst Pharm 2005;62:1574-1581. Vitamin K in the treatment and prevention of osteoporosis and arterial calcification. (meta-analysis)	43

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Reviews	-Berkner, Annu. Rev. Nutr. 25, 127-149, 2005 : The vitamin K dependent carboxylase (review)	
				Reviews	-Vermeer C et al. Beyond deficiency: Potential benefits of increased intakes of vitamin K for bone and vascular health. Eur J Nutr 2004;43:325-335 (critical review ; expert workshop)	
				Individual Studies	-Bolton-Smith et al. Ann Nutr Metab 2001;45 (suppl 1):246. Two-year intervention study with phylloquinone (vitamin K1), vitamin D and calcium: effect on bone mineral content.	
				Individual Studies	-Booth SL et al, Am J Clin Nutr 2000;71:1201-1208. Dietary vitamin K intakes are associated with hip fracture but not with bone mineral density in elderly men and women.	
				Individual Studies	-Braam et al. Calcif Tissue Int 2003;73:21-26. Vitamin K1 supplementation retards bone loss in postmenopausal women between 50 and 60 years of age	
				Individual Studies	-Feskanich D et al, Am J Clin Nutr 1999;69:74-79. Vitamin K intake and hip fractures in women: a prospective study.	
				Individual Studies	-Tsugawa et al, Am J Clin Nutr 2006;83: 380-386, Vitamin K status of healthy Japanese women: agerelated vitamin K requirement for y-carboxylation of osteocalcin	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				SCF Report	Opinion of the Scientific Committee on Food (SCF) on the Tolerable Upper Intake Level of Vitamin K. April 2003. (http://www.europa.eu.int/comm/food/fs/sc/scf/out196_en.pdf).	
				EVM Report	Revised Review of Vitamin K. Expert Group on Vitamins and Minerals. April 2002. (http://www.food.gov.uk/multimedia/pdfs/evm-01-09p.pdf).	
				COMA Report	Nutrition and Bone Health: with particular reference to calcium and vitamin D. Report of the Subgroup on Bone Health, Working Group on the Nutritional Status of the Population of the Committee on Medical Aspects of Food and Nutrition Policy. Report on Health and Social Subjects No. 49. DH: The Stationery Office, 1998.	

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					Cockayne S, Adamson J, Lanham-New S, Shearer MJ, Gilbody S, Torgerson DJ. Vitamin K and the prevention of fractures: systematic review and meta-analysis of randomized controlled trials.Arch Intern Med. 2006 Jun 26;166(12):1256-61. Review. JHCI -A report by the Joint Health Claims Initiative to the Food Standards Agency 2003 PART 2:A list of Well-Established Nutrient Function Statements.JHCI Ref: JHCI/76/03 Knapen MH, Schurgers LJ, Vermeer C. Vitamin K(2) supplementation improves hip bone geometry and bone strength indices in postmenopausal women. Osteoporos Int. 2007 Feb 8; Schurgers LJ, Teunissen KJ, Hamulyak K, Knapen MH, Vik H, Vermeer C. Vitamin K-containing dietary supplements: comparison of synthetic vitamin K1 and natto-derived menaquinone-7. Blood. 2007 Apr 15;109(8):3279-83. Schurgers LJ, Vermeer C. Determination of phylloquinone and menaquinones in food. Effect of food ma-trix on circulating vitamin K concentrations. Haemostasis. 2000 Nov-Dec;30(6):298-307 Cheese data.	
				Reviews	Ryan-Harshman M, Aldoori W. Bone health. New role for vitamin K? Can.Fam.Physician 2004; 50:993-997	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Clinical trials	Craciun AM, Wolf J, Knapen MH, et al. Improved bone metabolism in female elite athletes after vitamin K supplementation. Int.J.Sports Med. 1998;19(7):479-484. Katsuyama H, Ideguchi S, Fukunaga M, Fukunaga T, Saijoh K, Sunami S. Promotion of bone formation by fermented soybean (Natto) intake in premenopausal women. J Nutr Sci Vitaminol (Tokyo). 2004; 50(2): 114-20. Neogi T, Booth SL, Zhang YQ, Jacques PF, Terkeltaub R, Aliabadi P, Felson DT. Low vitamin K status is associated with osteoarthritis in the hand and knee. Arthritis Rheum. 2006; 54(4):1255-61. Ichikawa T, Inoue S.[Molecular mechanisms of vitamin K action in the bone homeostasis] Clin Calcium. 2005 May;15(5):839-44. Shiraki M, Shiraki Y, Aoki C, et al. Vitamin K2 (menatetrenone) effectively prevents fractures and sustains lumbar bone mineral density in osteoporosis. J.Bone Miner.Res. 2000;15(3):515-521. Iinuma N. Vitamin K2 (menatetrenone) and bone quality. Clin Calcium. 2005 Jun;15(6):1034-9.	

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				Published Review	Palacios C (2006) The role of nutrients in bone health. Crit Rev Food Sci Nutr; 46(8): 621-628. Plaza SM, Lamson DW (2005) Vitamin K2 in bone metabolism and osteoporosis. Altern Med Rev; 10(1): 24-35. Vermeer C et al (2004) Beyond deficiency: potential benefits of increased intakes of vitamin K for bone and vascular health. Eur J Nutr; 43: 325-335. Tucker KI (2003) Dietary intake and bone status with aging. Curr Pharm Des; 9(32): 2687-2704.	
		Bone calcification	Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC			885

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Expert Group Scientific Body Critical review of Expert Workshop Reviews Randomized controlled trial Cross-sectional observational study Analytical Study Animal Study	http://europa.eu.int/comm/food/fs/sc/scf/out196_en.pdf (Scientific Committee Foods, 2003) 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 Vermeer C et al (2004) Beyond deficiency: Potential benefits of increased intakes of vitamin K for bone and vascular health. Eur J Nutr 43; 325-335. Adams & Pepping (2005) Vitamin K in the treatment and prevention of osteoporosis and arterial calcification. Am J Health Syst Pharm 62; 1574-1581. Berkner (2005) The vitamin K dependent carboxylase. Annu Rev Nutr 25, 127-149. Braam et al (2004) Beneficial effects of vitamins D and K on the elastic properties of the vessel wall in postmenopausal women: a follow-up study. Thromb Haemost 91; 373-380. Geleijnse et al (2004) Dietary intake of menaquinone is associated with a reduced risk of coronary heart disease: the Rotterdam Study. J Nutr 134; 3100-3105. Schurgers & Vermeer (2000) Determination of	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
					phylloquinone and menaquinones in food. Effect of food matrix on circulating vitamin K concentrations. Haemostasis 30; 298-307. Spronk et al (2003) Tissue-specific utilisation of menaquinone-4 results in prevention of arterial calcification in warfarin-treated rats. J Vasc Res 40; 531-53.	
		Bone structure	Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC The product must contain at least 15% of the RDA	Authoritative Body Vitamins and Minerals Expert Group Report COMA Expert Report Scientific Body: International Expert Report	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 Expert Group on Vitamins and Minerals (May 2003) Safe Upper Levels for Vitamins and Minerals. (http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf) Department of Health. Nutrition and bone health: with particular reference to calcium and vitamin D. Report of the Subgroup on Bone Health, Working Group on the Nutritional Status of the Population of the Committee on Medical Aspects of Food and Nutrition Policy. London, The Stationery Office, 1998 (Report on Health and Social Subjects, No. 49). WHO Technical Report Series: Diet, Nutrition and the prevention of chronic diseases; Report of a joint WHO/FAO Expert Consultation (2003).	883

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				IOM DRV Expert Report	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	
				Encyclopaedia of Human Nutrition	Encyclopaedia of Human Nutrition 2E. Editor-in-chief Michele J. Sadler, editors J.J. Strain, Benjamin Caballero. San Diego: Academic Press c.1999	
				SCF Expert Opinion	Opinion of the Scientific Committee of Food (SCF) on the Tolerable Upper Intake Levels of Vitamin K, April 2003	
	Vitamin K1 + K2					
		Heart Health	Source of / 15% of RDA per 100 g	Scientific investigations	Geleijnse JM, Vermeer C, Grobbee DE, Schurgers LJ, Knapen MH, van der Meer IM, Hofman A, Witte-man JC. Dietary intake of menaquinone is associated with a reduced risk of coronary heart disease: the Rotterdam Study.J Nutr. 2004 ov;134(11):3100-5.	748
				Authoritative statements	JHCI -A report by the Joint Health Claims Initiative to the Food Standards Agency 2003 PART 2:A list of Well-Established Nutrient Function Statements.JHCI Ref: JHCI/76/03 Nordic Nutrition Recommendations 2004 Integrating nutrition and physical activity, 4th edition, NORD 2004:13	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin K2					
		Vascular health	MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006	Scientific Body	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	44
				IOM DRV Report	http://www.iom.edu/?id=12703 (Institute of Medicine of the National Academies, 2001)	
				Authoritative/Scientific Bodies	http://europa.eu.int/comm/food/fs/sc/scf/out196_en.pdf (Scientific Committe Foods, 2003)	
				Meta-Analysis	-Adams & Pepping, Am J Health Syst Pharm 2005;62:1574-1581. Vitamin K in the treatment and prevention of osteoporosis and arterial calcification.	
				Reviews	-Berkner, Annu. Rev. Nutr. 25, 127-149, 2005 : The vitamin K dependent carboxylase	
				Reviews	-Vermeer C et al. Beyond deficiency: Potential benefits of increased intakes of vitamin K for bone and vascular health. Eur J Nutr 2004;43:325-335	
				Intervention Studies	-Braam et al, Thromb Haemost 2004;91:373-380. Beneficial effects of vitamins D and K on the elastic properties of the vessel wall in postmenopausal women: a follow-up study. Thromb Haemost 2004;91:373-380.	

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
				Intervention Studies	-Schurgers & Vermeer, Haemostasis 2000;30:298-307. Determination of phylloquinone and menaquinones in food. Effect of food matrix on circulating vitamin K concentrations. (much higher bioavailability of K2 versus K1).	
				Intervention Studies	-Geleijnse et al, J Nutr 2004;134:3100-3105. Dietary intake of menaquinone is associated with a reduced risk of coronary heart disease: the Rotterdam Study.	
				Intervention Studies	-Spronk et al, J. Vasc. Res. 40, 531-537 (2003). Tissue-specific utilisation of menaquinone-4 results in prevention of arterial calcification in warfarin-treated rats.	
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	Vitamin-C 1					
		Due to its reducing power vitamin C can, improve absorption of non-haem iron	30mg /day equal to 50% of ADI (Acceptable Daily Intake) Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >1000 mg of vitamin C should carry the label advisory statement "[This amount of vitamin c] may cause mild stomach upset in sensitive individuals"	Expert Textbook RCT	Nordic Nutrition Recommendations (NNR) -Integrating nutrition and physical activity. Nordic Council of Ministers, Norden, 2004. Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Churchill Livingstone, 2000. Tetens I, Larsen TM, Kristensen MB et al. The importance of dietary composition for efficacy of iron absorption measured in a whole diet that includes rye bread fortified with ferrous fumerate: a radioisotope study in young women. Br J Nutr 2005;94:720-6.	1,878

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamin-C 2					
		Antioxidant properties	30 mg /day equal to 50% of ADI (Acceptable Daily Intake)	Expert	Nordic Nutrition Recommendations (NNR) -Integrating nutrition and physical activity. Nordic Council of Ministers, Norden, 2004.	1,879
			Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006.	Textbook	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Churchill Livingstone, 2000.	
				Textbook	Bender D.A. Nutritional Biochemistry of the Vitamins. Cambridge, 2003.	
			Agency guidance for supplements is that products containing >1000 mg of vitamin C should carry the label advisory statement "[This amount of vitamin c] may cause mild stomach upset in sensitive individuals"			

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	Vitamin-C 3					
		Vitamin C is a cofactor for several enzymes involved in the biosynthesis of collagen	30 mg /day equal to 50% of ADI (Acceptable Daily Intake) Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s], source of protein etc (delete as appropriate)" as per Annex to Regulation 1924/2006. Agency guidance for supplements is that products containing >1000 mg of vitamin C should carry the label advisory statement "[This amount of vitamin c] may cause mild stomach upset in sensitive individuals"	Expert Textbook Textbook	Nordic Nutrition Recommendations (NNR) -Integrating nutrition and physical activity. Nordic Council of Ministers, Norden, 2004. Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Churchill Livingstone, 2000. Bender D.A. Nutritional Biochemistry of the Vitamins. Cambridge, 2003.	1,880

Category	Food Component	Health Relationship	Suggested Conditions of Use	Nature of Evidence	References	Claim ID
	Vitamins in general					
		Development	MUST AT LEAST BE A SOURCE OF VITAMINS/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults 'All vitamins' refers to all vitamins listed in Annex 1 to the Food Supplements Directive (2002/46/EC)	Authoritative Body	CH - Switzerland - Ordonnance du March 1995 sur les dennrees alimentaires et les objets usuels (ODAIOUs) http://www.admin.ch/ch/f/rs/c817_02.html http://www.bag.admin.ch/themen/ernaehrung/02907/03002/index.html?lang=fr	1
				Authoritative Body	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	
				Authoritative Body Text Book	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	
				IOM DRV Reports	US Institute of Medicine - Dietary reference intakes for vitamins and minerals	
				Nutrition textbook	Encyclopedia of Human Nutrition 2E. Editor-in-chief, Michele J. Sadler, editors, J.J. Strain, Benjamin Caballero. San Diego : Academic Press, c1999.	
				SCF Reports	Reports of the European Scientific Committee on Food	
				EVM Reports	Draft reports of the UK Expert Group on Vitamins and Minerals	
				Nutrition textbook	Handbook of Nutrition and Food. Edited by Carolyn D Berdanier...[et al.]. Boca Raton, Fla.: CRC Press, 2002.	

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				Nutrition textbook	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.	
				Nutrition textbooks	Garrow JS, James WPT, Ralph A. Human Nutrition and Dietetics. Tenth Edition, Churchill Livingstone (Harcourt Publishers) London, 2000. Gibney MJ, Voster, HH, Kok FJ (eds) Introduction to human nutrition. Blackwell Publishing, Oxford, 2002. Mann J, Truswell AS. Essentials of Human Nutrition, 2nd ed. Oxford University Press, 2001.	