ANH International
The Atrium, Curtis Road
Dorking, Surrey RH4 1XA
United Kingdom
e: info@anhinternational.org
t: +44 (0)1306 646 600
f: +44 (0)1306 646 552
www.anhinternational.org
ANH-Intl Regional Offices
EUROPE anh-europe.org
USA anh-usa.org

Listing of selected negative health claim opinions by the European Food Safety Authority (EFSA)

Including reference to reasons for refusal and known health benefits*

October 2011

*Health benefits sourced from Natural Standard database (http://naturalstandard.com) unless separate reference to peer reviewed journal given.

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
Probiotics - many separate strains			
Bifidobacterium longum BB536	Improvement of bowel regularity	The human intervention studies provided had weaknesses in the study designs and statistical analyses, and no conclusions could be drawn from these studies for the scientific substantiation of the claimed effect The Panel concludes that a cause and effect relationship has not been established	Acute diarrhoea Prevention of atopic dermatitis/eczema in children Reduction of faecal acidity/ammonia in liver cirrhosis Possible reduction of childhood dental caries Possible faster growth in infants Possible immune enhancement Possible improvement of symptoms associated with irritable bowel syndrome May help prevent pancreatic infection (sepsis), reduce the number of operations needed, and reduce the length of hospital stay in treatment of acute pancreatitis
	Normal resistance to cedar pollen allergens	No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect The Panel concludes that a cause and effect relationship has not been established	
	Decreasing potentially pathogenic gastro-intestinal microorganisms	No human studies were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		The Panel concludes that a cause and effect relationship has not been established	May reduce frequency of relapses and the need for antibiotic therapy Improvement of ulcerative colitis May help treat allergic conditions, especially in infants May decrease duration of symptoms in amoebiasis Treatment of bacterial vaginosis during pregnancy Treatment of *Helicobacter pylori* infestation Reduced risk of severe necrotizing fasciitis and mortality in preterm infants Prevention of post-operative pouchitis
Bifidobacterium animalis ssp. *lactis* Bb-12	Immune defence against pathogens	No human studies have been provided from which conclusions for the scientific substantiation of the claimed effect could be drawn The Panel concludes that a cause and effect relationship has not been established	
	Decreasing potentially pathogenic gastro-intestinal microorganisms	From the human intervention studies provided, the only significant changes reported were related to bifidobacteria, Bacteroidaceae and Clostridium perfringens. The Panel notes that these microorganisms are part of the commensal intestinal microbiota, and that the studies did not provide evidence for the characterisation of any of these groups as pathogens. The Panel considers that no conclusions	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		can be drawn from these studies for the scientific substantiation of the claimed effect The Panel concludes that a cause and effect relationship has not been established	
	"Natural immune function"	The claimed effect is not sufficiently defined and no further details were given in the proposed wording or clarifications provided by Member States. Given the multiple roles of the immune system, the specific aspect of immune function that is the subject of the claim needs to be specified, but has not been indicated in the information providedThe Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
	Reduction of symptoms of inflammatory bowel conditions	The claimed effect is “natural immune function”. In the context of the proposed wording, the Panel assumes that the claimed effect refers to the reduction of symptoms of inflammatory bowel conditions. The Panel notes that inflammatory bowel conditions are associated with Crohn's disease or ulcerative colitis, and that the target population for the claim is patients with Crohn's disease or ulcerative colitis. The Panel considers that the claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006	
	Maintenance of normal blood LDL-cholesterol concentrations	No references have been provided from which conclusions could be drawn for the scientific substantiation of the claimed effect The Panel concludes that a	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		cause and effect relationship has not been established	
Bifidobacterium animalis Lafti B94 (CBS118.529)	"Intestinal flora"	The Panel assumes that the claimed effect refers to aspects of: "probiotic, enhance levels of beneficial microflora, support a balanced/beneficially affect intestinal microflora" The Panel notes that the human study cited in the list did not address the relationship between the consumption of Bifidobacterium animalis Lafti B94 (CBS118.529) and the claimed effect. The in vitro and animal studies provided limited evidence to support the claimed effect in humans and that the remaining references did not provide any scientific data that could be used to substantiate the claimed effect The Panel concludes that a	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		cause and effect relationship has not been established	
Bifidobacterium Bb-12 and soluble fibre in fermented dairy products	"Healthy digestion"	The claimed effect "healthy digestion" is not sufficiently defined but in the context of the proposed wording, the Panel assumes that the claimed effect relates to aspects of promoting the growth of "beneficial" bacteria and decreasing potentially pathogenic intestinal microorganisms.The soluble fibre is not sufficiently characterisedAs the information provided in the list is insufficient to characterise the soluble fibre in the fermented dairy products and the references cited did not	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		provide any scientific data that could be used to substantiate the claimed effect, the Panel concludes that a cause and effect relationship has not been established between the consumption of "Bifidobacterium animalis ssp. lactis Bb-12 and soluble fibre in fermented dairy products" and decreasing potentially pathogenic intestinal microorganismsThe Panel concludes that a cause and effect relationship has not been established	
Combination of *Lactobacillus delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *Streptococcus thermophilus* 9Y/CSL (LMG P-17225)	"Beneficial modulation of the intestinal microflora"	Based on current scientific knowledge, it is not possible to define the exact numbers/proportions of the different microbial groups which constitute a "beneficial" or "normal" intestinal microbiota. Increasing the number of any group of microorganisms, including lactobacilli and/or	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		bifidobacteria, is not considered in itself a beneficial physiological effect. Thus, the applicant was requested to provide the rationale regarding the extent to which the claimed effect is a beneficial physiological effect. No reply was received from the applicant to the Panel's request for supplementary information. The Panel considers that no evidence has been provided by the applicant to establish that the claimed effect, "beneficial modulation of the intestinal microflora", is a beneficial physiological effect The Panel concludes that a cause and effect relationship has not been established	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
Lactobacillus rhamnosus GR-1 (ATCC 55826) in combination with *Lactobacillus reuteri* RC-14 (ATCC 55845)	"Vaginal health/flora"	The Panel assumes that the claimed effect refers to defence against vaginal pathogens by increasing the number of lactobacilli and/or decreasing potentially pathogenic bacteria and/or yeasts No references were provided from which conclusions could be drawn for the scientific substantiation of the claim The Panel concludes that a cause and effect relationship has not been established	
Lactobacillus johnsonii NCC 533 (La1) (CNCM I-1225)	Improving immune defence against pathogenic gastro-intestinal microorganisms	No human studies from which conclusions could be drawn for the scientific substantiation of the claim were providedThe Panel concludes that a cause and effect relationship has not been established	
	Protection of the skin from UV-induced damage	No human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		The Panel concludes that a cause and effect relationship has not been established	
Lactobacillus rhamnosus ATCC 53103 (LGG)	"Gastro-intestinal health"	The claimed effect is not sufficiently defined, and no further details were provided in the proposed wordings. The Panel notes that the references provided addressed several effects, and that it was not possible to establish the effect which is the target for the claim The Panel considers that the claimed effect is general and non specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.	
	Maintenance of tooth mineralisation	The only human study provided from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of L. rhamnosus ATCC 53103 (LGG) consumption on reduction of	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		dental caries at any site compared to placebo, the reduction of which could indicate an effect on maintenance of tooth mineralisation The Panel concludes that a cause and effect relationship has not been established	
Lactobacillus rhamnosus LB21 NCIMB 40564	"Digestive system, immune system"	The Panel assumes that the claimed effect refers to the maintenance of individual intestinal microbiota in subjects receiving antibiotic treatment. No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect. The Panel concludes that a cause and effect relationship has not been established	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
Lactobacillus johnsonii BFE 6128	"Natural defences/immune system""Skin health"	The claimed effect is not sufficiently defined and no further details were given in the proposed wording or the clarifications provided by Member States.The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.	
Lactobacillus plantarum BFE 1685	"Natural defences/immune system"	The claimed effect is not sufficiently defined and no further details were given in the proposed wording or the clarifications provided by Member States. Several effects/parameters were mentioned in the information provided, and it was not possible to establish which specific effect is the target for the claim. The Panel considers that the claimed effect is general and	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.	
Lactobacillus fermentum ME-3	"A probiotic lactic acid bacterium *Lactobacillus fermentum* ME-3 helps to strengthen the organism's defence ability. ME-3 supports digestion by increasing in the intestine the total number of useful lactobacilli which ensure the break-down of nutrients into compounds that can be easily absorbed"	The Panel considers that the evidence provided does not establish that increasing numbers of intestinal microorganisms is a beneficial physiological effect. The Panel considers that decreasing potentially pathogenic gastro-intestinal microorganisms might be a beneficial physiological effect. No human studies were provided which addressed outcomes related to the claimed effect. The Panel concludes that a cause and effect relationship has not been established	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
Lactobacillus plantarum 299v	Reduction of flatulence and bloating	In weighing the evidence, the Panel took into account that no conclusions can be drawn for the scientific substantiation of the claimed effect from the three studies provided that addressed outcomes related to the claimed effect. The Panel concludes that a cause and effect relationship has not been established	
	Protection of DNA, proteins and lipids from oxidative damage	No human studies that addressed the effect of *Lactobacillus plantarum* 299v alone on outcomes related to the claimed effect were provided. The Panel concludes that a cause and effect relationship has not been established	
Lactobacillus paracasei LMG P-22043	Decreasing potentially pathogenic gastro-intestinal microorganisms	No human studies were provided which addressed outcomes related to the claimed effect.	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		The Panel concludes that a cause and effect relationship has not been established	
	Reduction of gastro-intestinal discomfort	No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.The Panel concludes that a cause and effect relationship has not been established	
Lactobacillus fermentum CECT5716	"Natural defence/immune system"	The Panel assumes that the claimed effect refers to the maintenance of the upper respiratory tract defence against pathogens by maintaining immune defences In weighing the evidence, the Panel took into account that the only human study provided did not show an effect of Lactobacillus fermentum CECT5716 consumption on the maintenance of the upper respiratory tract defence against pathogens by maintaining immune defences.	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		The Panel concludes that a cause and effect relationship has not been established	
Lactobacillus plantarum 299 (DSM 6595, 67B) (ID 1078)	"Increase the amount of lactobacilli in the intestine/decrease the amount of enterobacteriaceae/inhibit pathogenic bacteria"	No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect. The Panel concludes that a cause and effect relationship has not been established	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
Lactobacillus gasseri CECT5714 and *Lactoba coryniformis* CECT5711	"Natural defence/immune system"	The Panel assumes that the claimed effect refers to increasing/strengthening the immune system and natural defences by stimulating the production of antibodies and cytokines, increasing natural killer cell numbers/activity and increasing the phagocytic activity of granulocytes and monocytes. The Panel considers that the evidence provided does not establish that changing parameters of the immune system, such as the production of cytokines, increasing natural killer cell numbers/activity and increasing the phagocytic activity of granulocytes and monocytes, is per se a beneficial physiological effect. The Panel concludes that a cause and effect relationship has not been established	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
Lactobacillus reuteri ATCC 55730	"Natural defence"	"Natural defence" is not sufficiently defined and no further details were provided in the proposed wording. The references cited addressed several effects and endpoints, and it is not possible to establish which effect is the target for the claim.The Panel considers that the claimed effect is general and non-specific and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.	
Lactobacillus paracasei B21060	Decreasing potentially pathogenic gastro-intestinal microorganisms	No human studies were provided that addressed endpoints related to decreasing potentially pathogenic gastro-intestinal microorganisms and the evidence provided in in vitro studies alone is not sufficient to predict an effect of L. paracasei B21060 consumption on the claimed effect.	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		The Panel concludes that a cause and effect relationship has not been established	
	Maintenance of a normal intestinal transit time	No human studies were provided that addressed endpoints related to intestinal transit time. The Panel concludes that a cause and effect relationship has not been established	
	Reduction of gastro-intestinal discomfort	In weighing the evidence, the Panel took into account that the one human intervention study submitted measured endpoints related to the claimed effect, but failed to show a significant difference in the intention-to-treat analysis. The Panel concludes that a	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		cause and effect relationship has not been established	
"*Brassica oleracea* var. italica (broccoli)"	Protection of cells and molecules, including cells of the immune system, against oxidative damage	The information given in the consolidated list and in the references provided did not allow the Panel to sufficiently characterise the foods/food constituents which are the subject of this opinion. The Panel considers that the foods/food constituents which are the subject of this opinion are not sufficiently characterised, or are not sufficiently characterised in relation to the proposed claimed effects.	Protective effects against cancer, possibly due to high levels of glucosinolates Beneficial effects on fibromyalgia in women Treatment of *Helicobacter pylori* infection Antihyperlipidaemic effects

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
Green tea (*Camellia sinensis*)Including tea, catechins present in green tea, green tea extract and epigallo-catechin-3-gallate (EGCG)	Improvement of endothelium-dependent vasodilation	The Panel considers that whereas Camellia sinensis (L.) Kuntze (tea) and green tea extract are not sufficiently characterised in relation to the claimed effects, catechins in green tea (including EGCG) are sufficiently characterisedNo references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.The Panel concludes that a cause and effect relationship has not been established	May reduce allergy symptoms associated with Japanese cedar pollinosisMay have beneficial effects on anxietyMay safely improve blood pressure and cholesterol levels in obese childrenA specific formulation of green tea may help prevent cold and flu symptomsMay be effective in reducing dental plaqueMay decrease clinical signs of periodontal diseaseMay decrease viral load in carriers of the HTLV-1 virusMay have beneficial effects on blood lipids in individuals with hypercholesterolemiaMay decrease postprandial triglyceride levels in individuals with hypertriglyceridemiaMay reduce the risk of liver diseaseMay improve cognitionMay ameliorate serious obesity and cardiovascular disease riskMay reduce markers of oxidative stress in patients with pulmonary tuberculosis
	Maintenance of normal blood pressure	A claim on EGCG in green tea (Camellia sinensis (L.) Kuntze) and maintenance of normal blood pressure has already been assessed with an unfavourable outcome, and the references cited for this claim did not provide any additional scientific data which could be used to substantiate the claim. (The original ruling stated that "In weighing the evidence, the	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		Panel took into account that none of the human studies presented reported on daily intakes of the food constituent that is the subject of this health claim (i.e., EGCG in green tea), and that the evidence provided in the animal studies does not predict the occurrence of an effect of green tea (including EGCG) consumption on the maintenance of normal blood pressure in humans.") The Panel concludes that a cause and effect relationship has not been established	
	Maintenance of normal blood glucose concentrations	A claim on catechins (including EGCG) from green tea (Camellia sinensis (L.) Kuntze) and the long term maintenance of normal blood glucose concentrations has already been assessed with an unfavourable outcome, and the references cited for this claim	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		did not provide any additional scientific data which could be used to substantiate the claim. (The original decision stated: "No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.")	
	Maintenance of normal blood LDL cholesterol concentrations	A claim on catechins in green tea (Camellia sinensis (L.) Kuntze) and maintenance of normal blood cholesterol concentrations has already been assessed with an unfavourable outcome, and the references cited for this claim did not provide any additional scientific data which could be used to substantiate the claim.The Panel concludes that a cause and effect relationship has not been established	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
	Protection of the skin from UV-induced (including photo-oxidative) damage	No human studies which addressed outcome measures related to the claimed effect following consumption of the food that is the subject of the health claim were provided. The Panel concludes that a cause and effect relationship has not been established	
	Protection of DNA, proteins and lipids from oxidative damage	No studies with appropriate endpoints to assess oxidative damage of DNA within cells, oxidative damage to proteins, or studies investigating a sustained effect of green tea catechins on lipid peroxidation have been presented to substantiate the claimed effect. The Panel concludes that a cause and effect relationship has not been established	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
	Protection of lipids from oxidative damage	A claim on catechins (including EGCG) in green tea (Camellia sinensis (L.) Kuntze) and protection of DNA, proteins and lipids from oxidative damage has already been assessed with an unfavourable outcome, and the references cited for this claim did not provide any additional scientific data which could be used to substantiate the claim. The Panel concludes that a cause and effect relationship has not been established	
	Contribution to normal cognitive function	No human studies were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect. The Panel concludes that a cause and effect relationship has not been established	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
	"Cardiovascular system"	The claimed effect is not sufficiently defined and no further details were provided in the proposed wording or the clarifications provided.The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.	
	"Invigoration of the body"	The claimed effect is not sufficiently defined and no further details were provided in the proposed wording or the clarifications provided. The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
	Decreasing potentially pathogenic gastro-intestinal microorganisms	The Panel assumes that the claimed effect refers to increasing the number of “beneficial” bacteria and decreasing the number of potentially pathogenic bacteria. The Panel considers that the evidence provided does not establish that increasing numbers of gastro-intestinal microorganisms is a beneficial physiological effect. (NB The original decision felt that this "might" be a beneficial effect.) A claim on catechins in green tea (Camellia sinensis (L.) Kuntze) and decreasing potentially pathogenic intestinal microorganisms has already been assessed with an unfavourable outcome, and the references cited for this claim did not provide any additional scientific data which could be used to substantiate the claim. (The original decision stated	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		that "No human studies which addressed the effects of catechins in green tea (Camellia sinensis (L.) Kuntze) on the number of potentially pathogenic intestinal microorganisms were provided.) The Panel concludes that a cause and effect relationship has not been established	
	"Immune health"	The claimed effect is not sufficiently defined and no further details were provided in the proposed wording or the clarifications provided. The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
	"Mouth"	The target population is assumed to be the general population. The claimed effect is not sufficiently defined and no further details were provided in the proposed wording or the clarifications provided.The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.	
	Contribution to the maintenance or achievement of a normal body weight	In weighing the evidence, the Panel took into account that the only intervention study from which sufficient information was available for a scientific evaluation found no effect of EGCG consumption on body weight. The Panel concludes that a cause and effect relationship has not been established	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
	Increased beta-oxidation of fatty acids leading to a reduction in body fat mass	No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect. The Panel concludes that a cause and effect relationship has not been established	
	Maintenance of bone	No human studies which addressed the effects of either catechins or tannins in *Camellia sinensis* (L.) Kuntze on bone were provided. The Panel concludes that a cause and effect relationship has not been established	
	Reduction of acid production in dental plaque	No human studies investigating the effect of the consumption of either catechins or tannins in Camellia sinensis (L.) Kuntze on acid production were presented.	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		The Panel concludes that a cause and effect relationship has not been established	
	Maintenance of vision	No human studies which addressed the effects of catechins in green tea (*Camellia sinensis* (L.) Kuntze) on maintenance of normal vision were provided.The Panel concludes that a cause and effect relationship has not been established	
	Maintenance of normal blood cholesterol concentrations	In weighing the evidence, the Panel took into account that all three small-scale human randomised, placebo-controlled intervention trials presented failed to observe an effect of green tea catechin consumption on blood cholesterol concentrations. The Panel concludes that a cause and effect relationship	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		has not been established	
Vaccinium macrocarpon (cranberry)	Defence against bacterial pathogens in the lower urinary tract	The Panel considers that the foods/food constituents which are the subject of this opinion are not sufficiently characterised, or are not sufficiently characterised in relation to the proposed claimed effects.	There is highly suggestive evidence to support the use of cranberry for prophylaxis of urinary tract infections Reduces bacterial populations in paediatric urinary tract infections May possess antioxidant properties due to presence of ascorbic acid May be used to prevent urinary tract symptoms during external radiation therapy for patients being treated for prostate cancer May reduce urine odor associated with incontinence or intermittent bladder

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
			catheterization
Antioxidants: various food(s)/food constituent(s) and protection of cells from premature ageing, antioxidant activity, antioxidant content and antioxidant properties, protection of DNA, proteins and lipids from oxidative damage, and bioavailability of anthocyanins in blackcurrants	Protection of cells from premature ageing (including 'anti-cancer')	The Panel considers that the claimed effect “anti-cancer” relates to the prevention of a human disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.No definition has been provided of “premature (skin) ageing”, “healthy ageing”, “oxidation-induced ageing” or “cellular ageing” in relation to the antioxidant properties of foods. The Panel considers that these claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.	References in the following review: Ames BN. Optimal micronutrients delay mitochondrial decay and age-associated diseases. Mech Ageing Dev. 2010; 131 (7-8): 473-9. Epub 2010 Apr 24. Review.Phytonutrient dense diets exert anti-ageing effects:Willcox DC, et al. The Okinawan diet: health implications of a low-calorie, nutrient-dense, antioxidant-rich dietary pattern low in glycemic load. J Am Coll Nutr. 2009; 28 Suppl: 500S-516S.

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
	Antioxidant activity, antioxidant content and antioxidant properties	The Panel considers that claims made on the antioxidant capacity/content or properties of foods/food constituents based on their capability of scavenging free radicals in vitro refer to a property of the food/food constituent measured in model systems. The information provided does not establish that this capability as such exerts a beneficial physiological effect in humans. No evidence has been provided to establish that having antioxidant activity/content and/or antioxidant properties is a beneficial physiological effect. The Panel concludes that a cause and effect relationship has not been established	References in the following review: Obrenovich ME, et al. Antioxidants in health, disease and aging. CNS Neurol Disord Drug Targets. 2011; 10(2): 192-207.

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
	Protection of DNA, proteins and lipids from oxidative damage	No human studies that investigated the effects of the consumption of the food(s)/food constituent(s) on reliable markers of oxidative damage to body cells or to molecules such as DNA, proteins and lipids have been provided in relation to any of the health claims evaluated in this opinion. The Panel concludes that a cause and effect relationship has not been established	References in the following review: Ames BN. Low micronutrient intake may accelerate the degenerative diseases of aging through allocation of scarce micronutrients by triage. Proc Natl Acad Sci U S A. 2006; 103(47): 17589-94. Epub 2006 Nov 13.
Dried plums of 'prune' cultivars *(Prunus domestica* L.)	"Normal bowel function/normal gastrointestinal function/normal colonic function"	In weighing the evidence, the Panel took into account that one human intervention study did not find any significant difference between the two treatment groups or between different time-points within each group and that the other human intervention study showed some effect on faecal bulk but not on stool frequency or consistency. Another human	Piirainen L, et al. Prune juice has a mild laxative effect in adults with certain gastrointestinal symptoms, Nutrition Research, 2007; 27 (8): 511-513.Attaluri A, Donahoe R, Valestin J, Brown K, Rao SS. Randomised clinical trial: dried plums (prunes) vs. psyllium for constipation. Aliment Pharmacol Ther. 2011; 33(7): 822-8. doi: 10.1111/j.1365-2036.2011.04594.x. Epub 2011

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		intervention study cited used another intervention than dried “prunes” and the other references provided only background information and did not provide scientific data that could be used to substantiate the claim.The Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship	Feb 15.
Carotenoids (also see 'antioxidants')	“Antioxidant properties/protection of DNA”, “health during pregnancy/bioavailability” and “skin”	The Panel considers that the foods/food constituents, which are the subject of this opinion, are not sufficiently characterised in relation to the claimed effects.	References in the following: Podsędek A. Natural antioxidants and antioxidant capacity of Brassica vegetables: A review, LWT - Food Science and Technology, 2007; 40(1); 1-11.
Astaxanthin	Protection of the skin from UV-induced damage	No human studies have been provided from which conclusions could be drawn for the scientific substantiation of the claim. The Panel concludes that a cause and effect relationship has not been established	May inhibit LDL oxidation

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
	Defence against *Helicobacter pylori*	No human studies have been provided from which conclusions could be drawn for the scientific substantiation of the claim. The Panel concludes that a cause and effect relationship has not been established	
	Contribution to normal spermatogenesis	In weighing the evidence, the Panel took into account that the one human intervention study provided did not show an effect of astaxanthin, compared to placebo, on various measures of sperm quality in males. The Panel concludes that a cause and effect relationship has not been established	
	Contribution to normal muscle function	The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
	"Immune system"	The references provided addressed several outcomes, and it was not possible to establish which effect is the target for the claim. Given the multiple roles of the immune system, the specific aspect of immune function that is the subject of the claim needs to be specified, but has not been indicated in the information provided.The Panel concludes that a cause and effect relationship has not been established	
	Maintenance of joints, tendons, and connective tissue, maintenance of visual acuity, protection of DNA, proteins and lipids from oxidative damage, maintenance of blood cholesterol concentrations and maintenance of low plasma concentrations of C-reactive protein (CRP)	On the basis of the data available, the Panel concludes that a cause and effect relationship has not been established between the consumption of astaxanthin and the maintenance of normal joints, tendons or connective tissue, protection of DNA, proteins or lipids from oxidative damage, maintenance of normal visual acuity, and	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		maintenance of normal blood cholesterol concentrations or the maintenance of low plasma concentrations of CRP. The Panel concludes that a cause and effect relationship has not been established	
Pomegranate/pomegranate juice	Maintenance of normal blood cholesterol concentrations	No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect. The Panel concludes that a cause and effect relationship has not been established	Topical antifungal activity Decreases serum angiotensin converting enzyme (ACE) activity and lowered blood pressure in elderly hypertensive patients May have antibacterial activity and may be useful in dental conditions May have antihypertensive effects
	Maintenance of normal erectile function	Four references were provided in relation to this claim, including three references from which no conclusions could be drawn for the scientific substantiation of the claimed effect. The fourth reference reported on a randomised, double-blind, placebo-controlled, crossover	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		intervention study in male subjects with erectile dysfunction. The Panel notes that pomegranate juice has not been sufficiently characterised with respect to polyphenols (i.e., punicalagin and/or ellagic acid content not specified) and that there was no significant effect of pomegranate juice on erectile function measured using either the Global Assessment Questionnaires (GAQ) score or the International Index of Erectile Function (IIEF). The Panel concludes that a cause and effect relationship has not been established	
	Protection of lipids from oxidative damage	No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect. The Panel concludes that a cause and effect relationship	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		has not been established	
	"Antioxidant and anti-aging properties"	The Panel considers that no evidence has been provided to establish that having antioxidant properties is a beneficial physiological effect. In addition, no definition has been provided of having "anti-aging properties" in relation to the antioxidant properties of foods.	
	Increase in appetite after unintentional weight loss leading to an increase in energy intake	No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect. The Panel concludes that a cause and effect relationship has not been established	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
	Maintenance of normal blood glucose concentrations	No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect. The Panel concludes that a cause and effect relationship has not been established	
Gamma-linoleic acid (GLA)	Reduction of inflammation	The Panel notes that the provided review of gamma-linolenic acid and the mechanistic in vitro study provide little evidence for the claimed effect of gamma-linolenic acid on reduction of inflammation. The Panel concludes that a cause and effect relationship has not been established	May be a viable treatment for diabetic neuropathy GLA may aid in treating acute respiratory distress syndrome (ARDS) and may offer benefits in terms of blood pressure reduction GLA may act as a cytotoxic agent or at least as an adjunct agent to a chemotherapy regimen May enhance the effects of calcium supplementation in elderly patients with senile osteoporosis

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
			Potential for benefit of edema (swelling) in pregnancy and in terms of premenstrual syndrome symptoms May be associated with improvement of skin conditions with pruritus (severe itching) Significant therapeutic improvements in rheumatoid arthritis symptoms GLA may be a more tolerable alternative to the standard pain-reduction therapies, such as COX / COX2 inhibitors, and NSAIDs and their adverse events

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
Fructo-oligosaccharides (FOS) (prebiotic)	Decreasing potentially pathogenic gastro-intestinal microorganisms	No human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided.The Panel concludes that a cause and effect relationship has not been established	Alles, MS,et al. Fate of fructo-oligosaccharides in the human intestine. Br.J.Nutr. 1996;76(2):211-221.Bomba, A, et al. Improvement of the probiotic effect of micro-organisms by their combination with maltodextrins, fructo-oligosaccharides and polyunsaturated fatty acids. Br.J.Nutr. 2002;88 Suppl 1:S95-S99. View Bornet, FR, Brouns F. Immune-stimulating and gut health-promoting properties of short-chain fructo-oligosaccharides. Nutr.Rev. 2002;60(10 Pt 1):326-334. View AbstractBouhnik Y, et al. Effects of fructo-oligosaccharides ingestion on fecal bifidobacteria and selected metabolic indexes of colon carcinogenesis in healthy humans. Nutr.Cancer 1996;26(1):21-29. View AbstractBriet F, et al. Symptomatic response to varying levels of fructo-oligosaccharides
	Changes in short chain fatty acid (SCFA) production and pH in the gastro-intestinal tract	The Panel considers that changes in SCFA production and pH in the bowel are not per se beneficial physiological effects, but need to be linked to a beneficial physiological or	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		clinical outcome. No evidence has been provided to indicate the context in which the claimed effect could be considered as a beneficial physiological effect. The Panel concludes that a cause and effect relationship has not been established	consumed occasionally or regularly. Eur.J.Clin.Nutr. 1995;49(7):501-507.Cummings JH, et al. A study of fructo oligosaccharides in the prevention of travellers' diarrhoea. Aliment. Pharmacol. Ther. 2001;15(8):1139-1145.Giacco, R., Clemente, G., Luongo, D., Lasorella, G., Fiume, I., Brouns, F., Bornet, F., Patti, L., Cipriano, P., Rivellese, A. A., and Riccardi, G. Effects of short-chain fructo-oligosaccharides on glucose and lipid metabolism in mild hypercholesterolaemic individuals. Clin.Nutr. 2004; 23(3):331-340.Hartemink, R., Van Laere, K. M., and Rombouts, F. M. Growth of enterobacteria on fructo-oligosaccharides. J.Appl.Microbiol. 1997; 83(3):367-374.Hidaka, H. and Hirayama, M. Useful characteristics and commercial applications of fructo-oligosaccharides.
	Changes in bowel function	In weighing the evidence, the Panel took into account that the only relevant human study showed no effect of FOS on bowel function The Panel concludes that a cause and effect relationship has not been established	
	Reduction of gastro-intestinal discomfort	No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect The Panel concludes that a cause and effect relationship	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
		has not been established	Biochem.Soc.Trans. 1991; 19(3):561-565. La Rosa M, et al. [Prevention of antibiotic-associated diarrhea with Lactobacillus sporogens and fructo-oligosaccharides in children. A multicentric double-blind vs placebo study]. Minerva Pediatr. 2003; 55(5):447-452.Mitsuoka T, et al. Effect of fructo-oligosaccharides on intestinal microflora. Nahrung 1987; 31(5-6): 427-436.Schaafsma, G., Meuling, W. J., van Dokkum, W., and Bouley, C. Effects of a milk product, fermented by Lactobacillus acidophilus and with fructo-
	Increase in calcium and/or magnesium absorption leading to an increase in magnesium and/or calcium retention	In weighing the evidence, the Panel took into account that only two chronic studies in a low number of human subjects were provided and that these studies, though suggesting an effect on magnesium (but not calcium) absorption, do not show an effect of FOS from sucrose on mineral retention The Panel concludes that a cause and effect relationship has not been established	

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
	Maintenance of normal blood LDL-cholesterol concentrations and maintenance of normal (fasting) blood concentrations of triglycerides	In weighing the evidence, the Panel took into account that six out of the seven small intervention studies from which conclusions could be drawn for the scientific substantiation of the claim did not observe a significant effect of FOS from sucrose on blood cholesterol concentrationsThe Panel concludes that a cause and effect relationship has not been established	oligosaccharides added, on blood lipids in male volunteers. Eur.J.Clin.Nutr. 1998;52(6):436-440.Tahiri, et al. Five-week intake of short-chain fructo-oligosaccharides increases intestinal absorption and status of magnesium in postmenopausal women. J.Bone Miner.Res. 2001; 16(11): 2152-2160.Tuohy KM, et al. The prebiotic effects of biscuits containing partially hydrolysed guar gum and fructo-oligosaccharides--a human volunteer study. Br.J.Nutr. 2001; 86(3): 341-348.

Disallowed food/food ingredient	Claims(s) sought	Reasons for refusal	Known health benefits*
Medium-chain triglycerides (MCTs)	Reduction in body weight	The Panel took into account that the results from the human intervention studies provided are inconsistent with respect to the effects of medium-chain triglycerides on body weight loss, and that the evidence in support of a mechanism by which medium-chain triglycerides could exert the claimed effect is weak and not convincing. The Panel concludes that a cause and effect relationship has not been established	