

	Cell division	365	Established	"Magnesium contributes to normal cell division"	X	
	Maintenance of bone	239	Established	"Magnesium contributes to the maintenance of normal bone"	FNFC	
	Maintenance of teeth	239	Established	"Magnesium contributes to the maintenance of normal teeth"	FNFC	
	Blood coagulation	357	Not established		X	
	Protein synthesis	364	Established	"Magnesium contributes to normal protein synthesis"	X	
	Protection of DNA, proteins and lipids from oxidative damage	309	Established	"Manganese contributes to the protection of cell constituents from oxidative damage"	X	
5	Maintenance of bone	310	Established	"Manganese contributes to the maintenance of normal bone"	X	A food should be at least a source of manganese as per Annex to Regulation (EC) No 1924/2006. The target population is the general population.
	Energy-yielding metabolism	311	Established	Manganese contributes to normal energy-yielding metabolism	X	
	Cognitive function	340	Not established		X	
	Cell differentiation	14	Established	"Vitamin A contributes to normal cell differentiation."	X	
	Function of the immune system	14	Established	"Vitamin A contributes to a normal function of the immune system."	X	
	Maintenance of skin and mucous membranes	15, 17	Established	"Vitamin A contributes to the maintenance of normal skin and mucous membranes."	FNFC	A food should be at least a source of vitamin A as per Annex to Regulation (EC) No 1924/2006. The target population is the general population.
	Maintenance of vision	16	Established	"Vitamin A contributes to the maintenance of normal vision."	FNFC	
6	Maintenance of bone	13, 17	Not established		X	Tolerable Upper Intake Levels (UL) for pre-formed vitamin A have been established for children and adults. The
	Maintenance of teeth	13, 17	Not established		X	Tolerable Upper Intake Level for adults has been set at
	Maintenance of hair	17	Not established		X	3000 µg RE/day (SCF, 2002).
	Maintenance of nails	17	Not established		X	
	Metabolism of iron	206	Established	"Vitamin A contributes to normal iron metabolism."	X	
	Protection of DNA, proteins and lipids from oxidative damage	209	Not established		X	
7	Maintenance or achievement of a normal body weight	2428	Not established			
	Long-term maintenance of normal blood glucose concentrations	2429	Not established			
8	Daucus carota (Carrot)	2431	Not established			

9	Invigoration of the body	2437	Not established	
	Maintenance of skin	2438	Not established	
	Maintenance of hair	2438	Not established	
	Maintenance of bone	2439	Not established	
	Maintenance or achievement of a normal body weight	2783	Not established	
10	<i>Viola tricolor</i> L.	2356	Not established	
11	<i>Undaria pinnatifida</i> (Harvey)	2345	Not established	
12	Enhancement of mood Attention	1575	Not established	
		1828	Not established	
13	<i>Theobroma cacao</i> L. (Cocoa)	2724	Not established	
14	<i>Fagopyrum esculentum</i> Moench (Buckwheat)	2442	Not established	
15	Maintenance of bone	123, 127, 128, 2879	Established	FOSHU "Vitamin K contributes to maintenance of normal bone"
	Blood coagulation	124, 126	Established	"Vitamin K contributes to normal blood coagulation"
	Function of the heart and blood vessels	124, 125, 2880	Not established	A food should be at least a source of vitamin K as per Annex to Regulation 1924/2006. The target population is the general population.
16	Phosphorus	328	Established	"Phosphorus contributes to normal function of cell membranes"
	Energy-yielding metabolism	329, 373	Established	"Phosphorus contributes to energy metabolism"
	Maintenance of bone and teeth	324, 327	Established	"Phosphorus contributes to the maintenance of normal bone and teeth"
17	Energy-yielding metabolism	56, 59, 60, 64, 171, 172, 208	Established	"Pantothenic acid contributes to normal energy-yielding metabolism"
		57	Established	"Pantothenic acid contributes to normal mental performance"
		61	Not established	A food should be at least a source of pantothenic acid as per Annex to Regulation (EC) No 1924/2006.
	Maintenance of bone	61	Not established	
	Maintenance of teeth	61	Not established	
Maintenance of hair	61	Not established		
Maintenance of skin	61	Not established		
Maintenance of nails	61	Not established		
				FNFC
				X

	Synthesis and metabolism of steroid hormones, vitamin D and some neurotransmitters	181	Established	"Pantothenic acid contributes to normal synthesis and metabolism of steroid hormones, vitamin D and some neurotransmitters"	X	
18	Vitamin B6	Protein and glycogen metabolism	Established	"Vitamin B6 contributes to normal protein and glycogen metabolism"	FNFC	
		Function of the nervous system	Established	"Vitamin B6 contributes to the normal function of the nervous system"	X	A food should be at least a source of vitamin B6 as per Annex to Regulation (EC) No 1924/2006. The target population is the general population.
		Red blood cell formation	Established	"Vitamin B6 contributes to normal red blood cell formation"	X	
		Function of the immune system	Established	"Vitamin B6 contributes to normal function of the immune system"	X	Tolerable Upper Intake Levels (UL) have been established for vitamin B6 in children, adolescents and adults (SCF, 2000).
		Regulation of hormonal activity	Established	"Vitamin B6 contributes to the regulation of hormonal activity"	X	
		Mental performance	Not comply with the criteria (excess consumption)	X		
19	Selenium	Protection of DNA, proteins and lipids from oxidative damage	Established	"selenium contributes to the protection of cell constituents from oxidative damage"	X	
		Function of the immune system	Established	"selenium contributes to the normal function of the immune system"	X	
		Thyroid function	Established	"selenium contributes to normal thyroid function"	X	A food should be at least a source of selenium as per Annex to Regulation (EC) No 1924/2006. The target population is the general population.
		Function of the heart and blood vessels	Not established		X	
		Prostate function	Not established		X	
		Cognitive function	Not established		X	
		Spermatogenesis	Established	"selenium contributes to normal spermatogenesis"	X	
		Protection of DNA, proteins and lipids from oxidative damage	Established	"Vitamin C contributes to the protection of cell constituents from oxidative damage."	FNFC	
		Antioxidant function of lutein	Not established		X	A food should be at least a source of vitamin C as per Annex to Regulation 1924/2006. The target population is the general population.
		Maintenance of vision	Not established		X	

									<p>“Vitamin C contributes to normal collagen formation and the normal function of bones, teeth, cartilage, gums, skin and blood vessels.”</p> <p>“Vitamin C contributes to the normal function of the nervous system.”</p> <p>“Vitamin C contributes to a normal function of the immune system.”</p> <p>“Vitamin C contributes to maintain the normal function of the immune system during and after intense physical exercise.”</p> <p>“Vitamin C increases non-haem iron absorption.”</p> <p>“Vitamin C contributes to normal energy-yielding metabolism.”</p>	<p>x</p> <p>x</p> <p>x</p> <p>x</p> <p>x</p> <p>x</p> <p>x</p> <p>x</p> <p>x</p>								
21	Tussilago farfara (Coltsfoot)																	
22	Niacin																	

23	Biotin	Energy-yielding metabolism Macronutrient metabolism Maintenance of skin and mucous membranes Maintenance of hair Function of the nervous system	114, 117 113, 114, 117 115 118, 2876 116	Established Established Established Established Established	“Biotin contributes to normal energy-yielding metabolism.” “Biotin contributes to normal macronutrient metabolism.” “Biotin contributes to the maintenance of normal skin and mucous membranes.” “Biotin contributes to the maintenance of normal hair.” “Biotin contributes to the normal function of the nervous system.”	X X FNFC X X	X X FNFC X X	A food should be at least a source of biotin as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.
24	Aegopodium podagraria L.	Digestive health	2384	Not established				
25	Boron	Maintenance of bone Maintenance of joints	218, 219 219, 220	Not established Not established				
26	Lathyrus pratensis L.	Respiratory health	2456	Not established				
27	Levisticum officinale W.D.J. Koch	Improvement of diuretic function	2292, 3420	Not established				
28	Amoracia rusticana P. Gaertn.	Improvement of diuretic function	2224, 2719	Not established				
29	Justicia adhatoda L.	Protection of DNA, proteins and lipids from oxidative damage Function of the upper respiratory tract	2508 3970	Not established Not established				
30	Lacprodan CGMP-10 (active ingredient: Sialic acid)	Plays a role in development of the brain	1594	Not established				
31	Heather blossom extract	Mental state and performance	2815	Not established				
32	Chondroitin or chondroitin sulphate	Joint health/joint health and mobility	1504, 1505	Not established				
33	Carthamus tinctorius L. (safflower oil)	Maintenance of skin Maintenance of hair	2748 4242	Not established Not established				
34	Ocimum basilicum L. (Basil)	Improvement of diuretic function	2314, 3465	Not established				
35	Hyaluronic acid	Maintenance of normal joints	1572, 1731, 1932, 3132	Not established				
36	Chenopodium quinoa L.	Hair growth	2746	Not established				
37	Ajuga reptans L.	Normal sebum production	2792	Not established				

38	Inositol	Cognitive and mental performance	1588	Not established	
39	Green lipped mussel	Joint and musculoskeletal system health	1571, 1813	Not established	
40	Amrri visnaga (L.) Lam.	Respiratory health	2211	Not established	
41	Fraxinus excelsior L.	Maintenance of joints Maintenance or achievement of a normal body weight	2256 3688	Not established Not established	
42	Hibiscus sabdariffa L.	Improvement of diuretic function Bowel motor function	2267, 3393 3391	Not established Not established	
43	Olive Biophenols (Food supplement)	Strong anti-bacterial properties	1877	Not established	
44	Methylsulfonylmethane (MSM)	maintenance of normal joints	395, 1616, 1617	Not established	
45	Sugar-free chewing gum	Dental and oral health, including gum and tooth protection and strength Plaque acid neutralisation Maintenance of tooth mineralisation Reduction of oral dryness Maintenance or achievement of a normal body weight	1149 1150 1151 1240 1152	Non-specific claim Established Established Established Not established	X X X X X
46	Angelica sinensis (Oliv.) Diels.	Maintenance of joints Oxygen transport	2392 3845	Not established Not established	
47	Justicia gendarussa L.	Improvement of diuretic function Reduction of inflammation of the lower urinary tract	2455 2455	Not established Not established	
48	Helianthus tuberosus L.	Decreasing potentially pathogenic intestinal microorganisms Breaking down lactose	2819 2819	Not established Not established	
49	Acacia gum (gum arabic)	Maintenance or achievement of a normal body weight Maintenance of normal blood cholesterol concentrations	2820 1976	Not established Not established	

50	Alpha-linolenic acid (LNA-Omega 3)	Maintenance of normal blood cholesterol concentrations Maintenance of normal blood pressure	493 625	Established Not established	"Alpha-linolenic acid contributes to maintenance of normal blood cholesterol concentrations"	X	A food should contain at least 15% of the proposed labelling reference intake value of 2 g ALA per day.
51	Shark cartilage	Joint health	1852, 1853	Not established			
52	Beta-glucans	Maintenance of normal blood cholesterol concentrations Maintenance or achievement of a normal body weight	754, 755, 757, 801, 1465, 2934 820, 823	Established Not established	"Regular consumption of beta-glucans contributes to maintenance of normal blood cholesterol concentrations"	X	Foods should provide at least 3 g/d of beta-glucans from oats, oat bran, barley, barley bran, or from mixtures of non-processed or minimally processed beta-glucans in one or more servings. The target population is adults with normal or mildly elevated blood cholesterol concentrations.
53	Picea abies (L.)Karsten	Relief in case of irritation in the upper respiratory tract	2827, 3493, 4095	Not established			
54	Soy isoflavones	Maintenance of bone mineral density in post-menopausal women	1655	Not established		FOSHU	
55	Glucosamine	Maintenance of joints	1561, 1562, 1563, 1564, 1565	Not established			
56	Dietary fibre or "water-soluble fibre"	Reduction of inflammation Maintenance of normal blood cholesterol concentrations	1869 747, 750, 811	Not established Not established		FOSHU	
57	Corylus avellana L. (Hazel nut oil)	Maintenance of normal skin	2749	Not established			
58	Isomalto-oligosaccharides	Maintenance of normal blood cholesterol concentrations	817	Not established		FOSHU	
59	Microorganisms		105 種類 171 件	Non-characterised ingredients			
60	Taurine	Protection of DNA, proteins and lipids from oxidative damage Energy-yielding metabolism Delay in the onset of fatigue and enhancement of physical performance	612, 1658, 1959 614 1660	Not established Not established Not established			
61	Lactobacillus rhamnosus HN001 AGAL NIM97/09514	Decreasing potentially pathogenic intestinal microorganisms	908	Not established			

62	Docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA), docosapentaenoic acid (DPA)	Maintenance of normal blood pressure Maintenance of normal HDL-cholesterol concentrations Maintenance of normal (fasting) blood concentrations of triglycerides Maintenance of normal LDL-cholesterol concentrations Maintenance of joints	502 515 517 528, 698 503, 505, 507, 511, 518, 524, 526, 535, 537	Established Not established Established Not established Not established	“DHA and EPA contribute to the maintenance of normal blood pressure” “DHA and EPA contribute to the maintenance of normal triglyceride concentrations”	x FOSHU	Intakes of EPA and DHA of about 3 g/d are required to obtain the claimed effect. The target population is adult men and women. Intakes of EPA and DHA of about 2-4 g/d are required to obtain the claimed effect. The target population is adult men and women.
63	Apple cider vinegar	Improvement of bowel motor function	1377	Not established			
64	Beta-Carotene	Maintaining normal physiological immune responses of the skin in relation to UV-radiation (sun exposure)	198, 1463	Not established			
65	Echium oil	maintenance of normal (fasting) blood concentrations of triglycerides	548	Not established			
66	Lactobacillus plantarum 299 (DSM 6595, 67B)	Immune system	1077	Not established			
67	Bifidobacterium animalis Lafti B94 (CBS118:529)	Support a balanced/beneficially affect intestinal microflora	867	Not established			
68	Lactobacillus plantarum 299v (DSM 9843)	Supporting a healthy intestinal flora	1084	Not established			
69	Kaki fruit	Maintenance of normal vision	1261	Not established			
70	Vitamin D + Calcium	Maintenance of normal bone	350	Established	“Calcium and vitamin D are needed for the maintenance of normal bone”	FNFC	A food should be at least a source of calcium and a source of vitamin D as per Annex to Regulation 1924/2006. The target population is the general population. The UL for calcium in adults is 2500 mg (SCF, 2003). ULs have been established for vitamin D in children, adolescents, and adults (25 μ g/day up to age 10 years; 50 μ g/day for age \geq 11 years) (SCF, 2002).

71	Bifidobacterium Bb-12 and soluble fibre in fermented dairy products	Decreasing potentially pathogenic intestinal microorganisms	1376	Not established				
72	Probiotic ingredient Lactobacillus casei F19 (LMG P-17806)	Improvement of bowel motor function	893	Not established				
73	Gamma - linolenic acid	Reduction of inflammation	1772	Not established				
74	Lactase enzyme (beta-galactosidase)	Breaking down lactose	1697, 1818	Established	"Lactase enzyme contributes to breaking down lactose"	X	The recommended dose is 4500 FCC (Food Chemicals Codex) units with each lactose containing meal.	
75	Phospholipids	Protection of DNA, proteins and lipids from oxidative damage Memory, learning and concentration, and function of the nervous system	1834 1836	Not established Not established				
76	Lactobacillus reuteri ATCC 55730	Decreasing potentially pathogenic intestinal microorganisms	904	Not established				
77	Lactobacillus johnsonii BFE 6128	Decreasing potentially pathogenic intestinal microorganisms	989	Not established				
78	Glucosaminan (Konjac)	Eduction of blood cholesterol concentrations	836, 1560	Established	"Regular consumption of glucosaminan helps maintain normal blood cholesterol concentrations"	X	A food should provide at least 4 g/d of glucosaminan in one or more servings. The target population is the general population.	
79	Silicon (as stabilised oligomeric orthosilicic acid (OSA))	Stimulating macrophages / increasing circulating lymphocytes	358	Not established				
80	Copper	Protection of DNA, proteins and lipids from oxidative damage	263, 1726	Established	"Copper contributes to the protection of cell constituents from oxidative damage"	X	A food should be at least a source of copper as per Annex to Regulation (EC) 1924/2006.	
		Function of the immune system	264	Established	"Copper contributes to normal function of the immune system"	X		
		Maintenance of connective tissues	265, 271, 1722	Established	"Copper contributes to maintenance of normal connective tissues"	FNFC	Tolerable Upper Intake Level (UL) has been established for copper as 5 mg/day in adults and during pregnancy and lactation. For children and adolescents UL was established as 1 mg/day for 1-3 years, 2 mg/day for 4-6 years, 3 mg/day for 7-10 years, 4 mg/day for 11-17 years (SCF, 2003).	
		Energy-yielding metabolism	266	Established	"Copper contributes to normal energy yielding metabolism"	X		
		Function of the nervous system	267	Established	"Copper contributes to normal function of the nervous system"	X		
		Maintenance of skin and hair pigmentation	268, 1724	Established	"Copper contributes to normal skin and hair pigmentation"	X		

	Iron transport	269, 270, 1727	Established	"Copper contributes to normal iron transport in the body"	FNFC	
	Cholesterol metabolism	369	Not established			
	Glucose metabolism	369	Not established			
81	Iron	Formation of red blood cells and haemoglobin	249, 1589	Established	"Iron contributes to normal formation of red blood cells and haemoglobin."	FNFC
		Oxygen transport	250, 254, 256	Established	"Iron contributes to normal oxygen transport in the body."	X
		Energy-yielding metabolism	251, 1589	Established	"Iron contributes to normal energy-yielding metabolism."	X
		Function of the immune system	252, 259	Established	"Iron contributes to a normal function of the immune system."	X
		Cognitive function	253	Established	"Iron contributes to normal cognitive function."	X
		Cell division	368	Established	"Iron contributes to normal cell division."	X
			maintenance of bone mineral density	1872	Not established	
82	Ipriflavone		Not established			
	Thyroid function and production of thyroid hormones	274	Established	"Iodine contributes to the normal production of thyroid hormones and normal thyroid function."	X	
83	Iodine	Energy-yielding metabolism	274	Established	"Iodine contributes to normal energy-metabolism."	X
		Maintenance of vision	356	Not established		
		Maintenance of hair	370	Not established		
		Maintenance of nails	370	Not established		
		Maintenance of skin	370	Established	"Iodine contributes to maintenance of normal skin."	X
84	Gamma - amino butyric acid (GABA)		Not established		FOSHU	
	normal cognitive function	1768	Not established			
	Blood formation	79	Established	"Folate contributes to normal blood formation."	X	
85	Folate	Homocysteine metabolism	80	Established	"Folate contributes to normal homocysteine metabolism."	X
		Energy-yielding metabolism	90	Not established		X
		Function of the immune system	91	Established	"Folate contributes to a normal function of the immune system."	X

	Function of blood vessels	94, 175, 192	Not established		X
	Cell division	193	Established	"Folate contributes to normal cell division"	X
	Maternal tissue growth during pregnancy	2882	Established	"Folate contributes to normal maternal tissue growth during pregnancy."	FOSHU
86	Linoleic acid (LA – omega 6)		Established	"Linoleic acid may help to maintain normal blood cholesterol concentrations"	X
	Energy-yielding metabolism	21, 24, 28	Established	"Thiamine contributes to normal energy-yielding metabolism"	X
	Cardiac function	20	Established	"Thiamine contributes to the normal function of the heart"	X
87	Thiamine	22, 27	Established	"Thiamine contributes to the normal function of the nervous system"	X
	Maintenance of bone	25	Not established		
	Maintenance of teeth	25	Not established		
	Maintenance of hair	25	Not established		
	Maintenance of nails	25	Not established		
	Maintenance of skin	25	Not established		
88	Lactobacillus paracasei 8700:2 (DSM 13434, 240HI)	1074	Not established	decreasing potentially pathogenic intestinal microorganisms	
	Lactobacillus gasseri	937	Not established	decreasing potentially pathogenic intestinal microorganisms	
89	CECT5714 and Lactobacillus coryniformis CECT5711	937	Not established	improvement of intestinal transit within the normal range might be beneficial to human health.	
90	L-glutamine	733	Not established	Immune health (Support of the immune system, contribution to the immune function/response to exercise)	
	Integrity of the intestinal lining and normal intestinal permeability	1602	Not established		
91	Tripeptides (isoleucine-proline-proline (IPP), valine-proline-proline (VPP))	615, 661, 1831, 1832, 2891	Not established	Maintenance of normal blood pressure	FOSHU
	Maintenance of the elastic properties of the arteries	1832	Not established		X

	Maintenance of joints, tendons, and connective tissue	1918, 1978, 3142	Not established			
	Protection of DNA, proteins and lipids from oxidative damage	1449, 3141	Not established			
	Maintenance of visual acuity	1448	Not established			
	Maintenance of blood cholesterol concentrations and maintenance of low plasma concentrations of C-reactive protein	1450	Not established			
92	Astaxanthin					
	Function of the immune system	291, 1757	Established	"Zinc contributes to a normal function of the immune system"	x	
	DNA synthesis and cell division	292, 1759	Established	"Zinc contributes to normal DNA synthesis and cell division"	FNFC	
	Protection of DNA, proteins and lipids from oxidative damage	294, 1758	Established	"Zinc contributes to the protection of cell constituents from oxidative damage"	x	
	Maintenance of bone	295, 1756	Established	"Zinc contributes to maintenance of normal bone"	x	
	Cognitive function	296	Established	"Zinc contributes to normal cognitive function"	x	
	Fertility and reproduction	297, 300	Established	"Zinc contributes to normal fertility and reproduction"	x	A food should be at least a source of zinc as per Annex to Regulation (EC) No 1924/2006.
	Reproductive development	298	Not comply with the criteria (Art. 14 claim)		x	Tolerable Upper Intake Levels (UL) have been established for zinc as 25 mg/day in adults and to pregnant and lactating woman. For children and adolescents UL was established as 7 mg/day for 1-3 years, 10 mg/day for 4-6 years, 13 mg/day for 7-10 years, 18 mg/day for 11-14 years and 22 mg/day for 15-17 years (SCF 2003).
93	Zinc					
	Muscle function	299	Not established		x	
	Metabolism of fatty acids	302	Established	"Zinc contributes to normal metabolism of fatty acids"	x	
	Maintenance of joints	305	Not established		x	
	Function of the heart and blood vessels	306	Not established		x	
	Prostate function	307	Not established		x	
	Thyroid function	308	Not established		x	
	Acid-base metabolism	360	Established	"Zinc contributes to normal acid-base metabolism"	FNFC	
	Vitamin A metabolism	361	Established	"Zinc contributes to normal metabolism of vitamin A"	x	
	Maintenance of vision	361	Established	"Zinc contributes to maintenance of normal vision"	x	

94	Vitamin D	Maintenance of bone and teeth	150, 151, 158	Established	"Vitamin D contributes to the maintenance of normal bones and teeth"	FNFC
		Absorption and utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations	152, 157	Established	"Vitamin D contributes to normal absorption/ utilisation of calcium and phosphorus and maintenance of normal blood calcium concentrations"	FNFC
		Cell division	153	Established	"Vitamin D contributes to normal cell division"	x
		Thyroid function	156	Not established		x

↓

Established: 当該物質の摂取と表示内容(機能性)の因果関係が科学的に裏証された。
 Not established: 当該物質の摂取と表示内容(機能性)の因果関係が科学的に裏証されない。

ヘルスクレーム使用時の共通条件:
 "Such amounts can be easily consumed as part of a balanced diet."

表 B : EU 栄養/健康強調表示に関する EFSA の評価 (第 13(5)条 : 新規な科学的根拠に基づくヘルスクレーム)

Product (Country)	Active Component(s)	Health Claim(s)	EFSA Opinion
Elancyl Global Silhouette® (France)	CLA, polyols, plants and cocoa extracts	Regulation of body composition	Insufficient 2008.08.12
LGG®MAX (Finland)	Mixtures of 4 bacterial strains	Reduction of abdominal discomfort	Insufficient 2008.10.30
Dairy product enriched with milk peptide and magnesium (France)	Tryptic hydrolysate from bovine casein and magnesium	Reduction of anxiety in mildly stress-sensitive adults	Insufficient 2008.12.04
Milk product, rich in fibre and protein (France)		Reduction of the sense of hunger in the female/general adult population	Insufficient 2008.12.04
Black tea from <i>Camellia sinensis</i> (Netherlands)		Helps to focus attention	Insufficient 2008.12.04
Algatrium® (Spain)	DHA	Promotes your antioxidant response by stimulation of the own cells antioxidant defences	Insufficient 2009.01.22
<i>Lactobacillus plantarum</i> 299v (Sweden)		Improvement of iron absorption	Insufficient 2009.03.13
Water-soluble tomato concentrate (WSTC I: syrup, II: powder) (UK)		Helps to maintain a healthy blood flow and benefits circulation ⇒ Helps maintain normal platelet aggregation	Substantiated 2009.05.15
Natural Push-Up® (Netherlands)	Hops	Imitating the female breast-enhancement process	Insufficient 2009.05.15
Bimuno™ (UK)	A β-galacto-oligosaccharide mixture	Supports the immune system by helping to increase the natural killer cell and phagocyte activity	Insufficient 2009.05.15
Gum Peribalance™ (Italy)	<i>Lactobacillus reuteri</i> strains DSM17938 and ATCC PTA5289	Helps to maintain a healthy gastro-intestinal function by stimulating and increasing the number of bifidobacteria in the gut	Insufficient 2009.05.15
Regulat® (Germany)	A liquid concentrate from a fermentation of 17 vegetable and fruit species involving five different strains of <i>Lactobacillus</i>	Rebalancing the oral microflora and improving oral health	Insufficient 2009.07.02
Immune Balance Drink (Germany)	Green tea/ Grape seed/ Shiitake/ extracts, and Vitamin C	Enhancement/modulation/improvement/regulation of the activity of the immune system	Insufficient 2009.07.02
		Strengthening the body's defences by supporting the immune system and reducing susceptibility to pathogens	Insufficient 2009.10.15
Substantiated: 1 out of 14 as of 2009.10.15 (7%)			

表 C : EU 栄養/健康強調表示に関する EFSA の評価 (第 14 条 : 疾病リスク低減)

Product (Country)	Active Component(s)	Health Claim(s)	EFSA Opinion
Plant Sterols (Sweden)	Plant sterols have been shown to lower/reduce blood cholesterol.	Blood cholesterol lowering may reduce the risk of coronary heart disease.	Substantiated 2008.07.11
Femarelle® (Austria)	Mixture of soy derivative and ground flaxseed	Bone mineral density (risk of osteoporosis or other bone disorders in post-menopausal women)	Insufficient 2008.08.04
NeOpuntia® (France)	Dehydrated leaves of the prickly pear cactus (<i>Opuntia ficus-indica</i>)	Blood lipid parameters (esp. LDL cholesterol)	Insufficient 2008.08.13
Evolus® (Finland)	Val-Pro-Pro, Ile-Pro-Pro (<i>Lactobacillus helveticus</i>)	Reduction of arterial stiffness in mildly hypertensive subjects	Insufficient 2008.10.02
Plant stanol esters (UK)	Plant stanol esters have been shown to lower/reduce blood cholesterol.	Blood cholesterol lowering may reduce the risk of coronary heart disease.	Substantiated 2008.10.02
Xylitol chewing gum/pastilles (Finland)	Xylitol chewing gum/pastilles reduces the risk of caries ⇒ Xylitol (100%) chewing gum reduces the risk of caries in children		Substantiated 2008.10.30
Melgaco® naturally sparkling mineral water (Portugal)		Reduction of hyperglycaemia in hyperglycaemic individuals	Insufficient 2009.01.22
Ocean Spray Cranberry Products® (UK)	Cranberry proanthocyanidins	Reduction of the risk of urinary tract infection in women	Insufficient 2009.01.22
Bimuno™ (UK)	A β -galacto-oligosaccharide mixture	Reduction of the bad bacteria that can cause travellers' diarrhoea	Insufficient 2009.05.15
Labelling Reference Intake Values (EC)	n-3 and n-6 polyunsaturated fatty acids	n-3 PUFA ALA: 2 g/d Long-chain n-3 PUFAs EPA + DHA: 250 mg/d n-6 PUFA LA: 10 g/d	EFSA Proposal 2009.06.30
Plant Sterols and Plant Stanols (EC, France)	While plant sterols/stanols added to foods such as margarine-type products, mayonnaise, salad dressings, and dairy products such as milk, yoghurts and cheese have been shown consistently to lower blood LDL-cholesterol, the efficacy of plant sterols/stanols added to other formats is less well established		Substantiated 2009.06.30
Danacol® (France)	A low fat fermented milk product enriched with plant sterols/stanols	Phytosterols have been shown to lower/reduce blood cholesterol. High blood cholesterol is a risk factor in the development of coronary heart disease.	Substantiated 2009.07.02
Lycopene-whey complex (UK)	Bioavailable lycopene with whey protein, 2% lycopene in the final product	Prevents oxidative damage of plasma lipoproteins, which reduces the build up of arterial plaques and reduces the risk of heart disease, stroke and other clinical complications of atherosclerosis.	Insufficient 2009.07.02
Calcium or Calcium and Vitamin D3 chewing tablets (Germany)	"Calcium (or Calcium and vitamin D) may reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor in the development of osteoporotic bone fractures".	Substantiated	Insufficient (condition of use, 1000mg Ca and 800 IU V.D) 2009.07.02
OPC Premium™ (Germany)	Oligomeric Procyanidins (OPC: <i>Vitis vinifera</i>) and berry-blend	Reduces blood LDL-cholesterol and may therefore reduce the risk of cardiovascular disease	Insufficient 2009.10.15
Glucosamine hydrochloride (Germany)	Slowing down/reduce the destruction process of cartilage of osteoarthritis	Reduces blood LDL-cholesterol and consequently reduce the risk of osteoarthritis	Insufficient 2009.10.15
Substantiated: 5 out of 16 as of 2009.10.15 (31%)			

表 D : EU 栄養/健康強調表示に関する EFSA の評価 (第 14 条 : 子供の発育および健康)

Product (Country)	Active Component(s)	Health Claim(s)	EFSA Opinion
ALA and LA (Netherlands)	Regular consumption of essential fatty acids is important for proper growth and development of children. ⇒ "essential fatty acids are needed for proper growth and development of children. Substantiated		Insufficient (condition of use) 2008.07.11
Regulat® pro.kid IMMUN BRAIN (Germany)	Fruits, vegetable, nuts and spices (<i>Lactoballi</i> strains)	Support/modulate/improve the immune system in children Mental and cognitive development of children	Insufficient 2008.07.11 2008.10.02
Dairy foods (Ireland)	Milk, cheese and yogurt Milk or cheese	Healthy body weight in children and adolescents Dental health in children	Insufficient 2008.08.08
DHA and ARA (UK)	Neural development of the brain and eyes in infants and young children		Insufficient 2008.09.08
Vitamin D (France)	Vitamin D is needed for normal growth and development of bone in children		Substantiated 2008.10.02
Calcium and Vitamin D (UK)	Calcium and vitamin D are needed for normal growth and development of bone in children		
Calcium (France)	Calcium is needed for normal growth and development of bone in children		
SII/ omega kids® /Pufan 3 kids® (Netherlands)	DHA, EPA	Serenity and room for beneficial development in children Calming in children Visual development in children Mental development in children Promotion of concentration in children Promotion of thinking capacity in children Learning ability in children	Insufficient 2008.10.02 2008.10.24
LACTORAL (Poland)	<i>Lactobacillus plantarum</i> , <i>Lactobacillus rhamnosus</i> , <i>Bifidobacterium longum</i>	Building of the natural intestinal barrier Maintenance of natural intestinal microflora during travel Living probiotic bacteria Normal functioning of the alimentary tract Improvement of the general immunity Proteins from animal origin contribute to children's bone growth	Insufficient 2008.10.28
Animal protein (France)			Substantiated 2008.10.31
Efalex® (UK)	n-3 (EPA, DHA) and n-6 (GLA, ARA)	Maintenance of coordination in healthy children Maintenance of concentration in healthy children Maintenance and support of brain development and function in healthy children Maintenance and support of the learning ability in healthy children Visual development and/or function in children	Insufficient 2008.12.04

Eye q (baby)® (UK)	n-3 (EPA, DHA) and n-6 (GLA)	Support of healthy central nervous system development in children Maintenance of healthy brain functions in healthy children Maintenance of concentration in healthy children	Insufficient 2008.12.04
Mumomega® (UK)		Central nervous system development in foetuses	Insufficient 2008.12.04
Dairy fresh cheese (Spain)	Calcium, phosphorus and vitamin D	Calcium/Vitamin D is needed for the normal growth and development of bone in children	Substantiated 2008.12.04
Follow-on formulae (Italy)	Short-chain galacto-oligosaccharides	Aids minor intestinal ailments	nsufficient 2009.01.22
Kinder Chocolate® (Italy)	Calcium	Helps grow in children and young adults	Insufficient 2009.01.22
DHA and ARA (France)	DHA and ARA contribute to the optimal visual development of infants DHA and ARA contribute to the optimal brain development in infants and young children	DHA and ARA contribute to the optimal visual development of infants and children. ⇒ DHA contributes to the visual development of infants DHA and ARA contribute to the optimal brain development in infants and young children	Substantiated 2009.01.22 Insufficient 2009.03.13
Lipil®/ Enfamil® Premium (France)	DHA and ARA	Lipil®/ Enfamil® Premium (DHA) contribute to the optimal visual development of infants Lipil®/ Enfamil® Premium contribute to the optimal brain development of infants.	Substantiated 2009.03.13 Insufficient 2009.03.13
ALA (Belgium)	Alpha-linolenic acid	contributes to the brain development	Substantiated 2009.03.13
DHA, EPA and d-α-tocopherol (Germany)	Visual development in unborn children or breastfed infants Cognitive development in unborn children or breastfed infants		Insufficient 2009.03.13
Iodine (France)	Iodine	contributes to the normal growth of children.	Substantiated 2009.10.15
Iron (France)	Iron	contributes to normal cognitive development of children.	Substantiated 2009.10.15
Substantiated: 11 out of 45 as of 2009.10.15 (24%)			

表 E : 米国健康福祉省 MEDWATCH 有害事象・製品の問題および製品誤使用のための自発的報告書

米国健康福祉省
MEDWATCH

FDA 安全性情報および有害事象報告プログラム

有害事象・製品の問題および製品誤使用のための
自発的報告書

OMB No. 09 10-0291, 有効期限: 12/31/11
OMBの声明は裏面参照

FDA使用欄	
優先順位ユニットシークエンス#	

Page 1 of _____

A. 患者情報			
1. 患者識別	2. 発症年齢 または生年月日	3. 性別 <input type="checkbox"/> 女性 <input type="checkbox"/> 男性	4. 体重 lbs または kgs

2. 用量	頻度	投与経路
#1		
#2		

B. 有害事象、製品の問題または誤使用	
1. <input type="checkbox"/> 有害事象 <input type="checkbox"/> 製品の問題 (伊製品の問題) <input type="checkbox"/> 製品誤使用 <input type="checkbox"/> 同じ医薬品で製造者が異なっている場合の問題	
2. 有害事象による症状 (該当するもの全てにチェック) <input type="checkbox"/> 死亡: _____ (mm/dd/yyyy) <input type="checkbox"/> 心身の失調または持続的な障害 <input type="checkbox"/> 生死係わる事象 <input type="checkbox"/> 先天的奇形または出生時欠損 <input type="checkbox"/> 入院を必要とする <input type="checkbox"/> その他 (医学的に重篤な症状) <input type="checkbox"/> 持続的な症状を防ぐ為に医学的な処置が必要	

3. 使用日 (不明な場合: 服用開始から中止までの期間、あるいは推定の期間) #1 _____ #2 _____	5. 使用を中止または用量を下げた後症状は治まりましたか #1 <input type="checkbox"/> はい <input type="checkbox"/> いいえ <input type="checkbox"/> 該当なし #2 <input type="checkbox"/> はい <input type="checkbox"/> いいえ <input type="checkbox"/> 該当なし
4. 使用のための診断 (適応症) #1 _____ #2 _____	8. 使用を再開した後に症状は繰り返されましたか #1 <input type="checkbox"/> はい <input type="checkbox"/> いいえ <input type="checkbox"/> 該当なし #2 <input type="checkbox"/> はい <input type="checkbox"/> いいえ <input type="checkbox"/> 該当なし
6. 製造番号 (Lot #) #1 _____ #2 _____	7. 使用期限 (賞味期限) #1 _____ #2 _____
9. NDC#または識別ID	

3. 発症年月日 (mm/dd/yyyy)	4. 報告年月日 (mm/dd/yyyy)
-----------------------	-----------------------

E. 疑わしい医療用機器

5. 有害事象または製品の問題に関する説明
6. 関連する試験結果/検査結果 (実施日を明記)
7. その他関連する既往歴、発症前の医学的状況 (例: アレルギー、RACE、妊娠、喫煙および飲酒、肝・腎機能障害等)

1. 製品名	
2. 一般的な機器名称	
3. 製造元名称および所在地	
4. モデル#	Lot#
カタログ#	使用期限 (mm/dd/yyyy)
シリアル#	その他#
5. 医療用機器業者 <input type="checkbox"/> 専門家 <input type="checkbox"/> 一般ユーザー/患者 <input type="checkbox"/> その他	
6. 埋め込み処置がある場合 実施年月日 (mm/dd/yyyy)	7. 摘出処置がある場合 実施年月日 (mm/dd/yyyy)
8. それは再加工あるいは再利用して使用されますか <input type="checkbox"/> はい <input type="checkbox"/> いいえ	
9. 8で「はい」の場合、再加工(再生)業者の名称および所在地	

C. 製品の入手	
製品は調査のために入手可能か (FDAに製品を送ってはいけない) <input type="checkbox"/> はい <input type="checkbox"/> いいえ <input type="checkbox"/> 製造者に返却した: _____ (mm/dd/yyyy)	

F. その他付随する医療用製品

D. 疑わしい製品	
1. 名前 強度 製造者 (製品ラベルより)	
#1	名前: 強度: 製造者:
#2	名前: 強度: 製造者:

製品名と治療日 (有害事象の処置を除く)

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G 報告者 (裏面の守秘義務セクションを参照)

1. 名前と住所 名前: 住所: 市: _____ 州: _____ 郵便番号: _____	
電話番号#	E-mail
2. 健康に関する専門職ですか <input type="checkbox"/> はい <input type="checkbox"/> いいえ	3. 職業 <input type="checkbox"/> 製造者 <input type="checkbox"/> 販売者 <input type="checkbox"/> 卸売業者 / 輸入者
4. すでに下記に対して報告している <input type="checkbox"/> 製造者 <input type="checkbox"/> 販売者 <input type="checkbox"/> 卸売業者 / 輸入者	
5. もしあなたが製造者に対してあなたのことを開示してほしくないならば、ボックスに×を書いてください: <input type="checkbox"/>	

B5 有害事象あるいは問題(続き)

B6 関連する試験/検査データ(実施日を含む)

B7 その他関連する既往歴、発症前の医学的状況
(例: アレルギー、RACE、妊娠、喫煙および飲酒、肝・腎機能障害等)(続き)

F その他付随する医療用製品と処置(有害事象の処置を除く)(続き)

表 F : 米国健康福祉省米国食品医薬品庁 MEDWATCH 販売業・輸入業・卸売業・流通業および製造業用義務的報告書

米国健康福祉省
米国食品医薬品庁
MEDWATCH
FORM FDA 3500A(1/09)

販売業・輸入業・卸売業・流通業および製造業用
義務的報告書

OMB No. 09 10-0291, 有効期限: 12/31/11
OMBの声明は裏面参照

Page 1 of _____

Mfr report#
販売業/輸入業報告書#
FDA記入欄

A. 患者情報

1. 患者識別	2. 発症年齢 または生年月日	3. 性別 <input type="checkbox"/> 女性 <input type="checkbox"/> 男性	4. 体重 または lbs kgs
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B. 有害事象または製品の問題

1. <input type="checkbox"/> 有害事象 およびまたは <input type="checkbox"/> 製品の問題 (例: 欠陥/効果なし)	
2. 有害事象による症状 (該当するもの全てにチェック) <input type="checkbox"/> 死亡 : (mm/dd/yyyy) <input type="checkbox"/> 心身の失調または持続的な障害 <input type="checkbox"/> 生死係わる事象 <input type="checkbox"/> 先天的奇形または出生時欠損 <input type="checkbox"/> 入院を必要とする <input type="checkbox"/> その他(医学的に重篤な症状) <input type="checkbox"/> 持続的な症状を防ぐ為に医学的な処置が必要	
3. 発症年月日 (mm/dd/yyyy)	4. 報告年月日 (mm/dd/yyyy)
5. 有害事象または製品の問題に関する説明	

C. 疑わしい製品

1. 製品名(パッケージまたはラベルの写しを添付する) #1 _____ #2 _____	
2. 用量、用法および投与経路 #1 _____ #2 _____	3. 使用日 (不明な場合: 服用開始から中止までの期間、あるいは推定の期間) #1 _____ #2 _____
4. 使用のための診断(適応症) #1 _____ #2 _____	5. 使用を中止または用量を下げた後 症状は治まりましたか #1 <input type="checkbox"/> はい <input type="checkbox"/> いいえ <input type="checkbox"/> 該当なし #2 <input type="checkbox"/> はい <input type="checkbox"/> いいえ <input type="checkbox"/> 該当なし
6. 製造番号(Lot #) #1 _____ #2 _____	7. 使用期限(賞味期限) #1 _____ #2 _____
9. NDC#または識別ID	8. 使用を再開した後に症状は繰り返 されましたか #1 <input type="checkbox"/> はい <input type="checkbox"/> いいえ <input type="checkbox"/> 該当なし #2 <input type="checkbox"/> はい <input type="checkbox"/> いいえ <input type="checkbox"/> 該当なし
10. 関連する医薬品の使用または治療日 (本有害事象の為に用いたもの以外で)	

D. 疑わしい医療用機器

1. 製品名		
2. 一般的な機器名称		
3. 製造元名称および所在地		
4. モデル#	Lot#	5. 医療用機器作業者 <input type="checkbox"/> 専門家 <input type="checkbox"/> 一般ユーザー/患者 <input type="checkbox"/> その他
カタログ#	使用期限 (mm/dd/yyyy)	
シリアル#	その他#	
6. 埋め込み処置がある場合 実施年月日 (mm/dd/yyyy)		7. 摘出処置がある場合 実施年月日 (mm/dd/yyyy)
8. それは再加工あるいは再利用して使用されますか <input type="checkbox"/> はい <input type="checkbox"/> いいえ		
9. 8で「はい」の場合、再加工(再生)業者の名称および所在地		
10. 医療用機器は調査可能ですか(FDAに製品を送ってはいけない) <input type="checkbox"/> はい <input type="checkbox"/> いいえ <input type="checkbox"/> 製造元への返却日: _____ (dd/mm/yyyy)		
11. 関連する医薬品および治療日(本有害事象のために用いたもの以外で)		

E. 最初の報告者

1. 氏名および住所	電話番号:
2. 専門職ですか	
3. 職業	4. 最初の報告者はすでにFDAに報告を 送っている <input type="checkbox"/> はい <input type="checkbox"/> いいえ <input type="checkbox"/> 不明

報告書の提出をもって、本事象に関連する医療従事者、販売業、輸入業、卸売業あるいは当該物質あるいはその事象に関連する承認とはなり得ない。