



	Applicant	Description of Food or Food Ingredient	Scientific Evidence	Notification	Transmission to Member States
31v	Gebr. Woerle GmbH Postfach 18 Enzing 26 5302 Henndorf bei Salzburg ÖSTERREICH	Milk type products such as semi skimmed and skimmed milk type products, possibly with the addition of fruits and/or cereals, fermented milk type products such as yoghurt, soya drinks, cheese type products (fat content $\leq$ 12 g per 100 g), where the milk fat and/or protein has been partly or fully replaced by vegetable fat or protein  a portion will not contain more than 3 g (in case of one portion per day) or more than 1 g (in case of 3 portions per day) of added phytosterols;  a container of beverages will not contain more than 3 g of added phytosterols	The phytosterol esters are provided by Cognis	6 October 2008	7 November 2008
31w	Mills of Crete SA Eth. Veniselou 40 73 200 Souda Crete GREECE	rye bread with flour containing $\geq$ 50 % rye and $\leq$ 30 % wheat; and with $\leq$ 4 % sugar but no fat added with added phytosterols  a portion will not contain more than 3 g (in case of one portion per day) or more than 1 g (in case of 3 portions per day) of added phytosterols;	The phytosterol esters are provided by Cognis	5 December 2008	11 December 2008
31x	Valio Ltd PO Box 10 Meieritie 6, Pitäjänmäki FI-00039 Valio Helsinki SUOMI/FINLAND	Yellow fat spreads excluding cooking and frying fats and spreads based on butter or other animal fat with added phytosterols  Milk type products such as semi skimmed and skimmed milk type products, possibly with the addition of fruits and/or cereals, fermented milk type products such as yoghurt, soya drinks, cheese type products (fat content $\leq$ 12 g per 100 g), where the milk fat and/or protein has been partly or fully replaced by vegetable fat or protein  a portion will not contain more than 3 g (in case of one portion per day) or more than 1 g (in case of 3 portions per day) of added phytosterols;  a container of beverages will not contain more than 3 g of added phytosterols	The phytosterols are provided by Cognis	2 December 2008	11 December 2008

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31y	Viotros SA Block 31 DA 13 Phase B 574 00 Industrial Area of Sindos (Echedoros — Thessaloniki) GREECE	Cheese type products (fat content $\leq$ 12 g per 100 g), where the milk fat and/or protein has been partly or fully replaced by vegetable fat or protein  a portion will not contain more than 3 g (in case of one portion per day) or more than 1 g (in case of 3 portions per day) of added phytosterols	The phytosterols are provided by Cognis	24 April 2008	30 April 2008
40e	R & L Holdings Ltd. P.O. Box 977 Vaitele Apia SAMOA	Noni juice (juice of the fruits of <i>Morinda citrifolia</i> )	ACNFP <sup>(3)</sup> (UK) Opinion on substantial equivalence of Noni Juice produced on a number of Pacific Islands considered under Article 5 of the Novel Foods Regulation	17 January 2008	28 January 2008
41	Forbes Medi-Tech Inc. 750 West Pender Street Vancouver B.C. V6C 2T8 CANADA	Foods listed in Article 1 of Commission Decision 2000/500/EC and in annex 1 of Commission Decisions 2004/333/EC, 2004/334/EC, 2004/335/EC and 2004/336/EC (yellow fat spreads, salad dressings, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks) with added phytosterols/ phytostanols (Reducol™)  Rye bread  Cheese products (fat content < 12 g per 100 g) with added phytosterols and/or phytosterol esters	NFB <sup>(2)</sup> (FIN) Opinion on the substantial equivalence of foods enriched with Reducol™ phytosterols/ phytostanols (Forbes Medi-Tech Inc.) of 28 February 2005  NFB <sup>(2)</sup> (FIN) Opinion on substantial equivalence for rye bread enriched with REDUCOL™ plant sterol ingredient  Letter of 6 September 2006 by the FSAI <sup>(4)</sup> concerning the substantial equivalence	22 April 2005  12 June 2006  3 October 2006	6 June 2005  3 August 2006  6 November 2006
41l	Caseificio Pinzolo Fiavè Rovereto S.c.r.l. Via A. Degasperi 12/A 38075 Favé (Trento) TN ITALIA	Yogurt type products with added phytosterols  a portion will not contain more than 3 g (in case of one portion per day) or more than 1 g (in case of 3 portions per day) of added phytosterols/phytostanols  a container of beverages will not contain more than 3 g of added phytosterols	The phytosterols are provided by Forbes MediTech	3 March 2008	18 March 2008
41m	Rupp Käseexport GmbH Krüzastraße 8 6912 Hörbranz ÖSTERREICH	Cheese type products with added phytosterols  a portion will not contain more than 3 g (in case of one portion per day) or more than 1 g (in case of 3 portions per day) of added phytosterols/phytostanols	The phytosterols are provided by Forbes MediTech	7 July 2008	28 October 2008

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54	Triple Crown AB Stenslingan 10 SE-182 38 Stockholm SVERIGE  Stenslingan 10 SE-182 38 Danderyd SVERIGE	Phytosterols to be used in milk type, yoghurt type products  Low fat soft cheese/melt cheese (fat content $\leq$ 12 g per 100 g) and rye bread	ACNFP <sup>(?)</sup> Opinion on substantial Equivalence of free phytosterols considered under Article 5 of the Novel Foods Regulation  NFB <sup>(?)</sup> Opinion on substantial equivalence of a plant sterol ingredient manufactured by Triple Crown company and foods enriched with it (Triple Crown AB)	11 November 2005  16 October 2006	8 December 2005  7 November 2006
54b	Koninklijke ERU Kaasfabrik BV Postbus 7 3440 AA Woerden NEDERLAND  Middelands Zee 7 3446 CG Woerden NEDERLAND	Cheese type products with added phytosterols a portion will not contain more than 3 g (in case of one portion per day) or more than 1 g (in case of 3 portions per day) of added phytosterols/phytostanols	the phytosterols are supplied by Triple Crown	23 April 2008	14 May 2008
57	Vitae-Caps S.A. Polígono Industrial Torrehierro C/ Gutemberg, 356 45600 Talavera de la Reina (Toledo) ESPAÑA	Rice drinks with added phytosterols a portion will not contain more than 3 g (in case of one portion per day) or more than 1 g (in case of 3 portions per day); a container of beverages will not contain more than 3 g of added phytosterols/phytostanols	AESA <sup>(?)</sup> Opinion on substantial equivalence for phytosterols and esters of phytosterol from the company VitaeCaps S.A. on the basis of Art. 5 of Regulation (EC) No 258/97 (26 of May of 2008)	25 June 2008	9 July 2008
62	Oy Foodfiles Ltd Niementie 2 L 6 FI-70210 Kuopio SUOMI/FINLAND on behalf of Arboris LLC	Yellow fat spreads as defined by Council Regulation (EC) No 2991/94, excluding cooking and frying fats and spreads based on butter or other animal fat; milk type and fermented milk type products; yoghurt type products; cheese type products; soya drinks and salad dressings and spicy sauces  rye bread with flour containing $\geq$ 50 % rye and $\leq$ 30 % wheat; and with $\leq$ 4 % sugar but no fat added with added phytosterols  a portion will not contain more than 3 g (in case of one portion per day) or more than 1 g (in case of 3 portions per day) of added phytosterols/phytostanols;  a container of beverages will not contain more than 3 g of added phytosterols/phytostanols;  salad dressings and spicy sauces will be packed as single portions.	NFB <sup>(?)</sup> (FIN) Opinion on substantial equivalence for Arboris® sterol AS-2™ plant sterol ingredient and foods enriched with it (Arboris® LLC)	5 April 2006  7 December 2006	27 April 2006  19 February 2007

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62b	Dale Farm Ltd Shap Road Kendal Cumbria LA9 6NS UNITED KINGDOM	Yogurt drinks with added phytosterols a portion will not contain more than 3 g (in case of one portion per day) or more than 1 g (in case of 3 portions per day) of added phytosterols/phytostanols; a container of beverages will not contain more than 3 g of added phytosterols/phytostanols	The phytosterols are provided by Arboris	19 September 2008	1 October 2008
80	Lipofoods Calle Issac Peral, 17 08850 Gavà (Barcelona) ESPAÑA	Yellow fat spreads as defined by Council Regulation (EC) No 2991/94, excluding cooking and frying fats and spreads based on butter or other animal fat; products based on milk, such as products based on skimmed and semi — skimmed milk, possibly with the addition of fruits and/or cereals, fermented milk type products, such as yoghurt and cheese type products (fat content ≤ 12 g per 100 g) where the milk fat and or protein has been fully or partly replaced by vegetable fat or protein; milk based fruit drinks; salad dressings and spicy sauces; soya drinks with added phytosterols  salad dressings and spicy sauces; soya drinks with added phytosterols  a portion will not contain more than 3 g (in case of one portion per day) or more than 1 g (in case of 3 portions per day) of added phytosterols/phytostanols;  a container of beverages will not contain more than 3 g of added phytosterols/phytostanols; spicy sauces and salad dressings will be packed as single portions	ACNFP <sup>(3)</sup> Opinion on substantial equivalence of phytosterols considered under Article 5 of the Novel Foods Regulation (FSA <sup>(1)</sup> 15 February 2007; NFU 632)	16 February 2007	12 March 2007
80a	Nöm AG Vöslauer Strasse 2500 Baden ÖSTERREICH	Products based on milk, such as products based on skimmed and semi — skimmed milk, possibly with the addition of fruits and/or cereals, fermented milk type products, such as yoghurt with added phytosterols  a portion will not contain more than 3 g (in case of one portion per day) or more than 1 g (in case of 3 portions per day) of added phytosterols/phytostanols;  a container of beverages will not contain more than 3 g of added phytosterols/phytostanols;	The phytosterols are provided by Lipofoods	19 November 2008	1 December 2008
103	SanoVia Im Kühstiefel 19 56653 Wehr DEUTSCHLAND	Argan oil	The DGCCRF <sup>(6)</sup> (F) confirmed that the previously issued opinion by AFSSA <sup>(3)</sup> (see No 13) was also applicable to the Argan oil placed on the market by Huilerie F.J. Moog SARL	17 February 2008	17 March 2008

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104	ARGANA d.o.o. Rentje 50 SI-4294 Križe SLOVENIJA  Arganoil Company 213, Lot Habiba El Oulfa Casablanca MAROC	Argan oil	The DGCCRF <sup>(6)</sup> (F) confirmed that the previously issued opinion by AFSSA <sup>(3)</sup> (see No 13) was also applicable to the Argan oil placed on the market by ARGANA d.o.o. and Arganoil Company	17 March 2008	14 April 2008
105	BPF Bioactive Products Faktory ul. Sloneczna 4 95-020 Justynów POLSKA/POLAND	Noni juice (juice of the fruits of <i>Morinda citrifolia</i> )	IZIZ <sup>(7)</sup> (PL) has delivered an opinion that the Noni juice to be placed on the market by the company BPF Bioactive Products Factory was substantially equivalent to Noni juice that is already on the market	31 March 2008	16 April 2008
106	Hygieia Global Building #54,5F 1089 N, Quinzhou Rd Shanghai CHINA  Hygieia Europe Postfach 1601 40641 Meerbusch DEUTSCHLAND	Glucosamine HCl from <i>Aspergillus niger</i> for use in food supplements	FSAI <sup>(4)</sup> (IRL) Substantial equivalence opinion of GlucosaGreen® branded Glucosamine HCL	3 April 2008	7 May 2008
107	Alga Technologies Ltd. Kibbutz Ketura D.N. Hevel Eliot 88840 ISRAEL	Astaxanthin rich extract from <i>Haematococcus pluvialis</i>	ACNFP <sup>(3)</sup> (UK) Opinion on substantial equivalence of Astaxanthin-rich oleoresin extracted from <i>Haematococcus pluvialis</i> algae considered under Article 5 of the Novel Foods Regulation	14 April 2008	13 May 2008
108	KitoZyme sa Rue Haute Claire 4 Parc Industriel Huats Sarts, Zone 2 4040 Herrstal BELGIQUE/BELGIË	Chitosan	CSS <sup>(8)</sup> (B) Opinion No 8319 issued by the Superior Health Council: Substantial equivalence of the chitosan (KiOnutrime-Cs™)	30 April 2008	28 May 2008
109	Thiele Lifestyle Baymex Außenhandelsges. mbH Am Bahnhof 12 94538 Fürstenstein DEUTSCHLAND	Argan oil	The DGCCRF <sup>(6)</sup> (F) confirmed that the previously issued opinion by AFSSA <sup>(3)</sup> (see No 13) was also applicable to the Argan oil placed on the market by the company Thiele Lifestyle	29 April 2008	4 June 2008

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110	EZA Natürlich Fair Wenger Straße 5 5203 Köstendorf ÖSTERREICH	Argan oil	The DGCCRF <sup>(6)</sup> (F) confirmed that the previously issued opinion by AFSSA <sup>(3)</sup> (see No 13) was also applicable to the Argan oil placed on the market by the company EZA natürlich Fair	16 June 2008	7 July 2008
111	Hygieia Global Building #54,5F 1089 N, Quinzhou Rd Shanghai CHINA  Hygieia Europe Postfach 1601 40641 Meerbusch DEUTSCHLAND	Glucosamine sulphate NaCl from <i>Aspergillus niger</i> for use in food supplements  Glucosamine sulphate KCl from <i>Aspergillus niger</i> for use in food supplements	FSAI <sup>(4)</sup> (IRL) Substantial Equivalence Opinion of Glucosamine Sulphate NaCl  FSAI <sup>(4)</sup> (IRL) Substantial Equivalence Opinion of Glucosamine Sulphate KCl	14 August 2008	11 September 2008
112	EFIT Srl Via Bramante 41 05100 Terni TR ITALIA	Argan oil	The DGCCRF <sup>(6)</sup> (F) confirmed that the previously issued opinion by AFSSA <sup>(3)</sup> (see No 13) was also applicable to the Argan oil placed on the market by the company EFIT Srl	11 August 2008	11 September 2008
113	Korzonek Gottfried Kellerstr. 61a 94315 Straubing DEUTSCHLAND	Argan oil	The DGCCRF <sup>(6)</sup> (F) confirmed that the previously issued opinion by AFSSA <sup>(3)</sup> (see No 13) was also applicable to the Argan oil placed on the market by the company Korzonek	21 August 2008	17 September 2008
114	EUROFROID Rue Denis Papin Zone industrielle 24100 Bergerac FRANCE	Argan oil	The DGCCRF <sup>(6)</sup> (F) confirmed that the previously issued opinion by AFSSA <sup>(3)</sup> (see No 13) was also applicable to the Argan oil placed on the market by the company EUROFROID	11 September 2008	1 October 2008
115	ArganEden SARL BP 60331 33164 La Teste Cedex FRANCE	Argan oil	The DGCCRF <sup>(6)</sup> (F) confirmed that the previously issued opinion by AFSSA <sup>(3)</sup> (see No 13) was also applicable to the Argan oil placed on the market by the company ArganEden	1 December 2008	11 December 2008
116	Copram Société de commercialisation des produits alimentaires du Maroc 17 rue Copenhague B.P. 80168 13745 Vitrolles Cedex FRANCE	Argan oil	The DGCCRF <sup>(6)</sup> (F) confirmed that the previously issued opinion by AFSSA <sup>(3)</sup> (see No 13) was also applicable to the Argan oil placed on the market by the company copram	16 December 2008	19 January 2009

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118	I.R.B. s.r.l. Istituto di Ricerche Biotecnologiche Via Piave 24/B 36077 Altavilla Vic. NA VI ITALIA	Extracts from <i>Ajuga reptans</i>	DSPVNSA <sup>(9)</sup> Subject: Substantial equivalence for <i>Ajuga reptans</i> extracts from plant tissue cultures	19 December 2008	19 January 2009
119	Arganpur KlönneStr. 94 44143 Dortmund DEUTSCHLAND	Argan oil	The DGCCRF <sup>(6)</sup> (F) confirmed that the previously issued opinion by AFSSA <sup>(3)</sup> (see No 13) was also applicable to the Argan oil placed on the market by the company Arganpur	25 June 2008	17 July 2008
122	FORMOR Polska Ul. Objazdowa 1 05-119 Legonovo POLSKA/POLAND	Noni juice (juice of the fruits of <i>Morinda citrifolia</i> )	IRPZ <sup>(10)</sup> Opinion on the substantial equivalence of 'NONI SOK' juice with 'TAHITIAN NONI®' juice as authorised by Commission Decision 2003/426/EC	26 November 2008	27 March 2009

<sup>(1)</sup> FSA: Food Standards Agency (UK).

<sup>(2)</sup> NFB: Novel Food Board (FIN).

<sup>(3)</sup> ACNFP: Advisory Committee on Novel Foods and Processes (UK).

<sup>(4)</sup> FSAI: Food Safety Authority of Ireland (IRL).

<sup>(5)</sup> AESA: Agencia española de seguridad alimentaria (E).

<sup>(6)</sup> DGCCRF: Direction Générale de la Concurrence, de la consommation et de la Répression des Fraudes (F).

<sup>(7)</sup> IZIZ: Instytut Żywności i Żywienia (PL).

<sup>(8)</sup> CSS: Conseil Supérieur de la Santé (B).

<sup>(9)</sup> DSPVNSA: Ministero della Salute — Dipartimento per la Sanità Pubblica veterinaria, la Nutrizione e la Sicurezza degli Alimenti (I).

<sup>(10)</sup> IRPZ: Instytut Roślin i Przetworów Zielarskich (PL).