SUBSTANTIAL EQUIVALENCE APPLICATION FOR THE APPROVAL OF LowChol®Phytosterol Ester FOR USE IN FOOD INDUSTRY Under regulation (EC) No.258/97 OF THE EUROPEAN PARLIAMENT

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Index

LIST OF APPENDICES

SUMMARY

Under Regulation (EC) No.258/97 of the European Parliament and of the Council, Archer Daniels Midland received approval of placing on the market of yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients under European Commission Decision 2004/333/EC on 31 March 2004. In their request the definition of Phytosterols and phytostanols are sterols and stanols that are extracted from plants and may be presented as free sterols and stanols or esterified with food grade fatty acids.

LowChol®Phytosterol Ester of Xi'an Healthful Biotechnology Co., Ltd is produced by it's wholly owned subsidiary Shaanxi Healthful Bioengineering Co., Ltd., under brand ®LowChol.

Xi'an Healthful Biotechnology's phytosterol Ester is an ester form of phytosterol, which obtained from by-products of traditional vegetable oil refining. The sources is commonly a blend of crude edible oils, consisting largely of soy bean oil and lesser amount of other edible oils, e.g.corn, rapeseed. Then phytosterol esterify with food grade fatty acid. The phytosterol is a mixture of beta-sistosterol, beta-sistostanol, campesterol, campestanol, stigmasterol, brassicasterol and a small percentage of other sterols/stanols. The chromatograms (Appendix 5) provides demonstrate a composition in sterols in compliance with the commission decision 2004/333/EC.

The manufacturing process of phytosterol which Xi'an Healthful Biotechnology used to produce LowChol®Phytosterol Ester is similar to the one described in the ADM Novel food Application. Then phytosterol esterify with food grade fatty acid to get Phytosterol Esters.

LowChol®Phytosterol Ester has minimal contamination and the purity and composition of the presented product would be considered safe for human consumption. We have provided the testing results of Aflatoxin, PAHs, solvent residual, pesticides, heavy metals and microbiological for reference (Appendix 7, Appendix 8, Appendix 9, Appendix10).

The LowChol®Phytosterol Ester is intended to be consumed in a manner identical to the ADM products. The labelling of the product will follow the requirement of the relevant commission regulation(608/2004), as well as the requirements of Annex III of Regulation 1669/2011 EC.

No additional source of phytosterols and their esters is added to the food chain by allowing the marketing of said Xi'an Healthful Biotechnoloyg ingredients for the use in yellow fat spreads, salad dressings, milk type products,fermented milk type products, soya drinks and cheese type products. The overall intake of phytosterols will not be affected, since there will be only alternative, not cumulative, consumption of multiple foods within one food category.

Consequently, it can be guaranteed that the safe daily dose of 3g in free phytosterol from is not exceeded by introducing said products to the market.

This dossier provides evidence to confirm that Xi'an Healthful Biotechnology's LowChol®Phytosterol Ester is substantially equivalent to ADM approval 2004/333/EC.

1. INTRODUCTION

The European Regulation (EC) No. 258/97 on Novel Foods and Novel Food Ingredients sets out rules for authorization of GM food products and other categories of novel foods. Phytosterols and phytosterols esters fall under the scope of the above mentioned regulation and are identified as "novel" food under article 1 [(1)].

Phytosterols and Phytosterol Esters were authorized to be placed on the EU market on 24 July 2000 (Commission Decision 2000/500/EC)[(2)]. Since then other applications were deposed which were authorized under the European commission decision 2004/333/EC[(3)], 2004/334/EC[(4)], 2004/335/EC[(5)], 2004/336/EC[(6)], 2004/845/EC[(7)], 2006/58/EC[(8)] and 2006/59/EC[(9)].

The purpose of the dossier is to demonstrate that the applicant Xi'an Healthful Biotechnology Co., Ltd whose LowChol®Phytosterol Ester produced by its wholly-owned subsidiary Shaanxi Healthful Bioengineering Co., Ltd. is substantially equivalent with the terms of article(3) of the regulation (EC) No. 258/97(1) to already approved ones and more specifically the Archer Daniels Midland (ADM) (2004/333/CE) (3).

Based on these decisions, the applicant Xi'an Healthful Biotechnology Co., Ltd applies for a favorable opinion in order to notify its LowChol®Phytosterol Ester as a ingredient in the range of product types into which Phytosterol Ester maybe added, according to decision 2004/333/CE(3) and according to the opinion of the Scientific Committee of Food expressed the 4th of April(11). The opinion of the Food Standards Agency will be used to support notifications to be made either by Xi'an Healthful Biotechnology Co., Ltd, on its own name for the benefit of its future customers or to support notifications by its customers.

This application is also based on the relevant SCF opinion on the safety of phytosterols and Phytosterol Esters (11,12,13) in relation to the authorizations that we are claiming substantial equivalence to.

2. ADMINISTRATIVE DATA

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3. COMPOSITION

The phytosterol Xi'an Healthful Biotechnology used to produce LowChol®Phytosterol Ester is extracted from by-products of edible oil refining from NON-GMO plants, largely from soybean oil. For phytosterol and phytosterol ester we have got a IP certificate. Then the phytosterol is esterified with food grade fatty acid. The free phytosterol is a mixture of beta-sistosterol, beta-sistostanol, campesterol, campestanol, stigmasterol, brassicasterol and a small percentage of other sterol/stanols.

The ester form of phytosterol is the final product we will sold to Europe market. It's much better fat-soluble in foods like yellow fat spreads, salad dressings and milk type products.

In appendix1, we will show specification sheet and analytical results on sterol ester composition.

3.1 Manufacturing process

The manufacturing process of Xi'an Healthful Biotechnology's LowChol®Phytosterol Ester is identical to those used to produce Phytosterol Esters that are authorized for use in yellow fat spreads. The production process is very close to the one described in ADM novel food application.

The crude oil, which is obtained by pressing or solvent extraction, undergoes a series of refining processes to remove solvents, colour bodies, off-odours and off-flavours. The distillate contains the sterol fraction. From this fraction, fatty acid, lecithins and other compounds are removed by fractional distillation, crystallization from a heptane solution, and the sterols are further purified by re-crystallization using food grade materials and good manufacturing practices.

The extraction and purification steps are standard methods and similar to the procedures used traditionally by the food industry for the production of plant sterol. Sterol esters are produced from the sterols estify with food grade vegetable oil derived fatty acids and applying standard methods for esterification.

I attach a flow chart as below.

Confidential

Since the product we will sell to Europe market is Phytosterol ester, I make a further explaination for the process from phytosterol to phytosterol ester.

3.1.1 Raw material input

The main raw material of phytosterol and fatty acid be deliveried to reaction tank respectively by closed pipe at 1:1.2.

3.1.2 Estification reaction

The estification reaction between the raw material phytosterol and fatty acid last for 5~9 hours with catalyzer. The estification rate is about 95%.

3.1.3 Filtration

Filter the catalyzer for 20~60 minutes, the yield rate is 96%.

3.1.4 Film Evaporator

The purpose of this step is dehydration and degassing.

3.1.5 First Molecular Distillation

This step is to take off the fatty acid, the yield rate is above 99%.

3.1.6 Second Molecular Distillation

In this step the product LowChol®Phytosterol Ester be evaporated, the yield rate is 95%.

3.1.7 Package

This step is finished in filling room with ultraviolet disinfection facilities.

3.2 Specifications

In annex 2 of the Commission Decision 2004/333/CE(3) the sterol profile is defined under the following section “Specifications of phytosterols and phytostanols for the addition to foods and food ingredients”.

To be considered as “substantially equivalent”, Xi’an Healthful Biotechnology’s product must meet the same requirements. A comparative evaluation of the EU requirements for ADM(3) versus Xi’an Healthful Biotechnology’s specifications is presented here after:

Composition (with GC-FID or equivalent method)	**Requirements 2004/333/EC(3) ADM**	**Xi'an Healthful Biotechnology's phytosterol Specifications**
β-sitosterol(%)	<80	70-78
β-sitostanol(%)	<15	10-12
Campesterol(%)	<40	6-8
Campestanol(%)	<5	1-2
Stigmasterol(%)	<30	0-2
Brassicasterol(%)	<3	0-1
Other sterols/stanols(%)	<3	1-3

Our LowChol®Phytosterol Ester is ester form of phytosterol, which obtained from by-products of traditional vegetable oil refining. The sources is commonly a blend of crude edible oils, consisting largely of soy bean oil and lesser amount of other edible oils, e.g.corn, rapeseed. Then esterify with food grade fatty acid. The free phytosterol is a mixture of beta-sistosterol, beta-sistostanol, campesterol, campestanol, stigmasterol, brassicasterol and a small percentage of other sterols/stanols. The composition is same as above and our specification will be attached in appendix1, which will provide evidence to confirm it's the same specification.

In the following tables, a compilation of the GC analysis performed on different batches of Xi'an Healthful Biotechnology's LowChol®Phytosterol Ester is presented versus approved specification(the corresponding certificates of analysis are presented in Appendix3.)

Composition (with GC-FID or equivalent method)	**Requirements 2004/333/CE(3) ADM**	**Xi'an Healthful Biotechnology Batch(CPB160102)**	
		Free phytosterol	**Esterified phytosterol**
β-sitosterol(%)	< 80 %	76.86%	45.87%
β-sitostanol(%)	< 15 %	11.25%	6.71%
Campesterol(%)	< 40 %	7.32%	4.37%
Stigmasterol(%)	< 30 %	0.62%	0.37%
Brassicasterol(%)	< 3 %	0%	0%
Campestanol(%)	< 5 %	1.38%	0.82%
Other sterol/stanol(%)	< 3 %	2.56%	1.53%

Composition (with GC-FID or equivalent method)	**Requirements 2004/333/CE(3) ADM**	**Xi'an Healthful Biotechnology** Batch (CPB160301)	
	Requirements 2004/333/EC	Free phytosterol	Esterified phytosterol
beta-sitosterol	< 80 %	77.24%	46.86%
beta-sitostanol	< 15 %	11.10%	6.73%
Campesterol	< 40 %	7.12%	4.32%
Stigmasterol	< 30 %	0.72%	0.44%
Brassicasterol	< 3 %	0%	0%
Campestanol	< 5 %	1.37%	0.83%
Other sterol/stanol	< 3 %	2.44%	1.48%

Composition (with GC-FID or equivalent method)	**Requirements 2004/333/CE(3) ADM**	**Xi'an Healthful Biotechnology** Batch(CPB160801)	
	Requirements 2004/333/EC	Free phytosterol	Esterified phytosterol
beta-sitosterol	< 80 %	77.01%	45.99%
beta-sitostanol	< 15 %	11.15%	6.66%
Campesterol	< 40 %	7.22%	4.31%
Stigmasterol	< 30 %	0.62%	0.37%
Brassicasterol	< 3 %	0%	0%
Campestanol	< 5 %	1.32%	0.79%
Other sterol/stanol	< 3 %	2.68%	1.60%

As first and only one producer of phytosterol ester in China, our QC department cultivate four professional analysts. Their working standards and operation proficiency is competitive with international standards like ISO.

4. NUTRITIONAL VALUE / METABOLISM

Two potential nutritional effect are linked to the consumption of LowChol®Phytosterol Ester: reduction in circulating cholesterol and reduction of nutrient absorption like carotenoids.

4.1 Reduction in circulating cholesterol

The first studies demonstrating the cholesterol-lowering effect of phytosterols in humans were reported by Pollak in the early 1950's. Since then a large number of clinical studies with phytosterols have been conducted (Pollak, 1985)[14,15]. And the principal mechanism of serum cholesterol-lowering is considered to be competition between cholesterol and the phytosterols

for micellar solubilisation in the small intestine. Phytosterols lower serum cholesterol by decreasing cholesterol absorption in the small intestine, with a consequential increase in faecal excretion of cholesterol.

But in these studies the phytosterols were given as the free sterols and not as fatty acid esters. Since Phytosterol Ester will be hydrolysised to free phytosterols and fatty acids in vivo. Therefore LowChol®Phytosterol Ester should have the cholesterol-lowering effect.

Unilever has conducted a comprehensive investigation of the efficacy of Phytosterol Ester. To July 2002, over 30 clinical trials had been conducted involving over 2000 individuals at study sites in Europe, North America, Latin America, Africa, Asia and Australia. These studies showed that Phytosterol Ester can be used safely to provide an additional cholesterol-lowering effect to that of the medication alone.

Another study was carried out in a group of children with familial hypercholesterolaemia (Amundsen et al., 2001 & 2002)[16,17]. A significant cholesterol-lowering effect was seen in these children during the study period which was further maintained during a six month open label follow up period. The spreads were well tolerated by the children with no adverse events reported. Whilst there is no intention to market products containing Phytosterol Ester to children, this study confirmed the potential benefit of their use by children with familial hypercholesterolaemia.

Unilever also commissioned a trial studies on the cholesterol-lowering efficacy of Phytosterol Ester in milk at CSIRO Health Sciences and Nutrition, Adelaide, Australia. Thirty nine volunteers consumed both spread and milk in a four way comparison with each intervention lasting three weeks.

The cholesterol-lowering effect of Phytosterol Ester in salad dressings (Davidson et al., 2001; Judd et al., 2002)[18] and lean ground beef has also been reported (Carr et al., 2002; Matvienko et al., 2002) with similar results of cholesterol-lowering efficacy.

4.2 Reduction of nutrient absorption

Clinical studies using 1-4g day of phytosterols (given as Phytosterol Ester) have indicated a modest reduction (10-25%) in the absorption of the most lipophilic carotenoids (e.g. β-carotene). Comaparable reductions in carotenoids have been reported during both short term (three weeks) and long term (52 weeks) trials (Hendricks et al., 1999 & 2001). At the recommended intakes of 2-3g free phytosterols/day of the spreads, ‘milk’ and ‘yoghurt’ type products it is expected that any effects on carotenoid lowering will be within this range. Carotenoids levels are influenced by various factors such as diet, person to person variation and

seasonal variations (which are also linked to diet). The plasma level of carotenoids can vary from season to season by up to 30% depending on the main fruit and vegetables available at the time (Van Het Hof, 1999; Lux and Naidoo, 1994; Olmedilla et al., 1994; Saintot et al., 1995; Scott et al., 1996)[19,20]. Thus a reduction in carotenoids of 10-25% should be considered in the context of these other factors. Furthermore, phytosterol ester enriched spreads are recommended as part of a healthy diet rich in fruit and vegetables and the 'milk' and 'yoghurt' type products will be similarly labelled. As demonstrated by Judd et al.,(2002)[21] and Noakes et al., (2002)[22], this can have a significant influence on plasma carotenoid levels. For example in the study by Noakes et al., (2002)[22] the addition of one extra serving of a high carotenoid fruit or vegetable per day when consuming phytosterol ester containing spreads maintained plasma carotenoid levels. In another recently published study no changes in serum carotenoid concentrations were observed when spreads containing phytosterol and phytostanol esters were taken as part of a controlled diet (Raeini-Sarjaz et al., 2002)[23]. As the health benefits of carotenoids have not been established it cannot be assumed that a modest reduction will have any significance for public health.

Accordingly to Commission Regulation 608/2004, Xi'an Healthful Biotechnology and its customers will advice on the labelling that the foods or beverages enriched with Xi'an Healthful Biotechnology' product are to be used as a part of a balanced and varied diet, including regular consumption of fruit and vegetables to help maintain carotenoid levels.

5. INTENDED USE

5.1 Intended use

The intended use of LowChol®Phytosterol Ester product is claimed in accordance with the food applications covered by Commission Decision 2004/333/EC under Regulation (EC) No 258/97 of the European Parliament and of the Council. That is to say, LowChol®Phytosterol Ester product could be used in followings :

--Yellow fat spreads, as defined by Council Regulation (EC) No 2991/94 (1), excluding cooking and frying fats and spreads based on butter or other animal fat.
--Salad dressings including mayonnaise.
--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, and cheese type products (fat content $\leqslant$ 12 g per 100 g), where the milk fat and/or protein has been partly or fully replaced by vegetable fat or protein.

Xi'an Healthful Biotechnology also apply LowChol®Phytosterol Ester can be applied in these

above areas.

5.2 Anticipated intake

LowChol®Phytosterol Ester product will be added to the same products as those already approved in 2004/333/EC. And for this reason the daily intake of LowChol®Phytosterol Ester will not be increased within the European Community population. It is anticipated that the intake of LowChol®Phytosterol Ester from the range of food products will be consistent with the product labelling/consumer information that will accompany the marketing of the products and be in the range of 3.2-4.8g of LowChol®Phytosterol Ester per day (2-3g of free phytosterols).

6. LEVEL OF UNDESIRABLE SUBSTANCES

6.1 Chemical contaminants

A special focus must be brought on the high purity of the product. The raw material supplier realized several studies on the Phytosterol Ester in order to demonstrate that the low levels of contaminants are in compliance with European Regulations.

Analyses performed on the LowChol®Phytosterol Ester demonstrated the purity of the material in relation to the presence of PAH's , dioxin, herbicides and pesticides, heavy metals, organic solvents, and aflatoxins (Appendix 7, Appendix 8, Appendix 9, Appendix 10).

Important contaminants are more specifically discussed here below.
PAH (polycyclic aromatic hydrocarbons) (see Appendix 7, Appendix 9, Appendix 10)

- Benzo (a) pyrene

The level of Benzo (a) pyrene is not detected as show in Appendix 7, Appendix 9 and Appendix 10, and complies with the requirement of Oils and fats and with the maximum level of 2 μg/kg stated in the COMMISSION REGULATION (EU) No 835/2011 of 19 August 2011.

- Other products:
Other PAH(s) classified as priority pollutants by the US environmental Protection agency are all under acceptable levels.

- Dioxins

According to EC 1881/2006, the total amount of dioxin must be less than 0.75 pg/g expressed as toxicity equivalents. Our phytosterol ester meet the standard.

Herbicides and Pesticides
The possible contaminants such as, organochloride and organophosphorus were analyzed and were under the detection limits allowing levels inferior to pharmacopea limits for such product family (see Appendix 7, Appendix 9, Appendix 10).

6.2 Heavy Metals

Heavy metals were evaluated in one batch and the sum is under 10 ppm. (See Appendix 8, Appendix 9, Appendix 10). Thus a specific determination was performed for Cadmium, Arsenic, Mercury and Lead: all the obtained values are under 0.1 ppm that is inferior to the maxima accepted value (determined in the Commission Regulation (EC) No 1881/2006 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs).

6.3 Organic Solvents

The obtained value for the solvent used during the manufacturing process (methanol and acetone) are under 10 ppm that is comply with EC 32/2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

6.4 Biological Contaminants

Aflatoxins are toxic metabolites produced by certain fungi in/on foods and feeds. Aflatoxins have received greater attention than any other mycotoxins because of their demonstrated potent carcinogenic effect in susceptible laboratory animals and their acute toxicological effects in humans.

The obtained value (See Appendix 7, Appendix 9, Appendix 10) complies with the maximum level of 10 ppm stated in the COMMISSION REGULATION (EU) No 165/2010 of 26 February 2010.

6.5 Microbiological contamination

The microbiological quality contamination is one of the specifications of the product and was stated at less than 100 CFU/ without any pathogenic organism. Three batches were analyzed and demonstrated satisfactory results showing the good control of the whole process (See

appendix 8, Appendix 9, Appendix 10).
This high microbiological quality ensures that the incorporation of Healthful' product in further manufacturing process is safe.

7. OTHER RELEVANT DATA

7.1 LABELLING

Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, the following additional specific labelling requirements shall apply:

(a) The product shall be labelled such as: margarine (or vegetable fat spread) with phytosterol esters, in conformity with Council Regulation (EC) No 2991/94.

(b) The content of phytostrol esters shall be declared on the list of ingredients.

(c) There shall be a statement that the product is for people who want to lower their blood cholesterol levels.

(d) There shall be a statement that patients on cholesterol lowering medication should only consume the product under medical supervision.

(e) There shall be an easily visible and legible statement that the product may not be nutritionally appropriate for certain sections of the population (pregnant and breastfeeding women and children under the age of five years).

(f) Advice shall be given that the product should be used as part of a healthy diet, including regular consumption of fruit and vegetables (to help maintain carotenoid levels).

The labeling of the range of spreads, 'milk' and 'yogurt' type products will include the information from the original approval indicating target group, lack of suitability for children, pregnant and lactating women and advice to those receiving cholesterol lowering medication. All product types applied for will be labelled according to Regulation 1169/2011 EC.

For example:
The yogurt pot will be labelled:

Recommended: 2-3 servings daily for optimum
cholesterol reduction. This 125/150g pot is one serving
Extra servings will not provide additional cholesterol-lowering benefit.

The milk carton will be labelled:

Recommended: 2-3 servings daily for optimum

cholesterol reduction. One serving of this product is 250ml, equal to one medium sized glass.
Extra servings will not provide additional cholesterol-lowering benefit.

7.2 TOXICOLOGICAL ASSESSMENT

There is a history of safe consumption of phytosterol within the normal dietary intake of between 200-400mg/day. However, it was estimated that the use of Phytosterol Ester in Yellow Fat Spreads would lead to a five to ten fold increase in the consumption of phytosterols that required a thorough toxicological evaluation. Hence, a comprehensive safety testing programme was carried out to address the following:

- mutagenicity,
- absorption,
- sub-chronic toxicity,
- reproductive toxicity (including oestrogenicity), and
- tolerability of high doses in humans.

The conclusions from these studies were as follows:

- No evidence of genotoxicity (Wolfreys and Hepburn, 2002)[24]
- Absorption is very low (Sanders et al., 2000)[25]
- No evidence of subchronic toxicity – NOAEL of 4.1g phytosterols/kg/bodyweight/day in a 90 day rat feeding study (Hepburn et al.,1999)[26]
- No effect on the reproductive system, and no oestrogenic activity (Baker et al.,1999[27]; Waalkens-Berendsen., 1999)[28]
- High doses produced no adverse physiological effects in humans (Weststrate et al., 1999; Ayesh *et al*., 1999)[29]

A full toxicological assessment of LowChol®Phytosterol Ester using the above studies and data available from the literature was carried out as part of the previous Novel Foods submission (Unilever documents D97/042, D98/002 and D98/028).
Based on this assessment the EC Scientific Committee on Foods concluded that the use of LowChol®Phytosterol Ester in Yellow Fat Spreads at a maximum level corresponding to 8% free phytosterols is safe for human use.

7.3 Other information on long term use of high doses of phytosterols

From the 1950's through to 1982 β-sitosterol (actually mixtures of phytosterols) was marketed in the USA as a treatment for hypercholesterolaemia under the trade name Cytellin by Eli Lilly. Its use was discontinued by the FDA at the request of the Company (Federal Register, 1985). The reason for withdrawal was lack of palatability (and hence compliance) and the availability of more effective hypocholesterolaemic drugs (especially statins). Cytellin preparations

contained unesterified phytosterols suspended in a variety of vehicles, the main ones being methylcellulose and vegetable oils.
Initially a daily dose of 6-12g of phytosterols was recommended, but later the maximum effect in adults was achieved with 3g phytosterols per day. In clinical trials much higher doses had been used, for example in one study reported by Lees et al., (1977) 9-24g/day were given for between three months and three years. Between 1952 and 1954 the amount of sitosterol in preparations ranged from 0.3 to 53g/day, although doses between 1 and 10g/day were used in half the studies (Pollak and Kritchevsky, 1981)[30].

In their review of the vast number of clinical studies conducted on β-sitosterol, (Pollak and Kritchevsky 1981)[30]. concluded that there were no adverse effects or side effects of sitosterol, even when taken for a long time.

The study by Riley and Steiner (1957)[31]is an example of one of the studies where very high doses of β-sitosterol were given. Patients were treated with a 20% liquid suspension of Cytellin. The substance was administered orally before each of the three daily meals in divided dosages totalling 19 to 52g per day to 13 patients with coronary atherosclerosis. The period of sitosterol administration varied between one to six months per patient. There was no effect on liver function parameters and there was no mention of any adverse effects.

In summary, a thorough toxicological evaluation of LowChol®Phytosterol Ester has not identified any adverse health effects up to the maximum dose levels that it is possible to test. Also, human trials using involving large daily intakes of phytosterols have not reported any adverse health effects.

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(3) Decision 2004/333/CE of 31 March 2004 authorizing the placing on the market of yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council.

(4) Decision 2004/334/CE of 31 March 2004 authorizing the placing on the market of yellow fat spreads, milk type products, yoghurt type products, and spicy sauces with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council.

(5) Decision 2004/335/CE of 31 March 2004 authorizing the placing on the market of milk type products and yoghurt type products with added LowChol®Phytosterol Esters as novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council.

(6) Decision 2004/336/CE of 31 March 2004 authorizing the placing on the market of yellow fat spreads, milk based fruit drinks, yoghurt type products and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council.

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