

## COMMISSION DECISION

of 31 March 2004

**authorising 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**

*(notified under document number C(2004) 1244)***(Only the Finnish text is authentic)**

(2004/334/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients <sup>(1)</sup>, and in particular Article 7 thereof,

Whereas:

(1) On 24 September 2001 Pharmaconsult Oy Ltd. (formerly MultiBene Health Oy Ltd.) made a request to the competent authorities of Finland for placing phytosterols on the market.

(2) On 17 January 2002 the competent authorities of Finland issued their initial assessment report.

(3) In their initial assessment report, Finland's competent food assessment body came to the conclusion that the phytosterols/stanols are safe for human consumption.

(4) The Commission forwarded the initial assessment report to all Member States on 5 March 2002.

(5) Within the 60-day period laid down in Article 6(4) of the Regulation, reasoned objections to the marketing of the product were raised in accordance with that provision.

(6) The Scientific Committee on Food (SCF) in its opinion 'General view on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources, with particular attention to the effects on  $\beta$ -carotene' of 26 September 2002 indicated that there was no evidence of additional benefits at intakes higher than 3 g/day and that high intakes might induce undesirable effects and that it was therefore prudent to avoid plant sterol intakes exceeding 3 g/day. Furthermore, the SCF,

in its opinion on an application from MultiBene for approval of plant sterol-enriched foods of 4 April 2003, came to the conclusion that the addition of phytosterols is safe, provided that the daily consumption does not exceed 3 g.

(7) Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters <sup>(2)</sup> ensures that consumers receive the information necessary in order to avoid excessive intake of additional phytosterols.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

*Article 1*

Foods and food ingredients as described in Annex 1 with added phytosterols/phytostanols as specified in Annex 2, hereinafter called the products, may be placed on the market in the Community.

*Article 2*

The products shall be presented in such a manner that they can be easily divided into portions that contain either a maximum of 3 g (in case of one portion per day) or a maximum of 1 g (in case of three portions per day) of added phytosterols/phytostanols.

Spicy sauces shall be packed as single portions.

The amount of phytosterols/phytostanols added to a container of beverages shall not exceed 3 g.

<sup>(1)</sup> OJ L 43, 14.2.1997, p. 1.

<sup>(2)</sup> OJ L 97, 1.4.2004, p. 44.

*Article 3*

This Decision is addressed to Pharmaconsult Oy, Riippakoivunkuja 5, FIN — 02130 Espoo.

Done at Brussels, 31 March 2004.

*For the Commission*

David BYRNE

*Member of the Commission*

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## ANNEX 1

**Products referred to in Article 1**

Yellow fat spreads, as defined by Council Regulation (EC) No 2991/94 <sup>(1)</sup>, excluding cooking and frying fats and spreads based on butter or other animal fat.

Milk type products, such as semi-skimmed and skimmed milk type products and yoghurt type products, where the milk fat has been reduced or partly or fully replaced by vegetable fat.

Spicy sauces

## ANNEX 2

**Specifications of phytosterols and phytostanols for the addition to foods and food ingredients***Definition:*

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.

*Composition (with GC-FID or equivalent method):*

- < 80 %  $\beta$ -sitosterol
- < 15 %  $\beta$ -sitostanol
- < 40 % campesterol
- < 5 % campestanol
- < 30 % stigmasterol
- < 3 % brassicasterol
- < 3 % other sterols/stanols

*Contamination/Purity (GC-FID or equivalent method):*

Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/phytostanol ingredient.

<sup>(1)</sup> OJ L 316, 9.12.1994, p. 2.