

## COMMISSION DECISION

of 31 March 2004

**authorising the placing on the market of milk type products and yoghurt type products with added phytosterol esters as novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council***(notified under document number C(2004) 1245)***(Only the English text is authentic)**

(2004/335/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 6 August 2002 Unilever made a request to the competent authorities of the United Kingdom to place phytosterol esters as a novel food ingredient in a range of foods on the market.
- (2) On 21 November 2002 the competent authorities of the United Kingdom issued their initial assessment report.
- (3) In their initial assessment report the United Kingdom's competent food assessment body came to the conclusion that these extensions of uses of phytosterol esters are safe for human consumption.
- (4) The Commission forwarded the initial assessment report to all Member States on 11 December 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 applications for approval of a variety of plant sterol enriched foods of 5 March 2003, came to the conclusion that the addition of phytosterols is safe, provided that the daily consumption does not exceed 3g.

- (7) Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters<sup>(2)</sup>, phytosterols and/or phytosterol esters 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 phytosterol esters 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 3g (in case of one portion per day) or a maximum of 1g (in case of three portions per day) of added phytosterol esters (calculated as free sterols/stanolols).

The amount of phytosterols/phytosteranolols 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 Unilever, London Road, Purfleet, Essex RM19 1SD, United Kingdom.

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**

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

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## 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.

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