

## COMMISSION DECISION

of 24 July 2000

**on authorising the placing on the market of 'yellow fat spreads with added phytosterol esters' as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council**

(notified under document number C(2000) 2121)

(Only the English text is authentic)

(2000/500/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Having regard to the request by Unilever to the competent authorities of the Netherlands of 22 May 1998 for placing 'yellow fat spreads with added phytosterol-esters' on the market as a novel food or novel food ingredient,

Having regard to the initial assessment report drawn up by the competent authorities of the Netherlands, which the Commission forwarded to all Member States on 28 December 1998,

Whereas:

- (1) Within the 60 days period laid down in Article 6(4) of the Regulation, reasoned objections were raised in accordance with that provision. In accordance with Article 7 of the Regulation, a Decision is therefore to be taken in accordance with the procedure laid down in Article 13 of the Regulation.
- (2) The Scientific Committee for Food has been consulted on this matter in accordance with Article 11 of the Regulation. On 6 April 2000, the Scientific Committee for Food delivered its opinion that the 'yellow fat spreads with added phytosterol-esters' (maximum 8 % w/w phytosterol equivalent to 14 % w/w phytosterol esters) that are the subject of this application are safe for human consumption.
- (3) The marketing of the product will be focused on people who try to lower their blood cholesterol levels.
- (4) Patients on cholesterol-lowering medication should only consume the product under medical supervision.
- (5) A reduction in plasma Beta-carotene will be relevant for people whose vitamin A status is not optimal, in particular pregnant and lactating women as well as younger children. Therefore information about the Beta-carotene lowering effect of the product should be provided to the consumer, together with appropriate dietary advice

regarding the regular consumption of fruits and vegetables.

- (6) On this basis, it is established that the products comply with the criteria laid down in Article 3(1) of the Regulation.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DECISION:

*Article 1*

Yellow fat spreads with added phytosterol esters as specified in the Annex, hereinafter called the products, may be placed on the market in the Community as novel foods or novel food ingredients.

The addressee shall ensure that the products meet the requirements of Article 2.

*Article 2*

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 as: margarine (or vegetable fat spread) with plant sterol esters, in conformity with Council Regulation (EC) No 2991/94.
- (b) The content of plant sterol 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 breast-feeding 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).

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

*Article 3*

Unilever shall establish a surveillance programme accompanying the marketing of the product. This programme should encompass, in particular, information on individual intakes of the product. This programme shall be submitted for approval by the Commission prior to the placing on the market of the product.

The data collected should be made available to the Commission and Member States in order to estimate the extent to which the product is reaching its target group, people who try to control their elevated blood cholesterol, and to estimate exposures to phytosterols from this source in other population groups.

*Article 4*

This Decision is addressed to Unilever (UK) Central Resources Limited, Unilever House, Blackfriars, London, United Kingdom.

Done at Brussels, 24 July 2000.

*For the Commission*

David BYRNE

*Member of the Commission*

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*ANNEX***Specifications of yellow fat spread with added phytosterol esters**

1. The margarine/vegetable oil spread may contain up to 8 % w/w of added phytosterols (equivalent to 14 % w/w phytosterol-esters).
2. The composition of the phytosterols is specified in the table below:

Table 1: Composition of phytosterols

Component	Minimum	Maximum
Campesterol	10 %	40 %
Stigmasterol	6 %	30 %
$\beta$ -Sitosterol	30 %	65 %
Other	0 %	5 %