COMMISSION DECISION

of 15 May 2007

authorising the placing on the market of oil enriched with phytosterols/phytostanols as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2007) 2073)

(Only the English text is authentic)

(2007/343/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 [1], and in particular Article 7 thereof,

Whereas:

(1) On 4 May 2005 the company Enzymotec made a request to the competent authorities of the Netherlands to place oil enriched with phytosterols/phytostanols on the market as a novel food or a novel food ingredient.

(2) On 23 May 2006 the competent food assessment body of the Netherlands issued its initial assessment report. In that report it came to the conclusion that the oil enriched with phytosterols is safe for human consumption.

(3) The Commission forwarded the initial assessment report to all Member States on 29 May 2006.

(4) Within the sixty day-period laid down in Article 6(4) of Regulation (EC) No 258/97 reasoned objections to the marketing of the product were raised in accordance with that provision.

(5) The objections raised concerned issues of risk management rather than risk assessment issues, therefore there was no need to consult the European Food Safety Authority (EFSA).

(6) The authorisation of oil enriched with phytosterols/phytostanols should only cover use in foods where the addition of phytosterols/phytostanols is authorised. The rules concerning the presentation and the labelling of foods with added phytosterols/phytostanols apply.

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

(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

Oil enriched with phytosterols/phytostanols as specified in Annex 1 may be placed on the market in the Community as a novel food ingredient for use in the foods specified in Annex 2.

Article 2

The products containing the novel food ingredient 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.

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

Spicy sauces and salad dressings including mayonnaise shall be packed as single portions.

[1] OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

[2] OJ L 97, 1.4.2004, p. 44.

Article 3

This Decision is addressed to Enzymotec, 5 Hataasi ST, Ramat Gabriel Industrial Park, Migdal HaEmeq, Israel 23 106.

Done at Brussels, 15 May 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

Specifications of oil enriched with phytosterols/phytostanols

Definition:

Oil enriched with phytosterols/phytostanols is composed of an oil fraction and a phytosterol fraction.

Substance/Parameter	Content
Acylglycerol Distribution:	
Free fatty acids (expressed as oleic acid)	Not more than 2 %
Monoacylglycerols (MAG)	Not more than 10 %
Diacylglycerols (DAG)	Not more than 25 %
Triacylglycerols (TAG)	Making up the balance
Phytosterol fraction:	
β-sitosterol	Not more than 80 %
β-sitostanol	Not more than 15 %
campesterol	Not more than 40 %
campestanol	Not more than 5 %
stigmasterol	Not more than 30 %
brassicasterol	Not more than 3 %
other sterols/stanols	Not more than 3 %
Others:	
Moisture and volatile	Not more than 0,5 %
Peroxide value (PV)	< 5 meq/kg
Trans fatty acids	Not more than 1 %

Contamination/Purity (GC-FID or equivalent method) of phytosterols/phytostanols

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 %.

ANNEX II

Foods referred to in Article 1

Spreadable fats, as defined by Council Regulation (EC) No 2991/94 [1] Annex, points B and C, excluding cooking and frying fats and spreads based on butter or other animal fat.

Milk based products, such as products based on semi-skimmed and skimmed milk products, possibly with the addition of fruits and/or cereals, products based on fermented milk such as yoghurt and cheese based products (fat content ≤ 12 g per 100 g), where possibly the milk fat has been reduced and the fat or protein has been partly or fully replaced by vegetable fat or protein.

Soya drinks.

Spicy sauces and salad dressings including mayonnaise.

[1] OJ L 316, 9.12.1994, p. 2.