

**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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ⁽¹⁾, as amended by Directive 2003/89/EC ⁽²⁾, and in particular Article 4(2) and Article 6(7) thereof,

Whereas:

(1) Phytosterols, phytosterol esters, phytostanols and phytostanol esters reduce serum cholesterol levels but may also reduce the β -carotene levels in blood serum. Member States and the Commission therefore consulted the Scientific Committee on Food (SCF) about the effects of consumption of phytosterols, phytosterol esters, phytostanols and phytostanol esters from multiple sources.

(2) 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 β -carotene' of 26 September 2002 confirmed the need to label phytosterols, phytosterol esters, phytostanols and phytostanol esters as specified in Commission Decision 2000/500/EC 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 ⁽³⁾. The SCF also 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.

(3) Products containing phytosterols/phytostanols should thus be presented in single portions containing either maximum 3 g or maximum 1 g of phytosterols/phytostanols, calculated as free phytosterols/phytostanols. Where this is not the case, there should be a clear indication of what constitutes a standard portion of the food, expressed in g or ml, and of the amount of phytosterols/phytostanols, calculated as free phytosterols/phytostanols, contained in such a portion. In all events, the composition and labelling of products should be such as to allow users to easily restrict their consump-

tion to maximum 3 g/day of phytosterols/phytostanols through the use of either one portion containing maximum 3 g, or three portions containing maximum 1 g.

(4) In order to facilitate consumer understanding it appears appropriate to replace on the label the word 'phyto' with the word 'plant'.

(5) Decision 2000/500/EC allows the addition of certain phytosterol esters to yellow fat spreads. It sets out specific labelling requirements in order to ensure that the product reaches its target group, namely people who want to lower their blood cholesterol levels.

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

HAS ADOPTED THIS REGULATION:

Article 1

This Regulation shall apply to foods and food ingredients with added phytosterols, phytosterol esters, phytostanols or phytostanol esters.

Article 2

For labelling purposes, phytosterol, phytosterol ester, phytostanol and phytostanol ester shall be designated respectively by the terms 'plant sterol', 'plant sterol ester', 'plant stanol' or 'plant stanol ester' or their plural form, as appropriate.

Without prejudice to the other requirements of Community or national law concerning the labelling of foodstuffs, the labelling of foods or food ingredients with added phytosterols, phytosterol esters, phytostanols or phytostanol esters shall contain the following:

1. in the same field of vision as the name under which the product is sold there shall appear, easily visible and legible, the words: 'with added plant sterols/plant stanols';
2. the amount of added phytosterols, phytosterol esters, phytostanols or phytostanol esters content (expressed in % or as g of free plant sterols/plant stanols per 100 g or 100 ml of the food) shall be stated on the list of ingredients;

⁽¹⁾ OJ L 109, 6.5.2000, p. 29.

⁽²⁾ OJ L 308, 25.11.2003, p. 15.

⁽³⁾ OJ L 200, 8.8.2000, p. 59.

3. there shall be a statement that the product is intended exclusively for people who want to lower their blood cholesterol level;
4. there shall be a statement that patients on cholesterol lowering medication should only consume the product under medical supervision;
5. there shall be an easily visible and legible statement that the product may not be nutritionally appropriate for pregnant and breastfeeding women and children under the age of five years;
6. advice shall be included that the product is to be used as part of a balanced and varied diet, including regular consumption of fruit and vegetables to help maintain carotenoid levels;
7. in the same field of vision as the particular required under point 3 above, there shall be a statement that the consumption of more than 3 g/day of added plant sterols/plant stanols should be avoided;
8. there shall be a definition of a portion of the food or food ingredient concerned (preferably in g or ml) with a statement of the plant sterol/plant stanol amount that each portion contains.

Article 3

Foods and food ingredients with added phytostanol esters already on the market in the Community or 'yellow fat spreads with added phytosterol esters' that were authorised by Commission Decision 2000/500/EC produced from six months after entry into force of this Regulation shall comply with the labelling provisions of Article 2.

Article 4

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 31 March 2004.

For the Commission
David BYRNE
Member of the Commission
