

**EXPLANATORY MEMORANDUM TO THE
THE FOOD WITH ADDED PHYTOSTEROLS OR PHYTOSTANOLS (LABELLING)
(ENGLAND) REGULATIONS 2004**

2004 No.3344

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.
2. **Description**
 - 2.1 These Regulations provide for the administration and enforcement (including offences and penalty) of Commission Regulation (EC) No. 608/2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None
4. **Legislative Background**

Commission Regulation (EC) No. 608/2004 is binding in its entirety and directly applicable in all Member States. That Regulation is made pursuant to Directive 2000/13/EC on food labelling (paragraphs 2 to 4 of the Explanatory Note to the Regulations refer). The Regulations provide necessary legislative enforcement machinery.
5. **Extent**
 - 5.1 This instrument applies to England only.
6. **European Convention on Human Rights**
 - 6.1 Not applicable
7. **Policy background**
 - 7.1 Plant sterols occur naturally in plants and lower cholesterol levels in the blood by reducing the absorption of cholesterol from the intestine. The labelling of foods and food ingredients with added plant sterols is regulated under EC legislation for safety reasons.
 - 7.2 Foods and food ingredients with added plant sterols should only be consumed by people who wish to lower their blood cholesterol level. Furthermore, without evidence of additional benefits at higher intakes and the possibility that high intakes might induce undesirable effects, the EC Scientific Committee on Food (SCF) has advised that plant sterol intakes above the range 1-3g per day should be avoided.
 - 7.3 Plant sterols are also known to interfere with the absorption of fat-soluble vitamins and carotenoids such as β -carotene. Carotenoids are present in many

fruits and vegetables and act as a precursor to vitamin A. The consequences of the persistent decrease of β -carotene on human health are largely unknown due to wide variations in the mechanisms regulating the bioavailability of β -carotene, such as seasonal changes in the diet. However, the reduction of β -carotene levels is a particular concern for individuals with non-optimal vitamin A status such as pregnant and breastfeeding women, and children under the age of five years. In such case reduced vitamin A levels can have an effect on reproduction, nutritional status and growth.

- 7.4 In June 2000, yellow fat spreads with added plant sterols were authorised in the EU under the Novel Foods Regulation (EC) No 258/97. The authorisation was achieved through Commission Decision 2000/500/EC which defined specific labelling requirements for the relevant products. However, these requirements did not apply to similar products that were on the market before May 1997 and which are consequently not regulated as novel foods.
- 7.5 Consumers wishing to lower their blood cholesterol level should be provided with consistent and appropriate information to enable them to select from a range of plant sterol-fortified products without exceeding the recommended daily intake of 1-3g per day set by the SCF.
- 7.6 This instrument will also ensure that all foods or food ingredients with added plant sterols are labelled consistently and aimed exclusively at consumers who wish to lower their blood cholesterol level. It will also enable consumers in this target group to select from a range of products that contribute to the cholesterol lowering effect of plant sterols without exceeding the recommended upper daily intake set by the SCF. The instrument also discourages the consumption of plant sterols by pregnant and breast-feeding women, and children under the age of five years.

8. Impact

- 8.1 A Regulatory Impact Assessment has been placed in the Library.
- 8.2 The impact on the public sector is enforcement costs for ensuring that foods and food ingredients with added plant sterols are labelled correctly.

9. Contact

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