
STATUTORY INSTRUMENTS

2004 No. 3344

FOOD, ENGLAND

**The Food with Added Phytosterols or Phytostanols
(Labelling) (England) Regulations 2004**

Made - - - - *15th December 2004*
Laid before Parliament *21st December 2004*
Coming into force - - *12th January 2005*

The Secretary of State, in exercise of the powers conferred by sections 16(1)(e) and (f), 17, 26(1) and (3) and 48(1) of the Food Safety Act 1990⁽¹⁾ and now vested in him⁽²⁾, having had regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency and after consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council⁽³⁾ laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, makes the following Regulations:

Title, commencement and application

1. These Regulations may be cited as the Food with Added Phytosterols or Phytostanols (Labelling) (England) Regulations 2004; they come into force on 12th January 2005 and apply in relation to England only.

Interpretation

2.—(1) In these Regulations —
“the Act” means the Food Safety Act 1990;

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- (1) 1990 c. 16; section 1(1) and (2) (definition of “food”) was substituted by S.I.2004/2990; section 53(2) was amended by Schedule 6 to the Food Standards Act 1999 (1999 c. 28) and S.I. 2004/2990.
- (2) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999 and paragraphs 12 and 21 of that Schedule amend respectively sections 17 and 48 of the 1990 Act. Section 48 was also amended by S.I. 2004/2990. Functions of “the Ministers” so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act and those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.
- (3) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (OJ No. L245, 29.9.2003, p.4).

“biscuits” includes wafers, rusks, oatcakes and matzos;

“confectionery product” means any item of chocolate confectionery or sugar confectionery;

“Directive 2000/13” means Directive [2000/13/EC](#) of the European Parliament and of the Council⁽⁴⁾ on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, as amended by amendments up to and including those effected by Directive [2003/89/EC](#) of the European Parliament and of the Council⁽⁵⁾;

“edible ice” includes ice-cream, water ice and fruit ice, whether alone or in combination, and any similar food;

“fancy confectionery product” means any confectionery product in the form of a figure, animal, cigarette or egg or in any other fancy form;

“flour confectionery” means any cooked food which is ready for consumption without further preparation (other than reheating), of which a characterising ingredient is ground cereal, including shortbread, sponges, crumpets, muffins, macaroons, ratafias, pastry and pastry cases, and also includes meringues, petits fours and uncooked pastry and pastry cases, but does not include bread, pizzas, biscuits, crispbread, extruded flat bread or any food containing a filling which has as an ingredient any cheese, meat, offal, fish, shellfish, vegetable protein material or microbial protein material;

“the key particulars” means those particulars specified in items 1 and 5 in the second paragraph of Article 2 of Regulation 608/2004;

“prepacked for direct sale” means —

- (a) in relation to a food other than flour confectionery, bread and edible ices, prepacked by a retailer for sale by him on the premises where the food is packed or from a vehicle or stall used by him, and
- (b) in relation to flour confectionery, bread and edible ices, prepacked by a retailer for sale as in paragraph (a) of this definition, or prepacked by the producer of the food for sale by him either on the premises where the food is produced or on other premises from which he conducts business under the same name as the business conducted on the premises where the food is produced;

“preparation”, in relation to food, includes manufacture and any form of processing or treatment;

“Regulation 608/2004” means Commission Regulation [\(EC\) No. 608/2004](#)⁽⁶⁾ concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phyostanols and/or phytostanol esters;

“sell” includes offer or expose for sale and have in possession for sale, and “sale” shall be construed accordingly;

“the specified particulars” means the particulars required by Article 2 of Regulation 608/2004.

(2) Food shall be regarded as prepacked for the purposes of these Regulations if —

- (a) it is ready for sale to the ultimate consumer or to a mass caterer, and
- (b) it is —
 - (i) put into packaging before being offered for sale in such a way that the food, whether wholly or only partly enclosed, cannot be altered without opening or changing the packaging, or

⁽⁴⁾ OJ No. L109, 6.5.2000, p.29, as corrected by a Corrigendum (OJ No. L124, 25.5.2000, p.66).

⁽⁵⁾ OJ No. L308, 25.11.2003, p.15.

⁽⁶⁾ OJ No. L97, 1.4.2004, p.44.

(ii) wholly enclosed in packaging before being offered for sale and the food is intended to be cooked without opening the packaging,

but food shall not be regarded as prepacked for the purposes of these Regulations if it comprises an individually wrapped sweet or chocolate which is not enclosed in any further packaging and which is not intended for sale as an individual item.

(3) Other expressions used both in these Regulations and in Directive 2000/13 have the same meaning in these Regulations as they have in that Directive.

Offences and penalty

3. Subject to regulation 4, if any person —

- (a) sells any food in respect of which the labelling requirements of Regulation 608/2004 apply and which is not labelled with the specified particulars, or
- (b) sells any food which is not labelled in accordance with regulation 5, 6 or 7,

he shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Exemption

4. In the case of —

- (a) food which is not prepacked,
- (b) food which is prepacked for direct sale or
- (c) individually wrapped fancy confectionery products which are not enclosed in any further packaging and which are intended for sale as single items,

such food need not be labelled with any of the specified particulars other than the key particulars.

Manner of labelling: general requirement

5. When any food other than food to which regulation 6 applies is sold, any particulars with which it is required to be labelled by Regulation 608/2004 shall appear —

- (a) on the packaging,
- (b) on a label attached to the packaging, or
- (c) on a label which is clearly visible through the packaging,

save that, where the sale is otherwise than to the ultimate consumer, such particulars may, alternatively, appear only on the commercial documents relating to the food where it can be guaranteed that such documents, containing all such particulars, either accompany the food to which they relate or were sent before, or at the same time as, delivery of the food.

Manner of labelling: special rules

6.—(1) This regulation applies to —

- (a) food which is not prepacked;
- (b) food which is prepacked for direct sale; and
- (c) any individually wrapped fancy confectionery product which is not enclosed in any further packaging and which is intended for sale as a single item.

(2) When any food to which this regulation applies is sold to the ultimate consumer, the key particulars with which that food is required to be labelled by Regulation 608/2004 as read with regulation 4 shall appear —

- (a) on a label attached to the food, or
- (b) on a menu, notice, ticket or label which is readily discernible by an intending purchaser at the place where he chooses that food.

(3) When any food to which this regulation applies is sold otherwise than to the ultimate consumer, the key particulars with which that food is required to be labelled by Regulation 608/2004 as read with regulation 4 shall appear —

- (a) on a label attached to the food, or
- (b) on a ticket or notice which is readily discernible by the intending purchaser at the place where he chooses the food, or
- (c) in commercial documents relating to the food where it can be guaranteed that such documents either accompany the food to which they relate or were sent before, or at the same time as, delivery of the food.

Intelligibility of labelling

7.—(1) The particulars with which a food is required to be labelled as referred to in regulations 5 and 6, or which appear on a menu, notice, ticket or label pursuant to regulation 6, shall be easy to understand, clearly legible and indelible and, when a food is sold to the ultimate consumer, such particulars shall be marked in a conspicuous place in such a way as to be easily visible.

(2) Such particulars shall not in any way be hidden, obscured or interrupted by any other written or pictorial matter.

(3) Paragraph (1) shall not be taken to preclude the giving of such particulars at mass caterers, in respect of foods the variety and type of which are changed regularly, by means of temporary media (including the use of chalk on a blackboard).

Enforcement

8.—(1) Subject to paragraph (2), each food authority shall enforce and execute these Regulations in its area.

(2) Each port health authority shall enforce and execute these Regulations in its district in relation to imported food.

(3) In this regulation “food authority” does not include —

- (a) the council of a district in a non-metropolitan county except where the county functions have been transferred to that council pursuant to a structural change;
- (b) the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple).

Defence in relation to exports

9. In any proceedings for an offence under these Regulations, it shall be a defence for the person charged to prove that the food in respect of which the offence is alleged to have been committed —

- (a) was intended for export to a country, other than a Member State, which has legislation analogous to Regulation 608/2004 and that the food complies with that legislation; or
- (b) was intended for export to a Member State, is food to which Regulation 608/2004 applies and the food complies with the provisions of that Regulation as read with Directive 2000/13 as applied in that State.

Application of various provisions of the Act

10.—(1) The following provisions of the Act shall apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to these Regulations —

- (a) section 2 (extended meaning of “sale” etc.);
- (b) section 3 (presumption that food is intended for human consumption);
- (c) section 20 (offences due to fault of another person);
- (d) section 21 (defence of due diligence) as it applies for the purposes of section 14 or 15;
- (e) section 30(8) (which relates to documentary evidence);
- (f) section 35(1) (punishment of offences)(7) in so far as it relates to offences under section 33(1) as applied by paragraph (3) below;
- (g) section 35(2) and (3) in so far as it relates to offences under section 33(2) as applied by paragraph (3) below;
- (h) section 36 (offences by bodies corporate).

(2) In the application of section 32 of the Act (powers of entry) for the purposes of these Regulations, the references in subsection (1) to the Act shall be construed as including references to Regulation 608/2004.

(3) The following provisions of the Act shall apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act shall be construed as including a reference to these Regulations as read with Regulation 608/2004 —

- (a) section 33(1) (obstruction etc. of officers);
- (b) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b) above” shall be deemed to be a reference to any such requirement as is mentioned in that subsection as applied by sub-paragraph (a) above;
- (c) section 44 (protection of officers acting in good faith).

Signed by authority of the Secretary of State for Health

15th December 2004

Melanie Johnson
Parliamentary Under Secretary of State,
Department of Health

(7) Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c. 44), Schedule 26, paragraph 42, from a date to be appointed.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations, which apply to England only, provide for the enforcement of Commission Regulation (EC) No. 608/2004 (OJ No. L97, 1.4.2004, p.44) concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytosterols and/or phytosterol esters. That Regulation requires such foods and food ingredients to be labelled with additional information, including the words “with added plant sterols/plant stanols”.

2. Regulation 608/2004 was made pursuant to Directive 2000/13/EC of the European Parliament and of the Council (OJ No. L109, 6.5.2000, p.29) on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (“the Directive”). In consequence, the products covered by Regulation 608/2004 are foods and food ingredients which are to be delivered as such to the ultimate consumer or which are intended for supply to mass caterers. By virtue of Article 13(4) of the Directive, certain small packages and indelibly marked glass bottles are exempt from the labelling requirements of Regulation 608/2004. There is a transitional provision in Article 3 of that Regulation.

3. Pursuant to Articles 14 and 15 of the Directive, these Regulations contain an exemption from the need to be labelled with some of the particulars required by Regulation 608/2004 in the case of food which is not prepacked, certain similar foods and fancy confectionery products (regulation 4).

4. Pursuant to Articles 13(1) and (2) and 14 of the Directive, these Regulations make provision as to the manner of labelling in the case of the required particulars (regulations 5 to 7).

5. These Regulations also —

- (a) create offences and prescribe a penalty (regulation 3) and specify enforcement authorities (regulation 8);
- (b) provide a defence in relation to exports, in accordance with Articles 2 and 3 of Council Directive 89/397/EEC (OJ No. L186, 30.6.89, p. 23) on the official control of foodstuffs, as read with the ninth recital to that Directive (regulation 9);
- (c) incorporate specified provisions of the Food Safety Act 1990 (regulation 10).

6. A full Regulatory Impact Assessment of the effect that these Regulations will have on the costs of business has been prepared and placed in the Library of each House of Parliament. Copies may be obtained from the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.