

---

WELSH STATUTORY INSTRUMENTS

---

**2005 No. 1224 (W.82)**

**FOOD, WALES**

**The Food with Added Phytosterols or Phytostanols  
(Labelling) (Wales) Regulations 2005**

*Made* - - - - 26 April 2005

*Coming into force* - - 30 April 2005

The National Assembly for Wales, 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<sup>(1)</sup> and now vested in it<sup>(2)</sup>, 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<sup>(3)</sup> 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) (Wales) Regulations 2005; they come into force on 30 April 2005 and apply in relation to Wales only.

**Interpretation**

2.—(1) In these Regulations —

“the Act” (“*y Ddeddf*”) means the Food Safety Act 1990;

“biscuits” (“*bisgedi*”) includes wafers, rusks, oatcakes and matzos;

“confectionery product” (“*cynnyrch cyffraith*”) means any item of chocolate confectionery or sugar confectionery;

“Directive 2000/13” (“*Cyfarwyddeb 2003/13*”) means Directive 2000/13/EC of the European Parliament and of the Council<sup>(4)</sup> on the approximation of the laws of the Member States

---

(1) 1990 c. 16.

(2) Functions of the Secretary of State 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 Food Standards Act 1999 (1999 c. 28).

(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).

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

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<sup>(5)</sup>.

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

“fancy confectionery product” (“*cynnyrch cyffraith ffansi*”) means any confectionery product in the form of a figure, animal, cigarette or egg or in any other fancy form;

“flour confectionery” (“*cyffraith blawd*”) 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” (“*y manylion allweddol*”) means those particulars specified in items 1 and 5 in the second sub-paragraph of Article 2 of Regulation 608/2004;

“prepacked for direct sale” (“*wedi'i ragbacio i'w werthu'n uniongyrchol*”) means —

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

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

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

“sell” (“*gwerthu*”) includes offer or expose for sale and have in possession for sale, and “sale” is to be construed accordingly;

“the specified particulars” (“*y manylion penodedig*”) means the particulars required by Article 2 of Regulation 608/2004.

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

---

(5) OJ No. L308, 25.11.2003, p.15.

(6) OJ No. L97, 1.4.2004, p.44.

but food is not to 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 or she is guilty of an offence and 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 are to 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 are to 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 or she 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 are to 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 or she 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 marking or labelling**

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

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

(3) Paragraph (1) is not to be taken to preclude the giving of such particulars by 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 is to enforce and execute these Regulations in its area.

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

### **Defence in relation to exports**

9. In any proceedings for an offence under these Regulations, it is 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 apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof is to 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 are construed as including references to Regulation 608/2004.

(3) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act are 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” is 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 on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(8).

26 April 2005

*D. Elis-Thomas*  
The Presiding Officer of the National Assembly

---

(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  
(8) 1998 c. 38.

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

---

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations, which apply to Wales 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”.

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.

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).

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).

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).

A regulatory appraisal pursuant to section 65 of the Government of Wales Act 1998 has been prepared for these regulations and placed in the library of the National Assembly for Wales (together with a Transposition Note). Copies may be obtained from the Food Standards Agency, 11th Floor, Southgate House, Wood Street, Cardiff CF10 1EW.