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WELSH STATUTORY INSTRUMENTS

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**2007 No. 1040 (W.100)**

**FOOD, WALES**

**The Notification of Marketing of Food for Particular  
Nutritional Uses (Wales) Regulations 2007**

*Made* - - - - 27 March 2007

*Coming into force* - - 1 April 2007

The National Assembly for Wales makes the following Regulations in exercise of the powers conferred by sections 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990<sup>(1)</sup>, and now vested in it<sup>(2)</sup>.

In accordance with section 48(4A) of that Act, it has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council 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<sup>(3)</sup>, there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

**Title, commencement and application**

1. These Regulations—
  - (a) are called the Notification of Marketing of Food for Particular Nutritional Uses (Wales) Regulations 2007;
  - (b) come into force on 1 April 2007; and
  - (c) apply in relation to Wales.

**Interpretation**

- 2.—(1) In these Regulations—

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

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(1) 1990 c. 16.  
(2) Functions of the Secretary of State under the Food Safety Act 1990, 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).  
(3) OJ No. L31, 1.2.2002, p.1 as last amended as at the making of this instrument by Commission Regulation (EC) No.575/2006 (OJ No. L100, 8.4.2006, p.3).

“the Directive” (“*y Gyfarwydddeb*”) means Council Directive [89/398/EEC](#) on the approximation of the laws of the member States relating to foodstuffs intended for particular nutritional uses<sup>(4)</sup>;

“food authority” (“*awdurdod bwyd*”) has the same meaning as in section 5(1A) and (3)(a) and (b) of the Act;

“PNU food” (“*bwyd DMN*”) means a food for a particular nutritional use which—

- (a) owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption, and
- (b) is sold in such a way as to indicate its suitability for its claimed particular nutritional purpose,

but does not fall within any of the following classifications—

- (i) infant formulae and follow-on formulae,
- (ii) processed cereal-based foods and baby foods for infants and young children,
- (iii) food intended for use in energy-restricted diets for weight reduction,
- (iv) dietary foods for special medical purposes,
- (v) foods intended to meet the expenditure of intense muscular effort, especially for sportsmen, and
- (vi) foods for persons suffering from carbohydrate-metabolism disorders (diabetes);

“particular nutritional use” (“*defnydd maethol neilltuol*”) means the fulfilment of the particular nutritional requirements of—

- (a) certain categories of persons whose digestive processes are, or whose metabolism is, disturbed, or
- (b) certain categories of persons whose physiological condition renders them able to obtain a special benefit from the controlled consumption of any substance in food, or
- (c) infants or young children in good health; and

“sell” (“*gwerthu*”) includes possess for sale and offer, expose or advertise (otherwise than by means of a label or wrapper) for sale.

(2) Other expressions used in these Regulations and in the Directive have the same meaning in these Regulations as they have in the Directive.

### **Restriction on sale**

3.—(1) No person who, in respect of a PNU food product of a particular type—

- (a) is a manufacturer or an importer referred to in Article 9 of the Directive, but
- (b) has failed to comply with—
  - (i) a requirement to notify the competent authority, as referred to in paragraph 1 or 2 of that Article, or
  - (ii) a requirement to produce anything to the competent authority, as referred to in paragraph 3 of that Article,

may sell a PNU food product of that type.

(2) For the purposes of paragraph (1) the competent authority is—

(4) OJ No. L186, 30.6.89, p.27 as last amended as at the making of this instrument by Regulation (EC) No. 1882/2003 (OJ No. L284, 31.10.2003, p.1). Annex 1 to Council Directive [89/398/EEC](#) was replaced by Directive [1999/41/EC](#) (OJ No. L172, 8.7.99, p.38).

- (a) in respect of PNU food manufactured in Wales, or imported into Wales from outside the United Kingdom, the Food Standards Agency;
- (b) in respect of PNU food manufactured in (or imported from outside the United Kingdom into) another territory within the United Kingdom, the authority duly designated in that territory as the competent authority for the purposes of Article 9 of the Directive in respect of the food.

### **Declaration**

4.—(1) Where the Agency has detailed grounds for establishing that a foodstuff intended for a particular nutritional use which does not belong to one of the groups listed in Annex I to the Directive does not comply with Article 1(2) of the Directive or endangers human health, it may by written declaration suspend or restrict trade in that product.

(2) Such a declaration must be published in such manner as the Agency thinks fit and must specify the product concerned.

(3) A declaration which imposes conditions on trade in any product must specify those conditions.

(4) Where a declaration is in force suspending trade in any product, no person may trade in that product.

(5) Where a declaration is in force imposing conditions on trade in any product, no person may trade in that product unless the product complies with conditions specified in the declaration.

(6) A declaration may be modified, suspended or revoked by a further written declaration published, so far as is practicable, in the same manner and to the same extent as the original declaration.

### **Enforcement**

5. Each food authority is to enforce and execute these Regulations in its area.

### **Offences and penalties**

6. If any person without reasonable excuse contravenes regulation 3(1) or regulation 4(4) or (5), that person is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

### **Application of various provisions of the Food Safety Act 1990**

7. The following provisions of the Act apply for the purposes of these Regulations and any reference in those provisions to the Act or Part thereof are construed for the purposes of these Regulations as a reference to these Regulations:

- (a) section 2 (extended meaning of “sale” etc.);
- (b) section 3 (presumptions 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 of the Act;
- (e) section 22 (defence of publication in the course of business);
- (f) section 30(8) (which relates to documentary evidence);
- (g) section 33(1) (obstruction etc. of officers);

- (h) 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 paragraph (g);
- (i) section 35(1) (punishment of offences) in so far as it relates to offences under section 33(1) as applied by paragraph (g);
- (j) section 35(2) and (3) in so far as it relates to offences under section 33(2) as applied by paragraph (h);
- (k) section 36 (offences by bodies corporate);
- (l) section 36A (offences by Scottish partnerships); and
- (m) section 44 (protection of officers acting in good faith).

### **Revocation**

**8.** In so far as they apply in relation to Wales, the Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations 2002<sup>(5)</sup> are revoked.

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998<sup>(6)</sup>

27 March 2007

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

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<sup>(5)</sup> S.I. 2002/333.  
<sup>(6)</sup> 1998 c. 38.

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## EXPLANATORY NOTE

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

1. These Regulations, which apply in relation to Wales, implement Articles 9 and 11 of Council Directive [89/398/EEC](#) on the approximation of the laws of the member States relating to foodstuffs intended for particular nutritional uses, (OJ No. L186, 30.6.1989, p.27), as last amended by Regulation [\(EC\) No. 1882/2003](#) (OJ No. L284, 31.10.2003, p.1).

2. The Regulations concern foods which, owing to their special composition or manufacturing process, are clearly distinguishable from foods for normal consumption, and which are marketed as suitable for categories of consumers with disturbed digestive processes or metabolism or in a special physiological condition, or for infants or young children in good health, but which are neither covered nor to be covered by other Directives on specific types of foodstuffs for particular nutritional uses (the definition of “PNU food” in regulation 2(1) refers).

3. These Regulations—

- (a) prohibit the sale of such products unless the requirements of Article 9 of the Directive (notification to competent authorities of such products) have been complied with (regulation 3); and
- (b) enable the Agency by written declaration to suspend or restrict trade in products intended for a particular nutritional use where it has detailed grounds for establishing that the product does not comply with Article 1(2) of the Directive (requirements for foodstuffs for particular nutritional uses) or endangers human health (regulation 4).

4. Enforcement responsibilities, offences and penalties and application of provisions of the Food Safety Act 1990 are set out in regulations 5, 6 and 7 of these Regulations.

5. These Regulations also revoke the Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations 2002 (S.I.[2002/333](#)) in so far as they apply to Wales (regulation 8).

6. Labelling provisions of the Directive are implemented in the Food Labelling Regulations 1996 (S.I. [1996/1499](#)).

7. A full regulatory appraisal has been prepared for these Regulations and has been placed in the Library of the National Assembly for Wales along with a copy of the transposition note setting out how the main elements of Articles 9 and 11 of the Directive are transposed. Copies are also available from the Food Standards Agency, 11th Floor, Southgate House, Cardiff CF10 1EW.