

# Statutory Instrument 2000 No. 1866 (W.125)

## The Medical Food (Wales) Regulations 2000

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### STATUTORY INSTRUMENTS

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## 2000 No. 1866 (W.125)

### FOOD, WALES

## The Medical Food (Wales) Regulations 2000

*Made*

*14th July 2000*

*Coming into force*

*1st November 2001*

In exercise of powers conferred on Ministers of the Crown by sections 6(4), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990<sup>[1]</sup> and now vested in the National Assembly for Wales<sup>[2]</sup>, the National Assembly for Wales, after having regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency, after consultation in accordance with section 48(4) of that Act with such organisations as appear to them to be representative of interests likely to be substantially affected by the Regulations, makes the following Regulations:

### **Citation, commencement and application**

1. These Regulations may be cited as the Medical Food (Wales) Regulations 2000, shall come into force on 1st November 2001 and shall apply to Wales.

### **Interpretation**

2. In these Regulations -

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

"the Directive" ("*y Gyfarwydddeb*") means Commission Directive 1999/21/EC on dietary foods for special medical purposes<sup>[3]</sup>; "medical food" ("*bwyd meddygol*") means food coming within the classification of dietary foods for special medical purposes for which compositional and labelling requirements are laid down in the Directive; and

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

### **Restrictions on sale**

3. - (1) No person shall sell a medical food unless -

(a) its formulation and composition, and the instructions for use, are such as to ensure compliance with Article 3 of the Directive as read with the Annex thereto;

(b) the name under which it is sold complies with Article 4(1) of the Directive; and

(c) it is labelled in accordance with Article 4(2) to (5) of the Directive.

(2) No person who, in respect of medical food of a particular type -

(a) is a designated notifier, that is to say a manufacturer or an importer covered by Article 5 of the Directive, but

(b) has failed to comply with the requirement to notify the competent authority referred to in that Article,

shall sell a medical food of that type.

(3) For the purposes of paragraph (2) above the competent authority is -

(a) in respect of medical food manufactured in Wales, or imported into Wales from outside the United Kingdom, the Food Standards Agency;

(b) in respect of medical food manufactured in (or imported from outside the United Kingdom into) other territory within the United Kingdom, the authority duly designated in that territory as the competent authority for the purposes of Article 5 of the Directive in respect of the food.

### **Enforcement**

4. Each food authority shall enforce and execute these Regulations in its area.

### **Offences and penalties**

5. If any person -

(a) contravenes regulation 3(1) above, or

(b) without reasonable excuse contravenes regulation 3(2) above,

he or she shall be guilty of an offence and liable on summary conviction to a fine not

exceeding level 5 on the standard scale.

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

6. In any proceedings for an offence under regulation 3(1) above 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 was intended for export to a country (other than a Member State) which has legislation analogous to these Regulations and that the food complies with that legislation.

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

7. The following provisions of the Act shall apply for the purposes of these Regulations and, unless the context otherwise requires, any reference in those provisions to the Act or Part thereof shall be 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 8, 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 (obstruction etc. of officers);
- (h) section 35(1) to (3) (punishment of offences) in so far as it relates to offences under section 33(1) and (2) as applied by paragraph (g) above;
- (i) section 36 (offences by bodies corporate); and
- (j) 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<sup>[4]</sup>

*Jane Davidson*

The Deputy Presiding Officer, National Assembly for Wales

14th July 2000

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### **EXPLANATORY NOTE**

*(This note does not form part of the Regulations)*

These Regulations, which come into force on 1st November 2001, implement in Wales

Commission Directive 1999/21/EC on dietary foods for special medical purposes.

Article 1(2) of the Directive classifies such foods as foods specially processed or formulated for the dietary management, under medical supervision, of patients who require a special diet, and regulation 2 of these Regulations defines medical food as food within that classification.

Article 2 of the Directive calls for Member States to ensure that such food may only be marketed if it complies with the Directive. Articles 3 and 4 of the Directive lay down requirements for formulation, composition and instructions for use of such food, and for its naming and labelling. Regulation 3(1) of these Regulations prohibits the sale of medical food unless those requirements are met.

Article 5 of the Directive requires notification to competent authorities of the placing on the market of products covered by the Directive whether manufactured within, or imported from outside the European Community. Regulation 3(2) and (3) prohibits sale of medical foods by manufacturers and importers covered by this notification requirement unless they have complied with it. In the case of medical foods manufactured in Wales, or imported into Wales from outside the United Kingdom, the Food Standards Agency is the relevant authority.

Regulations 4, 5 and 7 set out enforcement responsibilities, offences and penalties, and application of provisions of the Food Safety Act 1990.

The Regulations also provide a defence in relation to exports, in accordance with Articles 2 and 3 of Council Directive 89/397/EC (OJ No.L186, 30.6.89, p.23) on the official control of foodstuffs (regulation 6).

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*Notes:*

[1] 1990 c.16; Section 6(4) of the Act was amended by paragraph 6 of Schedule 9 to the Deregulation and Contracting Out Act 1994 (c.40) and by paragraph 10(3) of Schedule 5 to the Food Standards Act 1999 (c.28). Section 48 was amended by paragraph 21 of Schedule 5 to the Food Standards Act 1999. Functions vested in Ministers of the Crown were transferred, in relation to Wales, to the National Assembly for Wales by S.I. 1999/672 [.back](#)

[2] See the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672).[back](#)

[3] OJ No. L91, 7.4.1999, p.29.[back](#)

[4] 1998 p.38.[back](#)

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