
WELSH STATUTORY INSTRUMENTS

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⁽¹⁾ and now vested in the National Assembly for Wales⁽²⁾, 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.

Commencement Information

II [Reg. 1](#) in force at 1.11.2001, see [reg. 1](#)

Interpretation

2. In these Regulations —

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

[^{F1}“the Directive” (“*y Gyfarwyddeb*”) means Commission Directive [1999/21/EC](#) on dietary foods for special medical purposes as amended by—

the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of

(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](#).

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

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Changes to legislation: There are currently no known outstanding effects for the The Medical Food (Wales) Regulations 2000. (See end of Document for details)

Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded; Commission Directive 2006/82/EC adapting Directive 91/321 on infant formulae and follow-on formulae and Directive 1999/21/EC on dietary foods for special medical purposes, by reason of the accession of Bulgaria and Romania; and

Commission Directive 2006/141 on infant formulae and follow-on formulae and amending Directive 1991/21/EC.]

“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;

“sell” (“gwerthu”) includes possess for sale and offer, expose or advertise (otherwise than by means of a label or wrapper) for sale [^{F2}, and “sold” (“cael ei werthu”) is to be construed accordingly].

Textual Amendments

- F1** Words in [reg. 2](#) substituted (11.1.2008) by [The Infant Formula and Follow-on Formula \(Wales\) Regulations 2007 \(S.I. 2007/3573\)](#), regs. 1(2)(b), **30(2)**
- F2** Words in [reg. 2](#) inserted (2.8.2016) by [The Food for Specific Groups \(Information and Compositional Requirements\) \(Wales\) Regulations 2016 \(S.I. 2016/639\)](#), reg. 1(3), **Sch. 3 para. 2(a)**

Commencement Information

- I2** [Reg. 2](#) in force at 1.11.2001, see [reg. 1](#)

Restrictions on sale

- 3.—(1) No person shall sell a medical food unless —
- 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;
 - the name under which it is sold complies with Article 4(1) of the Directive; and
 - 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 —
- is a designated notifier, that is to say a manufacturer or an importer covered by Article 5 of the Directive, but
 - 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 —
- in respect of medical food manufactured in Wales, or imported into Wales from outside the United Kingdom, [^{F3}the Welsh Ministers];
 - 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.

Textual Amendments

- F3** Words in [reg. 3\(3\)\(a\)](#) substituted (23.5.2014) by [The Transfer of Functions \(Food\) \(Wales\) Regulations 2014 \(S.I. 2014/1102\)](#), [regs. 1\(2\), 2](#)

Commencement Information

- I3** [Reg. 3](#) in force at 1.11.2001, see [reg. 1](#)

Enforcement

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

Commencement Information

- I4** [Reg. 4](#) in force at 1.11.2001, see [reg. 1](#)

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.

Commencement Information

- I5** [Reg. 5](#) in force at 1.11.2001, see [reg. 1](#)

[^{F4}Application of the improvement notice provisions of the Act

5A.—(1) Section 10(1) and (2) of the Act (improvement notices) applies, with the modification (in the case of section 10(1)) specified in Part 1 of the Schedule, for the purposes of—

- (a) enabling an improvement notice to be served on a person requiring the person to secure compliance with regulation 3(1); and
- (b) making the failure to comply with a notice referred to in subparagraph (a) an offence.

(2) Section 32(1) to (8) of the Act (powers of entry) applies, with the modification (in the case of section 32(1)) specified in Part 2 of the Schedule, for the purposes of enabling an authorised officer of an enforcement authority—

- (a) to exercise a power of entry to ascertain whether food that does not comply with the requirements of regulation 3(1) is, or has been, sold; and
- (b) to exercise a power of entry to ascertain whether there is any evidence of any contravention of regulation 3(1).

(3) Section 35 of the Act (punishment of offences) applies, with the modification specified in Part 3 of the Schedule, for the purpose of specifying the punishment of an offence committed under paragraph (1)(b).

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(4) Section 37(1), (3), (5) and (6) of the Act (appeals) applies, with the modification (in the case of section 37(1), (5) and (6)) specified in Part 4 of the Schedule, for the purpose of enabling a decision to serve a notice referred to in paragraph (1)(a) to be appealed.

(5) Section 39 of the Act (appeals against improvement notices) applies, with the modification (in the case of section 39(3)) specified in Part 5 of the Schedule, for the purpose of dealing with appeals against a decision to serve a notice referred to in paragraph (1)(a).]

Textual Amendments

F4 [Reg. 5A](#) inserted (2.8.2016) by [The Food for Specific Groups \(Information and Compositional Requirements\) \(Wales\) Regulations 2016 \(S.I. 2016/639\)](#), reg. 1(3), [Sch. 3 para. 2\(b\)](#)

Defence in relation to exports

^{F5}6.

Textual Amendments

F5 [Reg. 6](#) revoked (1.1.2006) by [The Official Feed and Food Controls \(Wales\) Regulations 2005 \(S.I. 2005/3254\)](#), reg. 1, [Sch. 6 Pt. 2](#)

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).

Commencement Information

I6 [Reg. 7](#) in force at 1.11.2001, see [reg. 1](#)

[^{F6}Transitional arrangements

8. In respect of any contravention before 1 January 2010, no person commits an offence under regulation 5(a) consisting of a contravention of regulation 3(1)(a) where the action that would

otherwise constitute the offence consists of selling a medical food whose composition fails to comply with Article 3 of the Directive as read with the row relating to manganese set out in the second part of Table 1 (minerals) in the Annex to the Directive as it stood before it was amended by Commission Directive [2006/141/EC](#) on infant formulae and follow-on formulae and amending Directive 1999/21/EC.]

Textual Amendments

- F6** [Reg. 8](#) inserted (29.10.2008) by [The Infant Formula and Follow-on Formula \(Amendment\) \(Wales\) Regulations 2008 \(S.I. 2008/2602\)](#), regs. 1(b), **3(2)**

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998**(3)**

Jane Davidson
The Deputy Presiding Officer, National
Assembly for Wales

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[F7] SCHEDULE

Regulation 5A

Modification of the improvement notice provisions of the Act

Textual Amendments

- F7** Sch. inserted (2.8.2016) by [The Food for Specific Groups \(Information and Compositional Requirements\) \(Wales\) Regulations 2016 \(S.I. 2016/639\)](#), reg. 1(3), **Sch. 3 para. 2(c)**

PART 1

Modification of section 10(1)

1. For section 10(1) (improvement notices) substitute—

“(1) If an authorised officer of an enforcement authority has reasonable grounds for suspecting that a person is failing to comply with regulation 3(1) of the Medical Food (Wales) Regulations 2000, the authorised officer may, by a notice served on that person (in this Act referred to as an “improvement notice”)—

- (a) state the officer’s grounds for suspecting that the person is failing to comply or, as the case may be, that the food does not comply with the relevant provision;
- (b) specify the matters which constitute the failure to so comply;
- (c) specify the measures which, in the officer’s opinion, the person must take in order to secure compliance; and
- (d) require the person to take those measures, or such measures that are at least equivalent to them, within such period as may be specified in the notice.”

PART 2

Modification of section 32(1)

2. For paragraphs (a) to (c) of section 32(1) (powers of entry) substitute—

- “(a) to enter any premises within the authority’s area for the purpose of ascertaining whether there has been any contravention of regulation 3(1) of the Medical Food (Wales) Regulations 2000; and
- (b) to enter any business premises, whether within or outside the authority’s area, for the purpose of ascertaining whether there is on the premises any evidence of any contravention of that regulation;”.

PART 3

Modification of section 35

3. In section 35 (punishment of offences), after subsection (1), insert—

“(1A) A person guilty of an offence under section 10(2), as applied by regulation 5A(1) of the Medical Food (Wales) Regulations 2000, is liable, on summary conviction, to a fine.”

PART 4

Modification of section 37(1), (5) and (6)

4. For section 37(1) (appeals) substitute—

“(1) Any person who is aggrieved by a decision of an authorised officer of an enforcement authority to serve an improvement notice under section 10(1) as applied and modified by regulation 5A(1) of, and Part 1 of the Schedule to, the Medical Food (Wales) Regulations 2000, may apply to the magistrates’ court.”

5. For section 37(5) substitute—

“(5) The period within which such an appeal as is mentioned in subsection (1) above may be brought shall be—

- (a) one month from the date on which notice of the decision was served on the person desiring to appeal; or
- (b) the period specified in the improvement notice,

whichever ends the earlier; and in the case of such an appeal, the making of the complaint shall be deemed for the purposes of this subsection to be the bringing of the appeal.”

6. In section 37(6)—

- (a) for “(3) or (4)” substitute “(1)”; and
- (b) in paragraph (a), omit “or to the sheriff”.

PART 5

Modification of section 39(3)

7. In section 39(3) (appeals against improvement notices), omit “for want of prosecution”.]

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

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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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