STATUTORY INSTRUMENTS

2000 No. 845

FOOD, ENGLAND

The Medical Food (England) Regulations 2000

Made - - - -	*21st March 2000*
Laid before Parliament	*31st March 2000*
Coming into force - -	*1st November 2001*

The Minister of Agriculture, Fisheries and Food and the Secretary of State, acting jointly in exercise of the powers conferred on them by sections 6(4), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(**1**) and of all other powers enabling them in that behalf, 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, hereby make the following Regulations:

Title, commencement and extent

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

Commencement Information
I1 Reg. 1 in force at 1.11.2001, see **reg. 1**

Interpretation

2. In these Regulations–

"the Act" means the Food Safety Act 1990;

[[F1]"the Directive" 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 Hungary, the Republic of Malta, the Republic of Poland, the

(**1**) 1990 c. 16; the "Ministers" is defined, in relation to England and Wales, in section 4(1)(a) of the Act. Section 6(4) of the Act was amended by paragraph 6 of Schedule 9 to the Deregulation and Contracting Out Act 1994 (c. 40). Functions were transferred, in relation to Wales, to the National Assembly for Wales by S.I.1999/672, and by virtue of S.I. 1999/3141 functions exercisable in England were transferred to the Minister of Agriculture, Fisheries and Food and the Secretary of State acting jointly.

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.**]**

"food authority" does not include–

(a) the council of a district of a non-metropolitan county except where the county functions have been transferred to that council pursuant to a structural change, or

(b) the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner and the Middle Temple);

[[F2]"medical food" 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 which has been developed to satisfy the nutritional requirements of infants; and**]**

"sell" includes possess for sale and offer, expose or advertise (otherwise than by means of a label or wrapper) for sale **[**[F3], and "sold" is to be construed accordingly**]**.

Textual Amendments

F1 Words in reg. 2 substituted (11.1.2008) by The Infant Formula and Follow-on Formula (England) Regulations 2007 (revoked) 2007 (S.I. 2007/3521), regs. 1(b)(ii), **30(2)**

F2 Words in reg. 2 substituted (22.2.2019) by The Food for Specific Groups (Information and Compositional Requirements) (Amendment) (England) Regulations 2019 (S.I. 2019/44), regs. 1, **5**

F3 Words in reg. 2 inserted (20.7.2016) by The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (S.I. 2016/688), 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–

(a) its formulation and composition comply with Article 3 of the Directive as read with the Annex thereto and its instructions for use are such that its use in accordance with those instructions would so comply;

(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 England, or imported into England from outside the United Kingdom, **[**F4the Secretary of State**]**;

(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.

Textual Amendments

F4 Words in reg. 3(3)(a) substituted (16.1.2012) by The Transfer of Functions (Food) Regulations 2011 (S.I. 2011/3012), regs. 1(1), **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 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**

[F5**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 modifications (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 applies, with the modifications specified in Part 3 of the Schedule, for the purpose of specifying the punishment of an offence committed under paragraph (1)(b).

(4) Section 37(1) and (6) of the Act (appeals) applies, with the modifications 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 modifications (in the case of section 39(1) and (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

F5 Reg. 5A inserted (20.7.2016) by The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (S.I. 2016/688), reg. 1(3), **Sch. 3 para. 2(b)**

Defence in relation to exports

[F6 6. . . . . . .

Textual Amendments

F6 Reg. 6 revoked (1.1.2006) by The Official Feed and Food Controls (England) Regulations 2005 (S.I. 2005/2626), reg. 1(b), **Sch. 6 Pt. 2**

Commencement Information

I6 Reg. 6 in force at 1.11.2001, see **reg. 1**

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

I7 Reg. 7 in force at 1.11.2001, see **reg. 1**

[F7Transitional arrangements

8. In respect of any contravention before 1st 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 I (minerals) in the Annex to the Directive if the composition of that medical food would have complied with Article 3 of the Directive as read with the row relating to manganese set out in the second part of Table I (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

F7 Reg. 8 inserted (29.10.2008) by The Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2008 (S.I. 2008/2445), regs. 1(b), **3(2)**

Hayman
Minister of State, Ministry of Agriculture,
Fisheries and Food

11th March 2000

Signed by authority of the Secretary of State for Health

Yvette Cooper
Parliamentary Under-Secretary of State for
Public Health,
Department of Health

21st March 2000

[F8SCHEDULE

Modification of the improvement notice provisions of the Act

Textual Amendments

F8 Sch. inserted (20.7.2016) by The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (S.I. 2016/688), reg. 1(3), **Sch. 3 para. 2(c)** (as amended (1.3.2017) by The Food for Specific Groups (Information and Compositional Requirements) (England) (Amendment) Regulations 2017 (S.I. 2017/62), regs. 1(3), **4**)

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 believing that a person is failing to comply with regulation 3(1) of the Medical Food (England) 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 believing 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 (England) 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;".

3. Section 32(9) does not apply.

PART 3

Modification of section 35 (punishment of offences)

4. In section 35, after subsection (1A), insert—

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

PART 4

Modification of section 37(1) and (6)

5. 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 (England) Regulations 2000, may apply to the First-tier Tribunal".

6. Section 37(2) does not apply.

7. For section 37(3) substitute—

"(3) The appeals procedure under the Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009 applies to appeals made under subsection (1)".

8. For section 37(5) substitute—

"(5) The notice of appeal period under rule 22 of the Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009 applies to appeals made under subsection (1)".

9. In section 37(6)—

(a) for "(3) or (4)" substitute "(1)", and

(b) in paragraph (a), for "magistrates' court or to the sheriff" substitute "the First-tier Tribunal".

PART 5

Modification of section 39(1) and (3)

10. For section 39(1) (appeals against improvement notices) substitute—

"(1) On an appeal against an improvement notice served under section 10(1), as applied and modified by regulation 5A(1) of, and Part 1 of the Schedule to, the Medical Food (England) Regulations 2000, the First-tier Tribunal may either cancel of affirm the notice and, if it affirms it, may do so either in its original form or with such modifications as the First-tier Tribunal may in the circumstances think fit.".

11. In section 39(3), omit "for want of prosecution".**]**

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which come into force on 1st November 2001, implement in England 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, and 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 placing on the market of products covered by the Directive when manufactured in, or imported from outside, the European Community, and regulation 3(2) and (3) of these Regulations prohibits sale of medical foods by manufacturers and importers covered by a notification requirement unless they have complied with it. In the case of medical foods manufactured in England, or imported into England from outside the United Kingdom, the Food Standards Agency is the relevant authority.

Enforcement responsibilities, offences and penalties, and application of provisions of the Food Safety Act 1990 are set out in regulations 4, 5 and 7 of these Regulations. The Regulations also provide a defence in relation to exports, in accordance with Articles 2 and 3 of Council Directive 89/397/EEC (OJNo. L186, 30.6.89, p. 23) on the official control of foodstuffs (regulation 6).

A Regulatory Impact Assessment, which includes a compliance cost assessment of the effect that these Regulations would have on business costs, has been prepared and placed in the Library of each House of Parliament. Copies may be obtained from the library of the Ministry of Agriculture, Fisheries and Food, at Nobel House, 17 Smith Square, London SW1P 3JR.

Status:
Point in time view as at 22/02/2019.

Changes to legislation:
There are currently no known outstanding effects for the The Medical Food (England) Regulations 2000.