Statutory Instrument 2000 No. 845

The Medical Food (England) Regulations 2000

The text of this Internet version of the Statutory Instrument has been prepared to reflect the text as it was Made. The authoritative version is the Queen's Printer copy published by The Stationery Office Limited as the **The Medical Food (England) Regulations 2000**, ISBN 0 11 099013 7, £1.50 sterling. For details of how to obtain an official copy see How to obtain The Stationery Office Limited titles.

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.

Interpretation
2. In these Regulations-

"the Act" means the Food Safety Act 1990;

"the Directive" means Commission Directive 1999/21/EC on dietary foods for special medical purposes[2];

"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);

"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

"sell" 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 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, 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 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).

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

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 (OJ No. 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.

Notes:

[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.back

[2] OJ No. L91, 7.4.1999, p. 29, as corrected by a corrigendum published on 5th January 2000 (OJ No. L2, 5.1.2000, p. 79).back

---

ISBN 0 11 099013 7