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SCOTTISH STATUTORY INSTRUMENTS

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**2000 No. 130**

**FOOD**

**Foods for Special Medical Purposes  
(Scotland) Regulations 2000**

*Made* - - - - 28th April 2000  
*Laid before the Scottish  
Parliament* - - - - 9th May 2000  
*Coming into force* - - 1st November 2001

The Scottish Ministers, in exercise of the powers conferred on them by sections 6(4), 16(1)(a), (e) and (f), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990<sup>(1)</sup> and of all other powers enabling them in that behalf, and 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:

**Citation, commencement and extent**

1.—(1) These Regulations may be cited as the Foods for Special Medical Purposes (Scotland) Regulations 2000 and shall come into force on 1st November 2001.

(2) These Regulations extend to Scotland only.

**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<sup>(2)</sup>;

“dietary food” means food coming within the classification of dietary foods for special medical purposes as defined in Article 1 of the Directive but does not include a food which is a medicinal product within the meaning of the Medicines Act 1968<sup>(3)</sup>;

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(1) 1990 c. 16; section 6(4) of the Act was amended by the Deregulation and Contracting Out Act 1992 (c. 40), Schedule 9, paragraph 6. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c. 46).  
(2) O.J. No. L91, 7.4.1999, p.29, as corrected by a corrigendum published on 5th January 2000 (O.J. No. L2, 5.1.2000, p.79)  
(3) 1968 c. 67.

“sell” includes possess, 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 dietary food in Scotland unless—
- (a) its formulation, composition and instructions for use comply 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) The manufacturer or importer of a dietary food—
- (a) shall provide the notification to the competent authority called for by Article 5 of the Directive in respect of that dietary food; and
  - (b) shall not sell that dietary food in Scotland unless notification has been provided in accordance with sub-paragraph (a) above.
- (3) For the purposes of paragraph (2) above the competent authority shall be—
- (a) in respect of a dietary food manufactured in Scotland or imported into Scotland from outside the United Kingdom, the Food Standards Agency;
  - (b) in respect of a dietary food manufactured in, or imported from outside the United Kingdom into, any other part of the United Kingdom, the authority designated as the competent authority for that part for the purposes of Article 5 of the Directive.

### **Enforcement**

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

### **Offences and penalties**

5. If any person contravenes regulation 3(1) and (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 these Regulations 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 sections of the Food Safety Act 1990**

7. The following provisions of the Act shall apply for the purposes of these Regulations and any reference in these 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 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).

St. Andrew's House,  
Edinburgh  
28th April 2000

*SUSAN C DEACON*  
A member of the Scottish Executive

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## EXPLANATORY NOTE

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

These Regulations, which come into force on 1st November 2001, implement Commission Directive [1999/21/EC](#) on dietary foods for special medical purposes (O.J. No. L91, 7.4.1999, p.29) and extend to Scotland only.

Article 1(2) of the Directive classifies such foods as foods specially processed or formulated for the dietary management of specified types of patients under medical supervision whose treatment calls for a special diet, and regulation 2 of these Regulations defines dietary 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, and regulation 3(1) of these Regulations prohibits the sale of dietary food unless those criteria 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, or imported from outside the European Community. Regulation 3(2) of these Regulations imposes that notification requirement, and regulation 3(3) specifies which authorities are to be recipients of the notification. For dietary foods manufactured in Scotland, or imported into Scotland 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 \(c. 16\)](#) 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](#) (O.J. No. L186, 30.6.89, p.23) on the Official Control of Foodstuffs (regulation 6).