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SCOTTISH STATUTORY INSTRUMENTS

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**2002 No. 50**

**FOOD**

**The Notification of Marketing of Food for Particular  
Nutritional Uses (Scotland) Regulations 2002**

<i>Made</i>	- - - -	<i>8th February 2002</i>
<i>Laid before the Scottish Parliament</i>	- - - -	<i>8th February 2002</i>
<i>Coming into force</i>	- -	<i>8th March 2002</i>

The Scottish Ministers, in exercise of the powers conferred 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 having regard in accordance with section 48(4A)(2) of that Act to relevant advice given by the Food Standards Agency and after consultation in accordance with section 48(4) and (4B)(3) of that Act, hereby make the following Regulations:

**Citation, commencement and extent**

1.—(1) These Regulations may be cited as the Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2002 and shall come into force on 8th March 2002.

(2) These Regulations extend to Scotland only.

**Interpretation**

2.—(1) In these Regulations—

“the Act” means the Food Safety Act 1990;

“the Directive” means Council Directive [89/398/EEC](#) on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses(4), as amended by Directive [1999/41/EC](#) of the European Parliament and of the Council amending Directive

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(1) 1990 c. 16; section 6(4) was amended by the Deregulation and Contracting Out Act 1994 (c. 40), Schedule 9, paragraph 6 and by the Food Standards Act 1999 (c. 28) (“the 1999 Act”), Schedule 5, paragraph 10(3); section 17(1) was amended by the 1999 Act, Schedule 5, paragraphs 8 and 12; section 26(3) was amended by Schedule 6 of the 1999 Act; section 48(1) was amended by the 1999 Act, Schedule 5, paragraph 8; amendments made by Schedule 5 of the 1999 Act shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c. 46) by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998.

(2) Section 48(4A) was inserted by the Food Standards Act 1999, Schedule 5, paragraph 21.

(3) Section 48(4B) was inserted by the Food Standards Act 1999, Schedule 5, paragraph 21.

(4) O.J. No. L 186, 30.6.89, p.27.

89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses<sup>(5)</sup>;

“PNU food” means a food for a particular nutritional use which—

- (a) owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal human consumption; and
- (b) is sold in such a way as to indicate its suitability, for its claimed particular nutritional purpose,

but does not fall within any of the following classifications—

- (i) infant formulae and follow-on formulae;
- (ii) processed cereal-based foods and baby foods for infants and young children;
- (iii) food intended for use in energy-restricted diets for weight reduction;
- (iv) dietary foods for special medical purposes;
- (v) foods intended to meet the expenditure of intense muscular effort, especially for sportsmen; or
- (vi) foods for persons suffering from carbohydrate-metabolism disorders (diabetes);

“particular nutritional use” means the fulfilment of the particular nutritional requirements of—

- (a) certain categories of persons whose digestive processes are, or whose metabolism is, disturbed;
- (b) certain categories of persons whose special physiological condition renders them able to obtain a special benefit from the controlled consumption of any substance in food; or
- (c) infants or young children in good health; and

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

(2) Other expressions used in these Regulations and in the Directive have the same meaning in these Regulations as they have in the Directive.

### **Restriction on sale**

3.—(1) No person who, in respect of PNU food of a particular type—

- (a) is a manufacturer or an importer referred to in Article 9 of the Directive; and
- (b) has failed to comply with—
  - (i) a requirement to notify the competent authority, as referred to in paragraph 1 or 2 of that Article; or
  - (ii) a requirement to produce anything to the competent authority, as referred to in paragraph 3 of that Article,

shall sell a PNU food of that type.

(2) For the purposes of paragraph (1) above the competent authority is—

- (a) in respect of PNU food manufactured in Scotland, or imported into Scotland from outside the United Kingdom, the Food Standards Agency;
- (b) in respect of PNU food manufactured in or imported from outside the United Kingdom into another territory within the United Kingdom, the authority duly designated in that territory as the competent authority for the purposes of Article 9 of the Directive in respect of the food.

(5) O.J. No. L 172, 8.7.99, p.38.

## **Enforcement**

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

## **Offences and penalties**

5. If any person without reasonable excuse contravenes regulation 3(1), that person shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

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

6. The following provisions of the Act shall apply for the purposes of these Regulations and 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);
- (j) section 36A (offences by Scottish partnerships); and
- (k) section 44 (protection of officers acting in good faith).

St Andrew’s House,  
Edinburgh  
8th February 2002

*MARY MULLIGAN*  
Authorised to sign by the Scottish Ministers

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## EXPLANATORY NOTE

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

These Regulations, which extend to Scotland only, implement Article 9 of Council Directive [89/398/EEC](#) on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, as amended by Directive [1999/41/EC](#) of the European Parliament and of the Council (“the Directive”).

The Regulations cover foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption and which are marketed as suitable for categories of consumers with disturbed digestive processes or metabolism or in a special physiological condition, or for infants or young children in good health, but which are neither covered, nor to be covered, by other Directives on specific types of foodstuffs for particular nutritional uses (definition of “PNU food” in regulation 2(1)).

Article 9 of the Directive requires notification (followed, where necessary, by provision of supplementary material) to competent authorities of placing on the market of such products; the requirement applies when the product is manufactured or imported, and regulation 3 of these Regulations prohibits sale of products of that type by manufacturers and importers covered by the requirement unless they have complied with the notification requirements. “Sell” is given an extended meaning (regulations 2(1) and 6(a)). In the case of products manufactured in Scotland, or imported into Scotland from outside the United Kingdom, the Food Standards Agency is the competent authority.

Enforcement responsibilities, offences and penalties and application of provisions of the Food Safety Act 1990 are set out in regulations 4, 5 and 6 of these Regulations.

Labelling provisions of the Directive are implemented in the Food Labelling Regulations 1996 (S.I.1996/1499).

A Regulatory Impact Assessment, which includes a compliance cost assessment of the effect which these Regulations would have on business costs, has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Standards Agency, 6th Floor, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ.