

**2007 No. 37**

**FOOD**

**The Notification of Marketing of Food for Particular Nutritional  
Uses (Scotland) Regulations 2007**

<i>Made</i>	- - - -	<i>1st February 2007</i>
<i>Laid before the Scottish Parliament</i>		<i>2nd February 2007</i>
<i>Coming into force</i>	- -	<i>1st March 2007</i>

The Scottish Ministers, in exercise of the powers conferred by sections 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(a) and of all other powers enabling them in that behalf, having had regard in accordance with section 48(4A)(b) of that Act to relevant advice given by the Food Standards Agency and after consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c), 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 2007 and come into force on 1st March 2007.

(2) These Regulations extend to Scotland only.

**Interpretation**

2.—(1) In these Regulations—

“the Act” means the Food Safety Act 1990;

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(a) 1990 c.16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990; section 17(1) was amended by the Food Standards Act 1999 (c.28) (“the 1999 Act”), section 40(1) and Schedule 5, paragraphs 8 and 12(a); section 26(3) was amended by the 1999 Act, section 40(4) and Schedule 6; section 48(1) was amended by the 1999 Act, section 40(1) and Schedule 5, paragraph 8; amendments made by Schedule 5 to the 1999 Act shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) (“the 1998 Act”) by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State, so far as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. In so far as not so transferred, those functions were transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc.) Order 2005 (S.I. 2005/849).

(b) Section 48(4A) was inserted by the 1999 Act, section 40(1) and Schedule 5, paragraph 21.

(c) O.J. No. L 31, 1.2.02, p.1, as amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council amending Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (O.J. No. L 245, 29.9.03, p.4) and Commission Regulation (EC) No. 575/2006 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the European Food Safety Authority (O.J. No. L 100, 8.4.06, p.3).

“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<sup>(a)</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 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 and sportswomen; 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 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 a PNU food product 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 product of that type.

(2) For the purposes of paragraph (1), 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

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(a) O.J. No. L 186, 30.6.89, p.27, as amended by Directive 96/84/EC of the European Parliament and of the Council amending Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (O.J. No. L 48, 19.2.97, p.20), Directive 1999/41/EC of the European Parliament and of the Council amending Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (O.J. No. L 172, 8.7.99, p.38) and Regulation (EC) No. 1882/2003 of the European Parliament and of the Council adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty (O.J. No. L 284, 31.10.03, p.1).

territory as the competent authority for the purposes of Article 9 of the Directive in respect of the food.

### **Declaration**

4.—(1) Where the Food Standards Agency has detailed grounds for establishing that a foodstuff intended for a particular nutritional use which does not belong to one of the groups listed in Annex I to the Directive does not comply with Article 1(2) of the Directive or endangers human health, it may by written declaration suspend or restrict trade in that product.

(2) Such a declaration shall be published in such manner as the Food Standards Agency thinks fit and shall specify the product concerned.

(3) A declaration which imposes conditions on trade in any product shall specify those conditions.

(4) Where a declaration is in force suspending trade in any product, no person shall trade in that product.

(5) Where a declaration is in force imposing conditions on trade in any product, no person shall trade in that product unless the product complies with conditions specified in the declaration.

(6) A declaration may be modified, suspended or revoked by a further written declaration published, so far as is practicable, in the same manner and to the same extent as the original declaration.

### **Enforcement**

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

### **Offences and penalties**

6. If any person without reasonable excuse contravenes regulation 3(1) or regulation 4(4) or (5), 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**

7. 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 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);
- (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).

**Revocation**

**8.** The Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2002(a) are revoked.

St Andrew's House,  
Edinburgh  
1st February 2007

*LEWIS MACDONALD*  
Authorised to sign by the Scottish Ministers

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(a) S.S.I. 2002/50.

## EXPLANATORY NOTE

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

These Regulations, which extend to Scotland only, implement Articles 9 and 11 of Council Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, (O.J. No. L 186, 30.6.89, p.27), as last amended by Regulation (EC) No. 1882/2003 (O.J. No. L 284, 31.10.03, p.1).

The Regulations concern foods which, owing to their special composition or manufacturing process, are clearly distinguishable from foods 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 (the definition of “PNU food” in regulation 2(1) refers).

These Regulations—

- (a) prohibit the sale of such products unless the requirements of Article 9 of the Directive (notification to competent authorities of such products) have been complied with (regulation 3); and
- (b) enable the Food Standards Agency by written declaration to suspend or restrict trade in products intended for a particular nutritional use where it has detailed grounds for establishing that the product does not comply with Article 1(2) of the Directive (requirements for foodstuffs for particular nutritional uses) or endangers human health (regulation 4).

Enforcement responsibilities, offences and penalties and application of provisions of the Food Safety Act 1990 are set out in regulations 5, 6 and 7 of these Regulations.

These Regulations also revoke the Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2002 (regulation 8).

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

A full regulatory impact assessment of the effect that this instrument will have on the costs to business has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Standards Agency (Scotland), 6th Floor, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ.





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