

---

STATUTORY INSTRUMENTS

---

**2002 No. 333**

**FOOD, ENGLAND AND WALES**

**The Notification of Marketing of Food for Particular  
Nutritional Uses (England and Wales) Regulations 2002**

<i>Made</i>	- - - -	<i>13th February 2002</i>
<i>Laid before Parliament</i>		<i>15th February 2002</i>
<i>Coming into force</i>	- -	<i>8th March 2002</i>

The Secretary of State, in exercise of the powers conferred on him by sections 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(1) and of all other powers enabling him in that behalf, having had regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency and after consultation in accordance with section 48(4) and (4B) of that Act, makes the following Regulations:

**Title, commencement and extent**

1. These Regulations may be cited as the Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations 2002; they come into force on 8th March 2002 and extend to England and Wales 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(2), as amended by Directive [1999/41/EC](#) of the European Parliament and of the Council(3);

“food authority” does not include—

---

(1) [1990 c. 16](#). Functions formerly exercisable by “the Ministers” are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act [1999 \(c. 28\)](#). Functions of “the Ministers” so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. [1999/672](#)) as read with section 40(3) of, and paragraph 8 of Schedule 5 to, the 1999 Act, but paragraph 5 of Schedule 3 to the Government of Wales Act [1998 \(c. 38\)](#) applies in the case of these Regulations. Functions of “the Ministers” so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act [1998 \(c. 46\)](#) as read with section 40(2) of the 1999 Act. Sections 17(1) and 48 of the 1990 Act were respectively amended by paragraphs 12 and 21 of Schedule 5 to the 1999 Act.

(2) OJNo. L186, 30.6.89, p.27.

(3) OJ No. L172, 8.7.99, p.38.

- (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 Temple and the Middle Temple);

“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
- (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, or
- (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, but
- (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) above the competent authority is—

- (a) in respect of PNU food manufactured in England or Wales, or imported into England or Wales 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.

#### **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) above, he 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, 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).

Signed by authority of the Secretary of State for Health

13th February 2002

*Yvette Cooper*  
Parliamentary Under-Secretary of State,  
Department of Health

---

## EXPLANATORY NOTE

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

1. These Regulations implement for England and Wales 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.

2. 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).

3. 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 it. “Sell” is given an extended meaning in the Regulations (regulations 2(1) and 6(a) refer). In the case of products manufactured in England or Wales, or imported into England or Wales from outside the United Kingdom, the Food Standards Agency is the competent authority.

4. 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.

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

6. A Regulatory Impact Assessment has been prepared and placed in the Library of each House of Parliament together with a Transposition Note setting out how the main elements of Article 9 of the Directive are transposed in these Regulations. Copies may be obtained from the Food Labelling and Standards Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.