

**2000 No. 768**

**FOOD, ENGLAND**

**The Genetically Modified and Novel Foods (Labelling)  
(England) Regulations 2000**

<i>Made - - - -</i>	<i>16th March 2000</i>
<i>Laid before Parliament</i>	<i>17th March 2000</i>
<i>Coming into force</i>	<i>10th April 2000</i>

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), 16(1)(e) and (f), 17, 18(1), 26(1) and (3) and 48(1) of the Food Safety Act 1990<sup>(a)</sup> and of all other powers enabling them in that behalf, hereby make the following Regulations, 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:

**Title, commencement and extent**

**1.** These Regulations may be cited as the Genetically Modified and Novel Foods (Labelling) (England) Regulations 2000, shall come into force on 10th April 2000 and shall apply to England.

**Interpretation**

**2.—(1)** In these Regulations—

“the Act” means the Food Safety Act 1990;

“biscuits” includes wafers, rusks, oatcakes and matzohs;

“confectionery product” means any item of chocolate confectionery or sugar confectionery;

“Directive 79/112” means Council Directive 79/112/EEC<sup>(b)</sup> on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, as amended (in so far as is relevant to these Regulations) by Council Directive 86/197/EEC<sup>(c)</sup> and Council Directive 89/395/EEC<sup>(d)</sup>;

“edible ice” includes ice-cream, water ice and fruit ice, whether alone or in combination, and any similar food;

“fancy confectionery product” means any confectionery product in the form of a figure, animal, cigarette or egg or in any other fancy form;

“flour confectionery” means any cooked food which is ready for consumption without further preparation (other than reheating), of which a characterising ingredient is ground cereal, including shortbread, sponges, crumpets, muffins, macaroons, ratafias, pastry and

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<sup>(a)</sup> 1990 c. 16; “the Ministers” is defined in relation to England and Wales in section 4(1) of the Act. Section 6(4)(a) of the Act was amended by the Deregulation and Contracting Out Act 1994 (c. 40), Schedule 9, paragraph 6. 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.

<sup>(b)</sup> OJ No. L33, 8.2.79, p.1.

<sup>(c)</sup> OJ No. L144, 29.5.86, p.38.

<sup>(d)</sup> OJ No. L186, 30.6.89, p.17.

pastry cases, and also includes meringues, petits fours and uncooked pastry and pastry cases, but does not include bread, pizzas, biscuits, crispbread, extruded flat bread or any food containing a filling which has as an ingredient any cheese, meat, offal, fish, shellfish, vegetable protein material or microbial protein material;

“the GMO particulars” means the additional specific labelling particulars required by Article 2(3) of Regulation 1139/98 and Articles 2 and 4 of Regulation 50/2000;

“novel food”, “novel food ingredient” and “place on the market” have the same meaning in these Regulations as they have in Regulation 258/97;

“prepacked for direct sale” means—

- (a) in relation to a food other than flour confectionery, bread and edible ices, prepacked by a retailer for sale by him on the premises where the food is packed or from a vehicle or stall used by him, and
- (b) in relation to flour confectionery, bread and edible ices, prepacked by a retailer for sale as in paragraph (a) of this definition, or prepacked by the producer of the food for sale by him either on the premises where the food is produced or on other premises from which he conducts business under the same name as the business conducted on the premises where the food is produced,

and in this definition “premises” includes any ship or aircraft;

“preparation”, in relation to food, includes manufacture and any form of processing or treatment, and “prepared” shall be construed accordingly;

“Regulation 258/97” means Regulation (EC) No. 258/97 of the European Parliament and of the Council(a) concerning novel foods and novel food ingredients;

“Regulation 1139/98” means Council Regulation (EC) No. 1139/98(b) (as corrected(c)) concerning the compulsory indication, on the labelling of certain foodstuffs produced from genetically modified organisms, of particulars other than those provided for in Directive 79/112/EEC, as amended by Commission Regulation (EC) No. 49/2000(d);

“Regulation 50/2000” means Commission Regulation (EC) No. 50/2000(e) (as corrected(f)) on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms;

“sell” includes offer or expose for sale and have in possession for sale, and “sale” shall be construed accordingly.

(2) Other expressions used both in these Regulations and in Regulation 1139/98 or Regulation 50/2000 have the same meaning in these Regulations as they have in the Regulation concerned.

(3) Food shall be regarded as prepacked for the purposes of these Regulations if—

- (a) it is ready for sale to the final consumer or to a mass caterer, and
- (b) it is—
  - (i) put into packaging before being offered for sale in such a way that the food, whether wholly or only partly enclosed, cannot be altered without opening or changing the packaging, or
  - (ii) wholly enclosed in packaging before being offered for sale and the food is intended to be cooked without opening the packaging,

but food shall not be regarded as prepacked for the purposes of these Regulations if it comprises an individually wrapped sweet or chocolate which is not enclosed in any further packaging and which is not intended for sale as an individual item.

(4) Any reference in these Regulations to a numbered regulation shall, unless the context otherwise requires, be construed as a reference to the regulation so numbered in these Regulations.

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(a) OJ No. L43, 14.2.97, p.1.  
(b) OJ No. L159, 3.6.98, p.4.  
(c) OJ No. L190, 4.7.98, p.86.  
(d) OJ No. L6, 11.1.2000, p.13.  
(e) OJ No. L6, 11.1.2000, p.15.  
(f) OJ No. L47, 19.2.2000, p.34.

## **Food to which Regulation 1139/98 or Regulation 50/2000 applies**

### **Exemptions**

**3.**—(1) Subject to paragraph (2) below, these Regulations shall not apply in respect of any food brought into England—

- (a) from a member State (other than the United Kingdom), or
- (b) from another part of the United Kingdom,

in which it was lawfully sold, having been produced in a member State, or in which it was in free circulation and lawfully sold, if the requirements of Regulation 1139/98 or Regulation 50/2000 (as applicable), as read in each case with Directive 79/112, are met in respect of that food.

(2) Nothing in paragraph (1) above shall prevent the enforcement of regulation 7(c).

(3) For the purposes of paragraph (1) above, “free circulation” has the same meaning as in Article 23(2) of the Treaty establishing the European Community.

(4) Any prepacked food, either contained in an indelibly marked glass bottle intended for re-use and having no label, ring or collar, or the largest surface of whose packaging has an area of less than ten square centimetres, need not be marked or labelled with the GMO particulars.

### **Manner of marking or labelling: general requirement**

**4.** When any food other than food to which regulation 5 applies is sold, any particulars with which it is required to be marked or labelled by Regulation 1139/98 or Regulation 50/2000 shall appear—

- (a) on the packaging,
- (b) on a label attached to the packaging, or
- (c) on a label which is clearly visible through the packaging,

save that, where the sale is otherwise than to the final consumer, such particulars may, alternatively, appear only on the commercial documents relating to the food where it can be guaranteed that such documents, containing all such particulars, either accompany the food to which they relate or were sent before, or at the same time as, delivery of the food.

### **Manner of marking or labelling: special rules**

**5.**—(1) This regulation applies to—

- (a) food which is not prepacked;
- (b) food which is prepacked for direct sale; and
- (c) any individually wrapped fancy confectionery product which is not enclosed in any further packaging and which is intended for sale as a single item.

(2) When any food to which this regulation applies is sold to the final consumer, any particulars with which it is required to be marked or labelled by Regulation 1139/98 or Regulation 50/2000 shall, except as provided in paragraph (3) below, appear—

- (a) on a label attached to the food, or
- (b) on a menu, notice, ticket or label which is readily discernible by an intending purchaser at the place where he chooses that food.

(3) In any case where food—

- (a) is food to which the labelling requirements of Regulation 1139/98 or Regulation 50/2000 apply,
- (b) is—
  - (i) not prepacked, or
  - (ii) prepacked for direct sale, and
- (c) is sold to the final consumer at appropriate premises,

use of alternative labelling in place of the GMO particulars shall not alone be treated as a contravention of those labelling requirements and for this purpose alternative labelling is used

where, instead of the particulars referred to in Article 2(3) of Regulation 1139/98 or in Articles 2 and 4 of Regulation 50/2000 appearing in the manner specified in paragraph (2)(a) or (b) above, alternative particulars are displayed in accordance with paragraph (4) below.

(4) Alternative particulars are displayed in accordance with this paragraph in relation to any food referred to in paragraph (3) above if there appears on a menu, notice, ticket or label which is readily discernible by an intending purchaser and which is located at the place at the premises where he chooses that food—

- (a) in the case of food to which the labelling requirements of Regulation 1139/98 apply, indications to the effect that some of the food sold at those premises contains ingredients produced from genetically modified soya beans or maize, or both, as the case may be, and that further information is available from the staff; and
- (b) in the case of food to which the labelling requirements of Regulation 50/2000 apply, indications to the effect that some of the food sold at those premises contains additives or flavourings, or both, as the case may be, produced from a genetically modified organism, and that further information is available from the staff.

(5) In this regulation, “premises” includes any ship or aircraft and “appropriate premises” means premises where—

- (a) the staff provide clarification at the request of an intending purchaser as to whether—
  - (i) particular food sold at those premises, other than food falling within Article 1(2) or 2(2) of Regulation 1139/98, is produced in whole or in part from a genetically modified product referred to in Article 1(1) of that Regulation, and
  - (ii) particular food sold at those premises contains additives or flavourings produced in whole or in part from a genetically modified organism; and
- (b) there is an established procedure at those premises for keeping staff informed of that information.

(6) When any food to which this regulation applies is sold otherwise than to the final consumer, the particulars with which it is required to be marked or labelled by Regulation 1139/98 or Regulation 50/2000 shall appear—

- (a) on a label attached to the food, or
- (b) on a ticket or notice which is readily discernible by the intending purchaser at the place where he chooses the food, or
- (c) in commercial documents relating to the food where it can be guaranteed that such documents either accompany the food to which they relate or were sent before, or at the same time as, delivery of the food.

### **Intelligibility of marking or labelling**

6.—(1) The particulars with which a food is required to be marked or labelled by Regulation 1139/98 or by Regulation 50/2000, or which appear on a menu, notice, ticket or label pursuant to these Regulations, shall be easy to understand, clearly legible and indelible and, when a food is sold to the final consumer, the said particulars shall be marked in a conspicuous place in such a way as to be easily visible.

(2) Such particulars shall not in any way be hidden, obscured or interrupted by any other written or pictorial matter.

(3) Paragraph (1) above shall not be taken to preclude the giving of such particulars at mass caterers, in respect of foods the variety and type of which are changed regularly, by means of temporary media (including the use of chalk on a blackboard).

### **General**

#### **Offences and penalties**

7. If any person—

- (a) sells any food to which the labelling requirements of Regulation 1139/98 or of Regulation 50/2000 apply which is not marked or labelled with the GMO particulars, except in the case of any food to which regulation 5(3) applies and in respect of which alternative particulars are displayed in accordance with regulation 5(4),

- (b) sells any food which is not marked or labelled in accordance with regulation 4, 5 or 6, or
- (c) places on the market any novel food or novel food ingredient in respect of which the additional requirements relating to consumer information set out in Article 8(1) of Regulation 258/97 have not been met,

he shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

### **Enforcement**

**8.**—(1) Subject to paragraph (2) below, each food authority shall enforce and execute these Regulations in its area and be the competent authority in its area for the purposes of the second paragraph of Article 2(2)(b) of Regulation 1139/98.

(2) Each port health authority shall enforce and execute these Regulations in its district in relation to imported food and be the competent authority in its district in relation to such food for the purposes of the second paragraph of Article 2(2)(b) of Regulation 1139/98.

(3) In this regulation “food authority” does not include—

- (a) the council of a district in a non-metropolitan county except where the county functions have been transferred to that council pursuant to a structural change;
- (b) the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple).

### **Defence in relation to exports**

**9.** In any proceedings for an offence under these Regulations, it shall be a defence for the person charged to prove—

- (a) that the food in respect of which the offence is alleged to have been committed was intended for export to a country which has legislation analogous to these Regulations and that it complies with that legislation; and
- (b) in the case of export to a member State of food to which Regulation 1139/98 or Regulation 50/2000 applies, that the legislation complies with the provisions of Regulation 1139/98 or Regulation 50/2000, as appropriate, as read with Directive 79/112.

### **Application of various provisions of the Act**

**10.**—(1) 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—

- section 2 (extended meaning of “sale” etc.);
- section 3 (presumption that food is intended for human consumption);
- section 20 (offences due to fault of another person);
- section 21 (defence of due diligence) as it applies for the purposes of section 8, 14 or 15;
- section 30(8) (which relates to documentary evidence);
- 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 (3) below;
- section 36 (offences by bodies corporate).

(2) In the application of section 32 of the Act (powers of entry) for the purposes of these Regulations, the reference in subsection (1)(a) to the Act shall be construed as including a reference to Regulation 258/97, Regulation 1139/98 and Regulation 50/2000.

(3) 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 shall be construed for the purposes of these Regulations as including a reference to these Regulations as read with Regulation 258/97, Regulation 1139/98 and Regulation 50/2000—

- section 33 (obstruction etc. of officers);
- section 44 (protection of officers acting in good faith).

## Consequential amendments

**11.**—(1) The Food Labelling Regulations 1996(a) shall be amended (in so far as they apply to England) in accordance with paragraphs (2) to (11) below.

(2) In regulation 2(1) (interpretation), the definitions of “the GMO particulars” and “Regulation 1139/98” shall be omitted.

(3) In regulation 3(1)(iv) (exemptions), there shall be substituted for the words “, Directive 94/54 and Regulation 1139/98” the words “and Directive 94/54”.

(4) In regulation 26 (small packages and certain indelibly marked bottles)—

(a) in paragraph (1), sub-paragraph (b) and the word “or” preceding it shall be omitted; and

(b) in paragraph (3A), the words “and the GMO particulars” shall be omitted.

(5) In regulation 35 (general requirement as to manner of marking or labelling), the words “or by Regulation 1139/98” shall be omitted.

(6) In regulation 36 (manner of marking or labelling in the case of food to which regulation 23 or 27 applies)—

(a) in paragraph (1), the words “or by Regulation 1139/98” and “or (4A)” shall be omitted; and

(b) paragraphs (4A) to (4C) shall be omitted.

(7) In regulation 38(1) (intelligibility of marking or labelling), the words “or by Regulation 1139/98” shall be omitted.

(8) In regulation 44(1) (offences and penalties), sub-paragraph (f) shall be omitted.

(9) In regulation 47(b) (defence in relation to exports), there shall be substituted for the words “, Directive 94/54 and Regulation 1139/98” the words “and Directive 94/54”.

(10) In regulation 48 (application of various provisions of the Food Safety Act 1990), paragraph (2) shall be omitted.

(11) In regulation 50 (transitional provision), paragraphs (5) to (7) shall be omitted.

**12.** The Novel Foods and Novel Food Ingredients Regulations 1997(b) shall be amended (in so far as they apply to England), by omitting item 7 in the Schedule (specified Community provisions).

## Transitional provisions

**13.**—(1) In any proceedings for an offence under—

(a) regulation 7(a), or

(b) regulation 7(b), as read with regulation 5 or 6,

in relation to the particulars with which any relevant food is required to be marked or labelled by Regulation 1139/98, it shall be a defence to prove that—

(i) in the case of food sold to the final consumer, it was prepared using an ingredient which was on sale before 1st September 1998, or

(ii) in the case of food sold to a mass caterer, it was prepared using an ingredient which was on sale before 10th April 2000.

(2) In any proceedings for an offence under—

(a) regulation 7(a), or

(b) regulation 7(b), as read with regulation 5 or 6,

in relation to the particulars with which any relevant food is required to be marked or labelled by Regulation 50/2000, it shall be a defence to prove that the food was sold to the final consumer

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(a) S.I. 1996/1499; the relevant amending instruments are S.I. 1998/1398, 1999/747, 1483.

(b) S.I. 1997/1335; to which there are amendments not relevant to these Regulations.

or to a mass caterer and was prepared using an ingredient which was on sale before 10th April 2000.

- (3) For the purposes of paragraphs (1) and (2) above, “relevant food” means food which is—
- (i) not prepacked, or
  - (ii) prepacked for direct sale.

16th March 2000

*Hayman*  
Minister of State,  
Ministry of Agriculture, Fisheries and Food

16th March 2000

*Gisela Stuart*  
Parliamentary Under Secretary of State for Health,  
Department of Health

## EXPLANATORY NOTE

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

These Regulations, which apply to England only, make continued provision for the enforcement of—

- (a) Council Regulation (EC) No. 1139/98 concerning the compulsory indication, on the labelling of certain foodstuffs produced from genetically modified organisms, of particulars other than those provided for in Directive 79/112/EEC, and
- (b) the labelling requirements in Article 8(1) of Council Regulation (EC) No. 258/97 concerning novel foods and novel food ingredients (as read with Articles 1 and 2 of that Regulation).

These Regulations also make provision for the enforcement of—

- (a) Commission Regulation (EC) No. 49/2000 which amended Regulation 1139/98; and
- (b) Commission Regulation (EC) No. 50/2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms.

The products covered by Regulation 1139/98 are foods and food ingredients which are to be delivered as such to the final consumer, having been produced in whole or in part from genetically modified soya beans or genetically modified maize, as referred to in Article 1 of that Regulation. Regulation 49/2000 extended the scope of Regulation 1139/98 to cover sales to mass caterers and established a *de minimis* threshold of 1% for adventitious contamination of an ingredient with material derived from genetically modified organisms. Regulation 50/2000 also applies in the case of food and food ingredients intended for final consumers and mass caterers. Regulation 1139/98, as amended, and Regulation 50/2000 contain transitional provisions. The labelling requirements in Regulation 258/97 are to ensure the final consumer is informed of any characteristic or food property rendering a novel food or novel food ingredient no longer equivalent to an existing food or food ingredient; of the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population or give rise to ethical concerns; and of the presence of a genetically modified organism.

Regulations 1139/98, as amended, and 50/2000 were made pursuant to Article 4(2) of Council Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. Pursuant to Articles 11 and 13 of that Directive, these Regulations—

- (a) contain an exemption from the need to be labelled with the particulars required by those EC Regulations in the case of small packages and certain indelibly marked glass bottles (regulation 3(4)); and
- (b) make provision as to the manner of marking or labelling in the case of the particulars required by those Regulations (regulations 4 to 6).

Further to Article 12 of that Directive, these Regulations—

- (a) allow alternative labelling arrangements instead of the particulars required by those EC Regulations in the case of sales to the final consumer by appropriate premises of food which is prepacked for direct sale or not prepacked (regulation 5); and
- (b) contain transitional arrangements in respect of sales of such food to the final consumer or to a mass caterer by analogy with Article 4(1) of Regulation 1139/98, Article 2 of Regulation 49/2000 and Article 5 of Regulation 50/2000 (regulation 13).

These Regulations also—

- (a) create offences and prescribe a penalty (regulation 7), contain exemptions (regulation 3) and specify enforcement authorities (regulation 8);
- (b) 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, as read with the ninth recital to that Directive (regulation 9);



- (c) incorporate specified provisions of the Food Safety Act 1990 (regulation 10); and
- (d) make consequential amendments of other legislation in relation to England (regulations 11 and 12).

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 Library of each House of Parliament. Copies may be obtained from the Additives and Novel Foods Division of the Ministry of Agriculture, Fisheries and Food, Room 239c, Ergon House, 17 Smith Square, London SW1P 3JR.

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