

**2010 No. 2281**

**FOOD, ENGLAND**

**The Foodstuffs Suitable for People Intolerant to Gluten  
(England) Regulations 2010**

<i>Made</i>	- - - -	<i>14th September 2010</i>
<i>Laid before Parliament</i>		<i>20th September 2010</i>
<i>Coming into force</i>	- -	<i>1st January 2012</i>

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(e), 17 (2), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(a) and now vested in him(b).

In accordance with section 48(4A) of the Food Safety Act 1990, the Secretary of State has had regard to relevant advice given by the Food Standards Agency.

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) there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

**Title application and commencement**

1. These Regulations may be cited as the Foodstuffs Suitable for People Intolerant to Gluten (England) Regulations 2010, apply in relation to England only and come into force on 1 January 2012.

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- (a) 1990 c.16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c. 28), (“the 1999 Act”). Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act, S.I. 2004/2990 and S.I. 2004/3279.
- (b) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. 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 the 1999 Act and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c.46) as read with section 40(2) of the 1999 Act.
- (c) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four (OJ No. 188, 18.7.2009, p.14).

## Interpretation

2.—(1) In these Regulations—

“the Act” means the Food Safety Act 1990;

“the Commission Regulation” means Commission Regulation (EC) No. 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten<sup>(a)</sup>;

“food authority” has the meaning that it bears by virtue of section 5(1) of the Act, except that it does not include the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and Middle Temple); and

“specified provision” means any provision of the Commission Regulation that is specified in Column 1 of the Schedule and whose subject-matter is described in Column 2 of the Schedule.

(2) Subject to paragraph (3), any expression other than one defined in paragraph (1) that is used both in these Regulations and in the Act has the meaning it bears in the Act.

(3) Any expression used both in these Regulations and in the Commission Regulation has the meaning that it bears in the Commission Regulation.

(4) Where any functions under the Act are assigned—

(a) by an order under section 2 or 7 of the Public Health (Control of Disease) Act 1984<sup>(b)</sup>, to a port health authority;

(b) by an order under section 6 of the Public Health Act 1936<sup>(c)</sup>, to a joint board for a united district; or

(c) by an order under paragraph 15(6) of Schedule 8 to the Local Government Act 1985<sup>(d)</sup>, to a single authority for a metropolitan county,

any reference in these Regulations to a food authority shall be construed, so far as relating to those functions, as a reference to the authority to whom they are so assigned.

## Offences, penalties and execution and enforcement

3.—(1) Any person who contravenes any of the specified provisions shall be guilty of an offence.

(2) A person guilty of an offence under paragraph (1) shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(3) Each food authority shall execute and enforce these Regulations within its area.

## Application of the specified provisions

4. For the purposes of these Regulations, the specified provisions shall apply in relation to foodstuffs for people intolerant to gluten that are placed on the retail market irrespective of whether they are in pre-packaged form.

## Application of various sections of the Food Safety Act 1990

5. The following provisions of the Act shall apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to these Regulations—

(a) section 3 (presumptions that food intended for human consumption);

(b) section 20 (offences due to fault of another person);

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(a) OJ No. L16, 21.1.2009, p.3.

(b) 1984 c.22; section 7(3)(d) was substituted by paragraph 27 of Schedule 3 to the Food Safety Act 1990 (1990 c.16).

(c) 1936 c.49; section 6 is to be read with paragraph 1 of Schedule 3 to the Food Safety Act 1990.

(d) 1985 c.51; paragraph 15(6) was amended by paragraph 31(b) of Schedule 3 to the Food Safety Act 1990.

- (c) section 21 (defence of due diligence)(a), with the modifications that subsections (2) to (4) shall apply in relation to an offence under regulation 3(1) as they apply in relation to an offence under section 14 or 15 and that in subsection (4)(b) the references to “sale or intended sale” shall be deemed to include references to “labelling, advertising or presentation”;
- (d) section 30(8) (which relates to documentary evidence);
- (e) section 33(1) (obstruction etc. of officers);
- (f) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b) above” shall be deemed to be a reference to any such requirement as is mentioned in that subsection as applied by sub-paragraph (e);
- (g) section 35(1) (punishment of offences)(b), in so far as it relates to offences under section 33(1) as applied by sub-paragraph (e);
- (h) section 35(2) and (3)(c), in so far as it relates to offences under section 33(2) as applied by sub-paragraph (f);
- (i) section 36 (offences by bodies corporate);
- (j) section 36A (offences by Scottish partnerships)(d); and
- (k) section 44 (protection of officers acting in good faith).

Signed by authority of the Secretary of State for Health.

*Anne Milton*  
Parliamentary Under-Secretary of State,  
Department of Health

14th September 2010

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(a) Section 21 was amended by S.I. 2004/3279.  
(b) Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c. 44), Schedule 26, paragraph 42, from a date to be appointed.  
(c) Section 35(3) was amended by S.I. 2004/3279.  
(d) Section 36A was inserted by the Food Standards Act 1999 (1999 c.28), Schedule 5, paragraph 16.

## THE SCHEDULE

Regulations 2(1) and 3(1)

### Specified Provisions of Commission Regulation (EC) No. 41/2009

<i>Provision of the Commission Regulation</i>	<i>Subject-matter</i>
Article 3(1), as read with Article 3(5)	<p>Requirement that foodstuffs for people intolerant to gluten—</p> <p>(a) consisting of or containing one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been especially processed to reduce gluten; or</p> <p>(b) containing both ingredients which substitute wheat, rye, barley, oats or their crossbred varieties and ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been especially processed to reduce gluten,</p> <p>must not contain a level of gluten exceeding 100 mg/kg in the food as sold to the final consumer.</p>
Article 3(2), as read with Article 3(5)	<p>Requirement that the labelling, advertising and presentation of foodstuffs for people intolerant to gluten—</p> <p>(a) consisting of or containing one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been especially processed to reduce gluten; or</p> <p>(b) containing both ingredients which substitute wheat, rye, barley, oats or their crossbred varieties and ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been especially processed to reduce gluten,</p> <p>must bear the term “very low gluten”, although the labelling, advertising and presentation of those foodstuffs may nevertheless bear the term “gluten-free” if the gluten content does not exceed 20 mg/kg in the food as sold to the final consumer.</p>

<i>Provision of the Commission Regulation</i>	<i>Subject-matter</i>
Article 3(3), as read with Article 3(5)	<ul style="list-style-type: none"> <li>- Requirement that oats contained in foodstuffs for people intolerant to gluten (including foodstuffs for people intolerant to gluten containing both ingredients which substitute wheat, rye, barley, oats or their crossbred varieties and ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been specially processed to reduce gluten) must have been specially produced, prepared and/or processed in a way to avoid contamination by wheat, rye, barley or their crossbred varieties.</li> <li>- Requirement that the gluten content of such oats must not exceed 20 mg/kg.</li> </ul>
Article 3(4)	<ul style="list-style-type: none"> <li>- Requirement that foodstuffs for people intolerant to gluten consisting of or containing one or more ingredients which substitute wheat, rye, barley, oats or their crossbred varieties must not contain a level of gluten exceeding 20 mg/kg in the food as sold to the final consumer.</li> <li>- Requirement that the labelling, presentation and advertising of those products must bear the term “gluten-free”.</li> </ul>
Article 3(6)	Requirement that the terms “very low gluten” and “gluten-free” referred to in Article 3(2) and (4) must appear in proximity to the name under which the relevant foodstuff for people intolerant to gluten is sold.
Article 4	<p>Prohibition on the labelling, advertising and presentation of—</p> <ul style="list-style-type: none"> <li>(a) foodstuffs for normal consumption; or</li> <li>(b) foodstuffs for particular nutritional uses which are specially formulated, processed or prepared to meet special dietary needs other than those of people intolerant to gluten but which are nevertheless suitable, by virtue of their composition, to meet the special dietary needs of people intolerant to gluten,</li> </ul> <p>bearing the term “very low gluten”, although the labelling, advertising and presentation of those foodstuffs may nevertheless bear the term</p>

<i>Provision of the Commission Regulation</i>	<i>Subject-matter</i>
	“gluten-free” provided that the gluten content does not exceed 20 mg/kg in the food as sold to the final consumer.

## EXPLANATORY NOTE

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

1. These Regulations, which apply in relation to England only, provide for the execution and enforcement there of Commission Regulation (EC) No. 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten (OJ No. L16, 21.1.2009, p.3) (“the Commission Regulation”) as read with Article 10(2) of Directive 2009/39/EC of the European Parliament and of the Council on foodstuffs intended for particular nutritional uses (OJ No. L124, 20.5.2009, p.21).

2. The Commission Regulation imposes requirements on the composition and labelling of foodstuffs for people intolerant to gluten and other foodstuffs suitable for people intolerant to gluten, in particular as regards the use of the terms “very low gluten” and “gluten-free”.

3. These Regulations–

- (a) provide that a person who contravenes specified provisions of the Commission Regulation is guilty of an offence (*regulation 3(1)*);
- (b) provide penalties for offences (*regulation 3(2)*);
- (c) specify the enforcement authority (*regulation 3(3)*);
- (d) provide that these Regulations apply in relation to foodstuffs for people intolerant to gluten that are placed on the retail market irrespective of whether they are in pre-packaged form as provided for in Article 10(2) of Directive 2009/39/EC (*regulation 4*); and
- (e) provide for the application, with modifications, of specified provisions of the Food Safety Act 1990 (1990 c.16) for the purposes of these Regulations (*regulation 5*).

4. A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Nutrition Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH and is annexed to the Explanatory Memorandum which is available alongside the instrument on the OPSI website.

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STATUTORY INSTRUMENTS

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