

**2010 No.2651 (W.219 )**

**FOOD, WALES**

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

**EXPLANATORY NOTE**

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

**1.** These Regulations, which apply in relation to Wales, 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 regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from the Food Standards Agency, 11<sup>th</sup> Floor, Southgate House, Cardiff, CF10 1EW.

**2010 No. 2651(W. 219)**

**FOOD, WALES**

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

*Made* 23 October 2010

*Laid before the National Assembly for Wales*  
2 November 2010

*Coming into force* 1 January 2012

The Welsh Ministers make 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<sup>(1)</sup> which are now vested in them<sup>(2)</sup>.

In accordance with section 48(4A) of the Food Safety Act 1990, they have 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

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- (1) 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.
- (2) 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) 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 virtue of section 162 of, and paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32).

requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>(1)</sup> there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

### **Title, commencement and application**

**1.**—(1) The title of these Regulations is the Foodstuffs Suitable for People Intolerant to Gluten (Wales) Regulations 2010, and they come into force on 1 January 2012.

(2) These Regulations apply in relation to Wales.

### **Interpretation**

**2.**—(1) In these Regulations—

“the Act” (“*y Ddeddf*”) means the Food Safety Act 1990;

“the Commission Regulation” (“*Rheoliad y Comisiwn*”) means Commission Regulation (EC) No. 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten<sup>(2)</sup>;

“food authority” (“*awdurdod bwyd*”) has the meaning that it bears by virtue of section 5(1A) of the Act; and

“specified provision” (“*darpariaeth benodedig*”) 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 of the Public Health (Control of Disease) Act 1984<sup>(3)</sup>, to a port health authority; or

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(1) 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. L188, 18.7.2009, p.14).

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

(3) 1984 c.22.

- (b) by an order under section 6 of the Public Health Act 1936<sup>(1)</sup>, to a joint board for a united district;

any reference in these Regulations to a food authority must 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 is guilty of an offence.

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

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

### **Application of the specified provisions**

**4.** For the purposes of these Regulations, the specified provisions 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 apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof must 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);
- (c) section 21 (defence of due diligence)<sup>(2)</sup>, with the modifications that subsections (2) to (4) 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” are 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);

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

(2) Section 21 was amended by S.I. 2004/3279.

- (f) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b) above” is deemed to be a reference to any such requirement as is mentioned in that subsection as applied by paragraph (e);
- (g) section 35(1) (punishment of offences)(1), in so far as it relates to offences under section 33(1) as applied by paragraph (e);
- (h) section 35(2) and (3)(2), in so far as it relates to offences under section 33(2) as applied by paragraph (f);
- (i) section 36 (offences by bodies corporate);
- (j) section 36A (offences by Scottish partnerships)(3); and
- (k) section 44 (protection of officers acting in good faith).

*Gwenda Thomas*

The deputy Minister for Social Services, under the authority of the Minister for Health and Social Services, one of the Welsh Ministers

23 October 2010

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(1) Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c. 44), Schedule 26, paragraph 42, from a date to be appointed.

(2) Section 35(3) was amended by S.I. 2004/3279.

(3) 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>
<p>Article 3(1), as read with Article 3(5)</p>	<p>Requirement that foodstuffs for people intolerant to gluten—</p> <ul style="list-style-type: none"> <li>(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</li> <li>(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,</li> </ul> <p>must not contain a level of gluten exceeding 100 mg/kg in the food as sold to the final consumer.</p>
<p>Article 3(2), as read with Article 3(5)</p>	<p>Requirement that the labelling, advertising and presentation of foodstuffs for people intolerant to gluten—</p> <ul style="list-style-type: none"> <li>(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</li> <li>(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,</li> </ul> <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 especially 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.