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SCOTTISH STATUTORY INSTRUMENTS

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**2010 No. 355**

**FOOD**

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

<i>Made</i>	- - - -	<i>6th October 2010</i>
<i>Laid before the Scottish Parliament</i>	- - - -	<i>8th October 2010</i>
<i>Coming into force</i>	- -	<i>1st January 2012</i>

The Scottish 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> and all other powers enabling them to do so.

In accordance with section 48(4A) of that Act, the Scottish Ministers have had regard to relevant advice given by the Food Standards Agency<sup>(2)</sup>.

There has been 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<sup>(3)</sup>.

**Citation, commencement and extent**

1.—(1) These Regulations may be cited as the Foodstuffs Suitable for People Intolerant to Gluten (Scotland) Regulations 2010 and come into force on 1st January 2012.

(2) These Regulations extend to Scotland only.

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- (1) 1990 c.16. Section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 16(1)(e) and 48(1) were amended by the Food Standards Act 1999 (c.28) (“the 1999 Act”), Schedule 5, paragraph 8. Section 17(2) was amended by the 1999 Act, Schedule 5, paragraphs 8 and 12. Section 26(3) was amended by the 1999 Act, Schedule 6, paragraph 1. Amendments made by Schedule 5 to the 1999 Act which extend to Scotland shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) by virtue of section 49(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 Scotland Act 1998. In so far as not transferred, relevant 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).
- (2) Section 48(4A) was inserted by the 1999 Act, Schedule 5, paragraph 21. Section 48(4) was disappplied in respect of these Regulations by virtue of section 48(4C) which was inserted by regulation 5(b) of S.I. 2004/2990.
- (3) O.J. No. L 31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council (O.J. No. L 188, 18.7.2009, p.14).

## Interpretation

### 2.—(1) In these Regulations—

“the Commission Regulation” means [Commission Regulation \(EC\) No. 41/2009](#) concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten<sup>(4)</sup>;

“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 that Schedule.

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

## 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 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 Food Safety Act 1990 shall apply for the purposes of these Regulations with the modification that any reference in those provisions to that 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);
- (c) section 21 (defence of due diligence)<sup>(5)</sup>, with the following modifications—
  - (i) 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
  - (ii) 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) (analysis etc. of samples);
- (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 section 33(1)(b) as applied by sub-paragraph (e);
- (g) section 35(1) (punishment of offences), in so far as it relates to offences under section 33(1) as applied by sub-paragraph (e);
- (h) section 35(2) and (3)<sup>(6)</sup>, 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);

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<sup>(4)</sup> O.J. No. L 16, 21.1.2009, p.3.

<sup>(5)</sup> Section 21 was amended by [S.I. 2004/3279](#).

<sup>(6)</sup> Section 35(3) was amended by [S.I. 2004/3279](#).

- (j) section 36A (offences by Scottish partnerships)(7); and
- (k) section 44 (protection of officers acting in good faith).

St Andrew's House,  
Edinburgh  
6th October 2010

*NICOLA STURGEON*  
A member of the Scottish Executive

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(7) Section 36A was inserted by the [1999 Act \(c.28\)](#), Schedule 5, paragraph 16.

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## SCHEDULE

Regulation 2(1)

## Specified Provisions

<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>

Article 3(3), as read with Article 3(5)

Requirement that—

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<i>Provision of the Commission Regulation</i>	<i>Subject-matter</i>
	<p>(a) 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; and</p> <p>(b) the gluten content of such oats must not exceed 20 mg/kg.</p>
Article 3(4)	<p>Requirement that—</p> <p>(a) 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; and</p> <p>(b) the labelling, presentation and advertising of those products must bear the term “gluten-free”.</p>
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> <p>(a) foodstuffs for normal consumption; or</p> <p>(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,</p> <p>bearing the term “very low gluten”, although the labelling, advertising and presentation of those</p>

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<i>Provision of the Commission Regulation</i>	<i>Subject-matter</i>
	foodstuffs may nevertheless bear the term “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)*

These Regulations provide for the execution and enforcement of Commission Regulation (EC) No. 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten (“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 (O.J. No. L 124, 20.5.2009, p.21). That Directive consolidated 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, 30.6.1989, p.27).

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”.

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 for the purposes of these Regulations (regulation 5).

A full Business and Regulatory Impact Assessment, which includes a compliance cost assessment of the effect that these Regulations will have on the costs of business and the voluntary sector, 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.