
SCOTTISH STATUTORY INSTRUMENTS

2009 No. 427

FOOD

**The Food for Particular Nutritional Uses
(Addition of Substances for Specific Nutritional
Purposes) (Scotland) Regulations 2009**

Made - - - - 26th November 2009

Laid before the Scottish

Parliament - - - - 26th November 2009

Coming into force - - 1st January 2010

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 16(1)(a) and (f), 17(2), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990^{M1} and paragraph 1A of Schedule 2 to the European Communities Act 1972^{M2} and all other powers enabling them to do so.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972(and it appears to the Scottish Ministers that it is expedient for any reference to the Annex to Commission Regulation (EC) No. 953/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses^{M3} to be construed as a reference to that Annex as amended from time to time.

In accordance with section 48(4A) of the Food Safety Act 1990, the Scottish Ministers have had regard to relevant advice given by the Food Standards Agency^{M4}.

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^{M5}.

Marginal Citations

M1 1990 c.16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990; sections 16(1) and 48(1) were amended by the Food Standards Act 1999 (c.28) (“the 1999 Act”), section 40(1) and Schedule 5, paragraph 8; section 17(2) was amended by the 1999 Act, section 40(1) and Schedule 5 paragraphs 8 and 12; section 26(3) was amended by the 1999 Act, section 40(4) and Schedule 6; section 48(4) is disapplied in respect of these Regulations by virtue of section 48(4C) inserted by S.I. 2004/2990; amendments made by Schedule 5 to the 1999 Act shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) (“the 1998 Act”) by

virtue of section 40(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 1998 Act. Insofar as not transferred and insofar as relating to food (including drink) including the primary production of food, those functions were transferred to the Scottish Ministers by the [Scotland Act 1998 \(Transfer of Functions to the Scottish Ministers etc\) Order 2005 \(S.I. 2005/849\)](#).

M2 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 ([2006 c.51](#))

M3 O.J. No. L 269, 14.10.2009, p.9.

M4 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 the Food Safety Act 1990 (Amendment) Regulations 2004 S.I. 2004/2990.

M5 O.J. No. L 31, 1.2.02, p.1 as amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (O.J. No. L 245, 29.9.2003, p.4), Commission Regulation (EC) No. 575/2006 (O.J. No. L 100, 8.4.2006, p.3), Commission Regulation (EC) No. 202/2008 (O.J. No. L 60, 5.3.2008, p.17) and Regulation (EC) No. 596/2009 of the European Parliament and of the Council (O.J. No. L 188, 18.7.2009, p.14).

Citation, commencement and extent **S**

1.—(1) These Regulations may be cited as the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2009 and come into force on 1st January 2010.

(2) These Regulations extend to Scotland only.

Interpretation **S**

2.—(1) In these Regulations—

“the Act” means the Food Safety Act 1990;

“the Commission Regulation” means Commission Regulation ([EC](#)) No. 953/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses; 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) 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 **S**

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 various sections of the Food Safety Act 1990 **S**

4. 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 of the Act 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) ^{M6}, as it applies for the purpose of section 14 or 15;
- (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 that subsection as applied by sub-paragraph (e);
- (g) section 35(1) (punishment of offences) ^{M7}, in so far as it relates to offences under section 33(1) as applied by sub-paragraph (e);
- (h) section 35(2) and (3) ^{M8}, 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) ^{M9}; and
- (k) section 44 (protection of officers acting in good faith).

Marginal Citations

- M6** Section 21 was amended by [S.I. 2004/3279](#).
- M7** Section 35(1) is amended by the [Criminal Justice Act 2003 \(2003 c.44\)](#), [Schedule 26](#), paragraph 42, from a date to be appointed.
- M8** Section 35(3) was amended by [S.I. 2004/3279](#).
- M9** Section 36A was inserted by the [Food Standards Act 1999 \(1999 c.28\)](#), [Schedule 5](#), paragraph 16.

Amendment to the Tryptophan in Food (Scotland) Regulations 2005 **S**

5.—(1) The Tryptophan in Food (Scotland) Regulations 2005 ^{M10} are amended in accordance with the following paragraphs.

- (2) In regulation 2 (interpretation)—
 - (a) in paragraph (1) for the definition “Directive [2001/15/EC](#)” substitute the following definition—

““Regulation 953/2009” means Commission Regulation ([EC](#)) No. [953/2009](#) on substances that may be added for specific nutritional purposes in foods for particular nutritional uses;”;

and
 - (b) after paragraph (2) insert the following paragraph—

“(3) The reference in regulation 5(2) to the Annex to Regulation 953/2009 is a reference to that Annex as amended from time to time.”.
- (3) For regulation 5(2)(c) (exceptions from prohibitions) substitute—

“(c) laevorotatory tryptophan, its sodium, potassium, calcium or magnesium salts or its hydrochloride, added in compliance with Regulation 953/2009 to any food for a particular nutritional use referred to in the Annex to that Regulation;”.

Marginal Citations

- M10** [S.S.I. 2005/479](#).

Revocation **S**

6. The following Regulations are revoked—

- (a) the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002 ^{M11};
- (b) the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes)(Scotland) Amendment Regulations 2004 ^{M12}; and
- (c) the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Amendment Regulations 2006 ^{M13}.

Marginal Citations

M11 [S.S.I. 2002/397](#), as amended by [S.S.I. 2004/90](#), [S.S.I. 2006/556](#) and [S.S.I. 2007/424](#).

M12 [S.S.I. 2004/90](#).

M13 [S.S.I. 2006/556](#).

St Andrew's House,
Edinburgh

SHONA ROBISON
Authorised to sign by the Scottish Ministers

SCHEDULE **S**

Regulations 2(1) and 3(1)

Specified Provisions

<i>Provision of the Commission Regulation</i>	<i>Subject-matter</i>
Article 2(1)	Requirement that among the substances belonging to the categories appearing in the Annex to the Commission Regulation, only those listed in that Annex, complying with the relevant specifications as necessary, may be added for specific nutritional purposes in the manufacture of foodstuffs for particular nutritional uses [^{F1} (foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability)].
Article 3(1)	Requirement that the use of substances added for specific nutritional purposes shall result in the manufacture of safe products that fulfil the particular nutritional requirements of the persons for whom they are intended, as established by generally accepted scientific data.
Article 3(2)	Requirement that upon request by the [^{F2} Food Standards Scotland], the manufacturer or, where appropriate, the importer shall produce the scientific work and the data establishing that the use of the substances complies with Article 3(1) of the Commission Regulation. If such work and data are contained in a readily available publication, a mere reference to that publication shall suffice.
Article 4(2)	Requirement that purity criteria established by [^{F3} [^{F4} assimilated] law] which apply to the substances listed in the Annex to the Commission Regulation when they are used in the manufacture of foodstuffs for purposes other than those covered by the Commission Regulation shall also apply to those substances when they are used for purposes covered by the Commission Regulation.
Article 4(3)	Requirement that for substances listed in the Annex to the Commission Regulation for which purity criteria are not established by [^{F3} [^{F4} assimilated] law], and until the adoption of such specifications, generally acceptable purity criteria recommended by international bodies shall apply.

Changes to legislation: There are currently no known outstanding effects for the The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2009. (See end of Document for details)

Textual Amendments

- F1** Words in sch. substituted (31.12.2020) by [The Nutrition \(EU Exit\) \(Scotland\) \(Amendment\) Regulations 2019 \(S.S.I. 2019/54\)](#), regs. 1, **7(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Words in sch. substituted (1.4.2015) by [The Food \(Scotland\) Act 2015 \(Consequential and Transitional Provisions\) Order 2015 \(S.S.I. 2015/100\)](#), arts. 1(2), 2, **sch. para. 24**
- F3** Words in sch. substituted (31.12.2020) by [The Nutrition \(EU Exit\) \(Scotland\) \(Amendment\) Regulations 2019 \(S.S.I. 2019/54\)](#), regs. 1, **7(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Word in sch. substituted (1.1.2024) by [The Retained EU Law \(Revocation and Reform\) Act 2023 \(Consequential Amendments\) \(Scotland\) Regulations 2023 \(S.S.I. 2023/374\)](#), reg. 1(1), **sch. 2 para. 15**

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which extend to Scotland only, make provision for the execution and enforcement of Commission Regulation [\(EC\) No. 953/2009](#) on substances that may be added for specific nutritional purposes in foods for particular nutritional uses (O.J. No. L 269, 14.10.2009, p.9) (“the Commission Regulation”). The Commission Regulation repeals and replaces Commission Directive [2001/15/EC](#) on substances that may be added for specific nutritional purposes in food for particular nutritional uses (O.J. No. L 52, 22.2.2001, p.19) and Commission Directive [2004/6/EC](#) derogating from Directive [2001/15/EC](#) to postpone the application of the prohibition of trade to certain products (O.J. No. L 15, 22.1.2004, p.31).

These Regulations—

- (a) provide that a person who contravenes specified provisions of the Commission Regulation set out in the Schedule to these Regulations, 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 for the application of specified provisions of the Food Safety Act 1990 for the purposes of these Regulations (*regulation 4*);
- (e) make consequential amendments to the Tryptophan in Food (Scotland) Regulations 2005 (S.S.I. 2005/479) (*regulation 5*); and
- (f) revoke the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002 and the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Amendment Regulations 2004 and 2006 (*regulation 6*).

Article 3(2) of the Commission Regulation refers to the competent authorities referred to in Article 11 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). The Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2007 (S.S.I. 2007/37) provide at regulation 3 that the Food Standards Agency is the competent authority in respect of food for a particular nutritional use manufactured in Scotland or imported into Scotland from outside the United Kingdom.

A Regulatory Impact Assessment has not been produced for this instrument as no impact on the private or voluntary sectors is foreseen.

Changes to legislation:

There are currently no known outstanding effects for the The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2009.