
WELSH STATUTORY INSTRUMENTS

2009 No. 3254 (W.283)

FOOD, WALES

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

<i>Made</i>	- - - -	<i>8 December 2009</i>
<i>Laid before the National Assembly for Wales</i>	- -	<i>10 December 2009</i>
<i>Coming into force</i>	- -	<i>1 January 2010</i>

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^{M1} and now vested in them^{M2}.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972^{M3} and it appears to the Welsh 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^{M4} 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 Welsh Ministers 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 requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety^{M5} there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Marginal Citations

- M1** 1990 c. 16.
- M2** Functions of 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 \(S.I. 1999/672\)](#) and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the [Government of Wales Act 2006 \(2006 c. 32\)](#).
- M3** 1972 c. 68. Paragraph 1A of Schedule 2 was inserted by section 28 of the [Legislative and Regulatory Reform Act 2006 \(2006 c. 51\)](#).
- M4** OJ No. L269, 14.10.2009, p.9.
- M5** OJ No. L31, 1.2.2002, p.1, as 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).

Title, application and commencement **E+W**

1. The title of these Regulations is The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2009, they apply in relation to Wales and come into force on 1 January 2010.

Interpretation **E+W**

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. 953/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses;

“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 or 7 of the Public Health (Control of Disease) Act 1984 ^{M6}, to a port health authority; or

(b) by an order under section 6 of the Public Health Act 1936 ^{M7}, to a joint board for a united district,

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

(5) In these Regulations any reference to the Annex to the Commission Regulation is a reference to that Annex as amended from time to time.

Marginal Citations

M6 1984 c. 22; section 7(3)(d) was substituted by paragraph 27 of Schedule 3 to the Food Safety Act 1990.

M7 1936 c. 49; section 6 is to be read with paragraph 1 of Schedule 3 to the Food Safety Act 1990.

Offences, penalties and execution and enforcement **E+W**

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) will be 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.

[^{F1} Application of the improvement notice provisions of the Act **E+W**]

3A.—(1) Section 10(1) and (2) of the Act (improvement notices) applies, with the modification (in the case of section 10(1)) specified in Part 1 of Schedule 2, for the purposes of—

- (a) enabling an improvement notice to be served on a person requiring the person to secure compliance with the specified provisions contained in Schedule 1; and
- (b) making the failure to comply with a notice referred to in subparagraph (a) an offence.

(2) Section 32(1) to (8) of the Act (powers of entry) applies, with the modification (in the case of section 32(1)) specified in Part 2 of Schedule 2, for the purposes of enabling an authorised officer of an enforcement authority—

- (a) to exercise a power of entry to ascertain whether food that does not comply with one or more of the specified provisions contained in Schedule 1 is, or has been, sold; and
- (b) to exercise a power of entry to ascertain whether there is any evidence of any contravention of the specified provisions contained in Schedule 1.

(3) Section 35 of the Act (punishment of offences) applies, with the modification specified in Part 3 of Schedule 2, for the purpose of specifying the punishment of an offence committed under paragraph (1)(b).

(4) Section 37(1), (3), (5) and (6) of the Act (appeals) applies, with the modification (in the case of section 37(1), (5) and (6)) specified in Part 4 of Schedule 2, for the purpose of enabling a decision to serve a notice referred to in paragraph (1)(a) to be appealed.

(5) Section 39 of the Act (appeals against improvement notices) applies, with the modification (in the case of section 39(3)) specified in Part 5 of Schedule 2, for the purpose of dealing with appeals against a decision to serve a notice referred to in paragraph (1)(a).]

F1 Reg. 3A inserted (2.8.2016) by *The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016* (S.I. 2016/639), reg. 1(3), **Sch. 3 para. 5(a)**

Application of various sections of the Act **E+W**

4. 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 is 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)^{M8}, as it applies for the purpose of section 14 or 15;
- (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” 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)^{M9}, in so far as it relates to offences under section 33(1) as applied by paragraph (e);
- (h) section 35(2) and (3)^{M10}, 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)^{M11}; and

(k) section 44 (protection of officers acting in good faith).

Marginal Citations

- M8** Section 21 was amended by [S.I. 2004/3279](#).
- M9** Section 35(1) is amended by the [Criminal Justice Act 2003 \(2003 c. 44\)](#), [Schedule 26](#), paragraph 42, from a date to be appointed.
- M10** Section 35(3) was amended by [S.I. 2004/3279](#).
- M11** Section 36A was inserted by the [Food Standards Act 1999 \(1999 c. 28\)](#), [Schedule 5](#), paragraph 16.

Amendment to the Tryptophan in Food (Wales) Regulations 2005 **E+W**

5.—(1) The Tryptophan in Food (Wales) Regulations 2005^{M12} are amended in accordance with the following paragraphs.

(2) In paragraph (1) of regulation 2 (interpretation), for the definition “Directive [2001/15/EC](#)” there is substituted the following definition— “ “Regulation 953/2009” (“*Rheoliad 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; ”.

(3) In regulation 5 (exceptions from prohibitions), for sub-paragraph (c) of paragraph (2) there is substituted the following sub-paragraph—

“(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

- M12** [S.I. 2005/3111 \(W.231\)](#).

Revocation **E+W**

6. The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002^{M13} are revoked.

Marginal Citations

- M13** [S.I. 2002/2939 \(W.280\)](#).

Gwenda Thomas
Deputy Minister for Social Services under
authority of the Minister for Health and Social
Services, one of the Welsh Ministers

[^{F2}Schedule 1] **E+W** [^{F3}Regulations 2(1), 3(1), and 3A(1) and (2)]

Specified Provisions

F2	Words in Sch. title substituted (2.8.2016) by The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (S.I. 2016/639) , reg. 1(3), Sch. 3 para. 5(b)
F3	Words in Sch. 1 substituted (2.8.2016) by The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (S.I. 2016/639) , reg. 1(3), Sch. 3 para. 5(c)

<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 [^{F4} (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 will 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 [^{F5} the Secretary of State, the Welsh Ministers or Food Standards Scotland], the manufacturer or, where appropriate, the importer will 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 will suffice.
Article 4(2)	Requirement that purity criteria established by [^{F6} [^{F7} 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 will also apply to those substances

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) (Wales) Regulations 2009. (See end of Document for details)

Article 4(3)	<p>when they are used for purposes covered by the Commission Regulation.</p> <p>Requirement that for substances listed in the Annex to the Commission Regulation for which purity criteria are not established by [^{F6}[^{F8}assimilated] law], and until the adoption of such specifications, generally acceptable purity criteria recommended by international bodies will apply.</p>
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F4	Words in Sch. 1 substituted (31.12.2020) by The Nutrition (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/179), regs. 1(2), 7(2)(a) ; 2020 c. 1, Sch. 5 para. 1(1)
F5	Words in Sch. 1 substituted (31.12.2020) by The Nutrition (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/179), regs. 1(2), 7(2)(b) (as amended by S.I. 2020/1252, regs. 1(2), 2(2)); 2020 c. 1, Sch. 5 para. 1(1)
F6	Words in Sch. 1 substituted (31.12.2020) by The Nutrition (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/179), regs. 1(2), 7(2)(c) ; 2020 c. 1, Sch. 5 para. 1(1)
F7	Word in Sch. 1 substituted (1.1.2024) by The Retained EU Law (Revocation and Reform) Act 2023 (Consequential Amendments) (Wales) Regulations 2023 (S.I. 2023/1332), regs. 1(2), 10(2)(a)
F8	Word in Sch. 1 substituted (1.1.2024) by The Retained EU Law (Revocation and Reform) Act 2023 (Consequential Amendments) (Wales) Regulations 2023 (S.I. 2023/1332), regs. 1(2), 10(2)(b)

[^{F9}SCHEDULE 2 E+W

Regulation 3A

Modification of the improvement notice provisions of the Act

F9	Sch. 2 inserted (2.8.2016) by The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (S.I. 2016/639), reg. 1(3), Sch. 3 para. 5(d)
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PART 1 E+W

Modification of section 10(1)

1. For section 10(1) (improvement notices) substitute—

“(1) If an authorised officer of an enforcement authority has reasonable grounds for suspecting that a person is failing to comply with the provisions specified in Schedule 1 of the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2009, the authorised officer may, by a notice served on that person (in this Act referred to as an “improvement notice”)—

- (a) state the officer’s grounds for suspecting that the person is failing to comply or, as the case may be, that the food does not comply with the relevant provision;
- (b) specify the matters which constitute the failure to so comply;
- (c) specify the measures which, in the officer’s opinion, the person must take in order to secure compliance; and
- (d) require the person to take those measures, or such measures that are at least equivalent to them, within such period as may be specified in the notice.”

PART 2 **E+W**

Modification of section 32(1)

2. For paragraphs (a) to (c) of section 32(1) (powers of entry) substitute—
 - “(a) to enter any premises within the authority’s area for the purpose of ascertaining whether there has been any contravention of the provisions specified in Schedule 1 of the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2009; and
 - (b) to enter any business premises, whether within or outside the authority’s area, for the purpose of ascertaining whether there is on the premises any evidence of any contravention of that regulation;”.

PART 3 **E+W**

Modification of section 35

3. In section 35 (punishment of offences), after subsection (1), insert—

“(1A) A person guilty of an offence under section 10(2), as applied by regulation 3A(1) of the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2009, is liable, on summary conviction, to a fine.”

PART 4 **E+W**

Modification of section 37(1), (5) and (6)

4. For section 37(1) (appeals) substitute—

“(1) Any person who is aggrieved by a decision of an authorised officer of an enforcement authority to serve an improvement notice under section 10(1) as applied and modified by regulation 3A(1) of, and Part 1 of Schedule 2 to, the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2009, may apply to the magistrates’ court.”
5. For section 37(5) substitute—

“(5) The period within which such an appeal as is mentioned in subsection (1) above may be brought shall be—

 - (a) one month from the date on which notice of the decision was served on the person desiring to appeal; or
 - (b) the period specified in the improvement notice,

whichever ends the earlier; and in the case of such an appeal, the making of the complaint shall be deemed for the purposes of this subsection to be the bringing of the appeal.”
6. In section 37(6)—
 - (a) for “(3) or (4)” substitute “(1)”; and
 - (b) in paragraph (a), omit “or to the sheriff”.

PART 5 **E+W**

Modification of section 39(3)

7. In section 39(3) (appeals against improvement notices), omit “for want of prosecution”.]

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations, which apply in relation to Wales, 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 (OJ No. L269, 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 (OJ No. L52, 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 (OJ No. L15, 22.1.2004, p.31).

2. 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 (1990 c. 16) for the purposes of these Regulations (*regulation 4*);
- (e) make consequential amendments to the Tryptophan in Food (Wales) Regulations 2005 (S.I. 2005/3111 (W.231)) (*regulation 5*); and
- (f) revoke the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002 (S.I. 2002/2939 (W.280)) (*regulation 6*).

3. 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 (OJ No. L124, 20.5.2009, p.21). The Notification of Marketing of Food for Particular Nutritional Uses (Wales) Regulations 2007 (S.I. 2007/1040 (W.100)) provide at regulation 3 that the Food Standards Agency is the competent authority in respect of food for a particular nutritional use manufactured in Wales or imported into Wales from outside the United Kingdom.

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) (Wales) Regulations 2009.