SCOTTISH STATUTORY INSTRUMENTS

2005 No. 479

FOOD

The Tryptophan in Food (Scotland) Regulations 2005

Made - - - -	*28th September 2005*
Laid before the Scottish Parliament - - - -	*30th September 2005*
Coming into force - -	*11th November 2005*

The Scottish Ministers, in exercise of the powers conferred by sections 6(4), 16(1)(a) and (f), 26(1) and (3) and 48(1) of the Food Safety Act 1990(**1**) and of all other powers enabling them in that behalf, having had regard in accordance with section 48(4A)(**2**) of that Act to relevant advice given by the Food Standards Agency and after consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council(**3**) 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, hereby make the following Regulations:

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Tryptophan in Food (Scotland) Regulations 2005 and shall come into force on 11th November 2005.

(2) These Regulations extend to Scotland only.

Interpretation

2.—(1) In these Regulations–

"the Act" means the Food Safety Act 1990;

(**1**) 1990 c. 16; section 1(1) and (2) (definition of "food") was substituted by S.I.2004/2990; section 6(4) was amended by the Deregulation and Contracting Out Act 1994 (c. 40), Schedule 9, paragraph 6 and by the Food Standards Act 1999 (c. 28) ("the 1999 Act"), section 40(1) and Schedule 5, paragraph 10(3); sections 16(1) and 48(1) were amended by the 1999 Act, section 40(1) and Schedule 5, paragraph 8; section 26(3) was amended by the 1999 Act, section 40(4) and Schedule 6; amendments made by Schedule 5 to the 1999 Act are 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 they are exercisable within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act and (so far as not so transferred) 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, section 40(1) and Schedule 5, paragraph 21.

(**3**) O.J. No. L 31, 1.2.02, p.1, as last amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (O.J. No. L 245, 29.9.03, p.4).

"appropriate medical certificate" means a certificate in writing, given by a registered medical practitioner, that a person requires food to which tryptophan has been added to treat a condition from which a registered medical practitioner has diagnosed that person to be suffering;

"Directive 2001/15/EC" means Commission Directive 2001/15/EC(**4**) on substances that may be added for specific nutritional purposes in foods for particular nutritional uses, as corrected by a Corrigendum(**5**) and as amended by Commission Directive 2004/5/EC(**6**);

"dose form" means a form such as capsules, pastilles, tablets, pills, and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities;

"European Pharmacopoeia" means the European Pharmacopoeia, 5th Edition (2004) published by the European Directorate for the Quality of Medicines;

"food supplement" means any food the purpose of which is to supplement the normal diet and which–

(a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and

(b) is sold in dose form;

"hospital" includes a clinic, nursing home or similar institution;

"infant formula" and "follow-on formula" have the meanings assigned to them by the Infant Formula and Follow-on Formula Regulations 1995(**7**);

"pharmacist" means a person lawfully conducting a retail pharmacy business within the meaning of section 69 of the Medicines Act 1968(**8**);

"processed cereal-based foods" and "baby foods" have the meanings assigned to them in the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Scotland) Regulations 2004(**9**); and

"tryptophan" means dextrorotatory tryptophan, laevorotatory tryptophan or racemic tryptophan, or any salt or peptide prepared from any of those forms.

(2) In these Regulations references to adding tryptophan to food–

(a) do not include cases where food which contains only tryptophan occurring naturally in it is added to any other such food or to food which contains no tryptophan;

(b) but otherwise include cases where food to which tryptophan has been added is added to any other food,

and references in regulations 4 and 5 to food containing tryptophan do not include cases where that tryptophan only occurs naturally in the food or an ingredient of the food.

Presumption

3. Where any requirements of these Regulations are contravened in respect of any food and that food is part of a batch, lot or consignment of food of the same class or description, it shall be presumed, until the contrary is proved, that all of the food in that batch, lot or consignment fails to comply with those requirements.

(**4**) O.J. No. L 52, 22.2.01, p.19.
(**5**) O.J. No. L 253, 21.9.01, p.34.
(**6**) O.J. No. L 14, 21.1.04, p.19.
(**7**) S.I. 1995/77, to which there are amendments not relevant to these Regulations.
(**8**) 1968 c. 67.
(**9**) S.S.I. 2004/8.

Prohibitions

4. Subject to regulation 5, no person shall–

(a) add tryptophan to food;

(b) sell, or offer for sale, food containing tryptophan; or

(c) expose for sale food containing tryptophan.

Exceptions from prohibitions

5.—(1) Food containing tryptophan may be sold or offered for sale–

(a) by a pharmacist; or

(b) by a person acting in the course of the activities of a hospital,

to a person in respect of whom there is an appropriate medical certificate or to someone acting on that person's behalf, and–

(i) any person may add tryptophan to food intended for sale in those circumstances; and

(ii) any person may sell, or offer for sale, food containing tryptophan for the purposes of its sale in those circumstances.

(2) Regulation 4 shall not apply in respect of–

(a) laevorotatory tryptophan added to any infant formula or follow-on formula;

(b) laevorotatory tryptophan added to any processed cereal-based foods or baby foods; or

(c) laevorotatory tryptophan, its sodium, potassium, calcium or magnesium salts or its hydrochloride, added in compliance with Directive 2001/15/EC to any food for a particular nutritional use referred to in the Annex to that Directive,

if that added substance complies with the purity criteria specified for that substance in the European Pharmacopoeia.

(3) Regulation 4 shall not apply in respect of laevorotatory tryptophan added to any food supplement if–

(a) the laevorotatory tryptophan complies with the purity criteria specified for that substance in the European Pharmacopoeia; and

(b) the recommended daily dose for that food supplement does not exceed 220 mg.

Offences and penalty

6.—(1) Subject to paragraph (2), a person who contravenes regulation 4 shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(2) A pharmacist or a person acting in the course of the activities of a hospital who contravenes or fails to comply with regulation 4(b) by reason only that a document purporting to be the appropriate medical certificate is not genuine does not commit an offence if, having exercised all due diligence, that pharmacist or person has reasonable cause to believe that the document was an appropriate medical certificate.

Enforcement

7. Each food authority shall enforce and execute the provisions of these Regulations in its area.

Application of various provisions of the Act

8. 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 2 (extended meaning of "sale" etc.);

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

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

(d) section 21 (defence of due diligence) as it applies for the purposes of section 14 or 15;

(e) section 30(8) (which relates to documentary evidence);

(f) section 33 (obstruction etc. of officers);

(g) section 35(1) to (3) (punishment of offences) in so far as it relates to offences under section 33(1) and (2) as applied by paragraph (f);

(h) section 36 (offences by bodies corporate);

(i) section 36A (offences by Scottish partnerships)(**10**); and

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

Condemnation of food

9. Where any food is certified by a food analyst to an authorised officer as being food which it is an offence under these Regulations to sell, that food shall be treated for the purposes of section 9 of the Act (inspection and seizure of suspected food)(**11**) as failing to comply with food safety requirements.

Revocations

10.—(1) The Tryptophan in Food (Scotland) Regulations 1990(**12**) are revoked.

(2) Regulation 9 of the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulation 2002(**13**) is revoked.

(3) Regulation 13 of the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Scotland) Regulations 2004(**14**) is revoked.

St Andrew's House, Edinburgh
28th September 2005

LEWIS MACDONALD
Authorised to sign by the Scottish Ministers

(**10**) Section 36A was inserted by the 1999 Act, section 40(1) and Schedule 5, paragraph 16.
(**11**) Section 9 was amended by S.I. 2004/3279.
(**12**) S.I. 1990/1792, relevantly amended by S.S.I. 2002/397 and 2004/8.
(**13**) S.S.I. 2002/397.
(**14**) S.S.I. 2004/8.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations consolidate with amendments the Tryptophan in Food (Scotland) Regulations 1990, as amended. They extend to Scotland only.

Tryptophan is an amino acid. These Regulations continue to prohibit the addition of tryptophan (as defined in regulation 2(1)) to food, and the sale, offer for sale and exposure for sale of food containing tryptophan, subject to exceptions (regulations 2(2), 4 and 5).

The main changes effected by these Regulations are–

(a) the addition of a new exception from the prohibitions in the Regulations in respect of laevorotatory tryptophan added to food supplements if certain conditions are met (regulation 5(3));

(b) the insertion of a qualification to the existing exception in respect of laevorotatory tryptophan, its sodium, potassium, calcium or magnesium salts or its hydrochloride added to certain foods for a particular nutritional use in that the added substance must comply with specified purity criteria (regulation 5(2)).

The Regulations also–

(a) continue to provide for offences and a penalty (regulation 6);

(b) make provision as to enforcement (regulation 7);

(c) apply various provisions of the Food Safety Act 1990 (regulations 8 and 9) and include a presumption as regards food which contravenes the Regulations in certain circumstances (regulation 3);

(d) make revocations (regulation 10).

The Regulations have been notified in draft to the European Commission in accordance with Article 8 of Directive 98/34/EC of the European Parliament and of the Council (O.J. No. L 204, 21.7.98, p.37) laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, as amended by Directive 98/48/EC of the European Parliament and of the Council (O.J. No. L 217, 5.8.98, p.18).

The European Pharmacopoeia may be obtained from the Stationery Office (customer services telephone number 0870 600 5522; e-mail: customer.services@tso.co.uk).

A Regulatory Impact Assessment which includes an assessment of the effect which these Regulations are likely to have on business costs 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.