STATUTORY INSTRUMENTS

2005 No. 2630

FOOD, ENGLAND

The Tryptophan in Food (England) Regulations 2005

Made - - - -	*21st September 2005*
Laid before Parliament	*28th September 2005*
Coming into force - -	*11th November 2005*

The Secretary of State, in exercise of the powers conferred by sections 16(1)(a) and (f), 26(1) and (3) and 48(1) of the Food Safety Act 1990(**a**) and now vested in her(**b**), having had regard in accordance with section 48(4A) 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(**c**) 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, makes the following Regulations:

Title, application and commencement

1. These Regulations may be cited as the Tryptophan in Food (England) Regulations 2005; they apply in relation to England only and come into force on 11th November 2005.

Interpretation

2.—(1) In these Regulations —

"the Act" means the Food Safety Act 1990;

"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 him to be suffering;

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

(**a**) 1990 c. 16; section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990; section 53(2) was amended by Schedule 6 to the Food Standards Act 1999 (1999 c. 28) and S.I. 2004/2990.

(**b**) 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) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999 and paragraph 21 of that Schedule amends section 48 of the 1990 Act. Section 48 was also amended by S.I. 2004/2990. Functions of "the Ministers" 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 those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.

(**c**) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (OJ No. L245, 29.9.2003, p.4).

(**d**) OJ No. L52, 22.2.2001, p.19, as corrected by a Corrigendum (OJ No. L253, 21.9.2001, p.34).

(**e**) OJ No. L14, 21.1.2004, p.19.

"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;

"follow–on formula" means a food intended for particular nutritional use by infants in good health who are aged over four months, and constituting the principal liquid element in a progressively diversified diet;

"food authority" does not include —

(a) the council of a district in a non–metropolitan county except where the county functions have been transferred to that council pursuant to a structural change;

(b) the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple);

"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" means a child under the age of twelve months;

"infant formula" means a food intended for particular nutritional use by infants in good health during the first four to six months of life, and satisfying by itself the nutritional requirements of such infants;

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

"port health authority" means —

(a) in relation to the London port health district (within the meaning given to that phrase for the purposes of the Public Health (Control of Disease) Act 1984(**b**) by section 7(1) of that Act), the Common Council of the City of London; and

(b) in relation to any port health district constituted by order under section 2(3) of the Public Health (Control of Disease) Act 1984, a port health authority for that district constituted by order under section 2(4) of that Act;

"processed cereal–based food" and "baby food" have the same meaning as in the Processed Cereal–based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003(**c**);

"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.

(**a**) 1968 c. 67; section 69 is amended by the Pharmacists (Fitness to Practise) Act 1997 (1997 c. 19), Schedule, paragraph 5, from a date to be appointed.
(**b**) 1984 c. 22.
(**c**) S.I. 2003/3207.

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.

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) 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 being sold 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 food or baby food; 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(**a**).

(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 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, he has reasonable cause to believe that the document was an appropriate medical certificate.

(**a**) European Pharmacopoeia 5th Edition, Volume II (2004) Pub. European Directorate for the Quality of Medicines, at pages 2636 to 2638.

Enforcement

7.—(1) Subject to paragraph (2), each food authority shall enforce and execute these Regulations in its area.

(2) Each port health authority shall enforce and execute these Regulations in its district in relation to imported food.

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 any Part of it 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(1) (obstruction etc. of officers);

(g) 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 paragraph (f) above;

(h) section 35(1) (punishment of offences)(**a**) in so far as it relates to offences under section 33(1) as applied by paragraph (f) above;

(i) section 35(2) and (3) in so far as it relates to offences under section 33(2) as applied by paragraph (g) above;

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

(k) section 36A (offences by Scottish partnerships)(**b**); and

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

Condemnation of food

9. Where any food is certified by a food analyst as being food which it is an offence under these Regulations to sell, that food may be treated for the purposes of section 9 of the Act (under which food may be seized and destroyed on the order of a justice of the peace)(**c**) as failing to comply with food safety requirements.

Revocations

10.—(1) The Tryptophan in Food Regulations 1990(**d**) are revoked in relation to England.

(2) Regulation 10 of the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002(**e**) and regulation 14 of the Processed Cereal–based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003(**f**) are revoked.

(**a**) Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c. 44), Schedule 26, paragraph 42, from a date to be appointed.
(**b**) Section 36A was inserted by the Food Standards Act 1999 (1999 c. 28), Schedule 5, paragraph 16.
(**c**) Section 9 and section 8 were amended by S.I. 2004/3279.
(**d**) S.I. 1990/1728, amended by S.I. 1990/2486, 2002/1817, 2003/3207.
(**e**) S.I. 2002/1817, to which there is an amendment not relevant to these Regulations.
(**f**) S.I. 2003/3207.

Signed by authority of the Secretary of State for Health

Caroline Flint
Parliamentary Under Secretary of State,
Department of Health

21st September 2005

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations consolidate with amendments the Tryptophan in Food Regulations 1990, as amended, in relation to England. Those Regulations extended to England and Wales.

2. 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).

3. 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)).

4. 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).

5. The Regulations were 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 (OJ No. L204, 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 (OJ No. L217, 5.8.98, p.18).

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

7. A full Regulatory Impact Assessment of the effect that these Regulations will have on the costs of business has been prepared and placed in the Library of each House of Parliament. Copies may be obtained from the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.

STATUTORY INSTRUMENTS

2005 No. 2630

FOOD, ENGLAND

The Tryptophan in Food (England) Regulations 2005

£3.00

Printed and published in the UK by The Stationery Office Limited
under the authority and superintendence of Carol Tullo, Controller of Her Majesty's
Stationery Office and Queen's Printer of Acts of Parliament.

E1355 9/2005 151355T 19585

ISBN 0-11-073370-3

9 780110 733708