WELSH STATUTORY INSTRUMENTS

2005 No. 3111 (W.231)

FOOD, WALES

The Tryptophan in Food (Wales) Regulations 2005

Made - - - -	*8 November 2005*
Coming into force - -	*11 November 2005*

The National Assembly for Wales, 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(**1**) and now vested in it(**2**), and having had regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency, and after consultation both 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(**3**), makes the following Regulations:

Title, application and commencement

1. The title of these Regulations is the Tryptophan in Food (Wales) Regulations 2005; they apply in relation to Wales and come into force on 11 November 2005.

Interpretation

2.—(1) In these Regulations—

"the Act" ("*y Ddeddf*") means the Food Safety Act 1990;

"appropriate medical certificate" ("*tystysgrif feddygol briodol*") 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" ("*Cyfarwyddeb 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 amended by Commission Directive 2004/5/EC(**5**);

(**1**) 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.
(**2**) Functions of the Secretary of State under the Food Safety Act 1990, 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. 1996/672).
(**3**) 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)
(**4**) OJ No. L52, 22.2.2001, p.19, as corrected by a Corrigendum (OJ No. L253, 21.9.2001, p.34).
(**5**) OJ No. L14, 21.1.2004, p.19.

"dose form" ("*ffurf dogn*") 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" ("*fformiwla ddilynol*") 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" ("*awdurdod bwyd*") has the same meaning as in section 5(1A) and (3)(a) and (b) of the Food Safety Act 1990;

"food supplement" ("*ategolyn bwyd*") 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" ("*ysbyty*") includes a clinic, nursing home or similar institution;

"infant" ("*baban*") means a child under the age of twelve months;

"infant formula" ("*fformiwla fabanod*") 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" ("*fferyllydd*") means a person lawfully conducting a retail pharmacy business within the meaning of section 69 of the Medicines Act 1968(**6**);

"port health authority" ("*awdurdod iechyd porthladd*") means in relation to any port health district constituted by order under section 2(3) of the Public Health (Control of Disease) Act 1984(a), a port health authority for that district constituted by order under section 2(4) of that Act.

"processed cereal-based food" ("*bwyd proses sydd wedi'i seilio ar rawn*") and "baby food" ("*bwyd babanod*") have the same meaning as in the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Wales) Regulations 2004(**7**);

"tryptophan" ("*tryptoffan*") 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 is presumed, until the contrary is proved, that all of the food in that batch, lot or consignment fails to comply with those requirements.

(**6**) 1968 c. 67, section 69 was amended by the Pharmacists (Fitness to Practise) Act 1997 (1997 c. 19), Schedule, paragraph 5, from a date to be appointed.
(**7**) S.I. 2004/314 (W.32).

Prohibitions

4. Subject to regulation 5, no person may—

(a) add tryptophan to food;

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

(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 does 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(**8**).

(3) Regulation 4 does 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 is guilty of an offence and will 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, that person has reasonable cause to believe that the document was an appropriate medical certificate.

Enforcement

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

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