



CYNULLIAD CENEDLAETHOL CYMRU

NATIONAL ASSEMBLY FOR WALES

OFFERYNNAU STATUDOL

STATUTORY INSTRUMENTS

2005 Rhif 3111 (Cy.231)

2005 No. 3111 (W.231)

BWYD, CYMRU

FOOD, WALES

**Rheoliadau Tryptoffan mewn
Bwyd (Cymru) 2005**

**The Tryptophan in Food (Wales)
Regulations 2005**

NODYN ESBONIADOL

EXPLANATORY NOTE

(Nid yw'r nodyn hwn yn rhan o'r Rheoliadau)

(This note is not part of the Regulations)

1. Mae'r Rheoliadau hyn yn cydgrynhoi gyda diwygiadau Rheoliadau Tryptoffan mewn Bwyd 1990, fel y'u diwygiwyd, o ran Cymru. Yr oedd y Rheoliadau hynny'n rhychwantu Cymru a Lloegr.

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

2. Mae tryptoffan yn asid amino. Mae'r Rheoliadau hyn yn parhau i wahardd ychwanegu tryptoffan (fel y'i diffinnir yn rheoliad 2(1)) at fwyd, a gwerthu, cynnig ar werth ac arddangos ar gyfer gwerthu fwyd sy'n cynnwys tryptoffan, yn ddarostyngedig i eithriadau (rheoliadau 2(2), 4 a 5).

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. Dyma'r prif newidiadau sy'n cael eu hachosi gan y Rheoliadau hyn-

3. The main changes effected by these Regulations are-

- (a) ychwanegu eithriad newydd o'r gwaharddiadau yn y Rheoliadau o ran tryptoffan chwithdroadol a ychwanegir at ychwanegion bwyd os bodlonir amodau penodol (rheoliad 5(3));
- (b) mewnosod cymhwysiad i'r eithriad bresennol o ran tryptoffan chwithdroadol, ei halwynau sodiwm, potasiwm, calsiwm neu fagnesiw neu ei hydroclorid a ychwanegwyd at fwydydd penodol ar gyfer defnydd maethol neilltuol o ran bod yn rhaid i'r sylwedd a ychwanegir gydymffurfio â meini prawf purdeb penodedig (rheoliad 5(2)).

- (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. Mae'r Rheoliadau hefyd-

4. The Regulations also-

- (a) yn parhau i ddarparu ar gyfer tramgwyddau a chosb (rheoliad 6);
- (b) yn gwneud darpariaeth o ran gorfodi (rheoliad 7);

- (a) continue to provide for offences and a penalty (regulation 6);
- (b) make provision as to enforcement (regulation 7);

(c) yn cymhwyso darpariaethau amrywiol o Ddeddf Diogelwch Bwyd 1990 (rheoliadau 8 a 9) ac yn cynnwys rhagdybiaeth o ran bwyd sy'n mynd yn groes i'r Rheoliadau mewn amgylchiadau penodol (rheoliad 3);

(ch) yn gwneud dirymiadau (rheoliad 10).

5. Hysbyswyd y Comisiwn Ewropeaidd am ddrafft o'r Rheoliadau hyn yn unol ag Erthygl 8 o Gyfarwyddeb 98/34/EC Senedd Ewrop a'r Cyngor (OJ Rhif L204, 21.7.98, t.37), sy'n gosod gweithdrefn ar gyfer darparu gwybodaeth ym maes safonau technegol a rheoliadau ac ar gyfer rheolau ar wasanaethau Cymdeithas Wybodaeth, fel y'i diwygir gan Gyfarwyddeb 98/48/EC Senedd Ewrop a'r Cyngor (OJ Rhif L217, 5.8.98, t.18).

6. Gellir cael Pharmacopoeia Ewrop o'r Llyfrfa (rhif ffôn gwasanaethau cwsmeriaid 0870 600 5522; e-bost: customer.services@tso.co.uk).

7. Paratowyd arfarniad rheoliadol llawn am yr effaith a gaiff y Rheoliadau hyn ar gostau busnes a'i osod yn llyfrgell Cynulliad Cenedlaethol Cymru. Gellir cael copïau oddi wrth yr Asiantaeth Safonau Bwyd, Llawr 11, Southgate House, Wood Street, Caerdydd CF10 1EW.

(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 appraisal of the effect that these Regulations will have on the costs of business has been prepared and placed in the library of the National Assembly for Wales. Copies may be obtained from the Food Standards Agency, 11th Floor, Southgate House, Wood Street, Cardiff CF10 1EW.

2005 Rhif 3111 (Cy.231)**2005 No. 3111 (W.231)****BWYD, CYMRU****FOOD, WALES****Rheoliadau Tryptoffan mewn
Bwyd (Cymru) 2005****The Tryptophan in Food (Wales)
Regulations 2005***Wedi'u gwneud* 8 Tachwedd 2005*Made* 8 November 2005*Yn dod i rym* 11 Tachwedd 2005*Coming into force* 11 November 2005

Mae Cynulliad Cenedlaethol Cymru, drwy arfer y pwerau a roddwyd gan adrannau 16(1)(a) ac (f), (26)(1) a (3) a 48(1) o Ddeddf Diogelwch Bwyd 1990(1) ac sydd bellach wedi'u breinio ynddo(2) ac wedi rhoi sylw yn unol ag adran 48(4A) o'r Ddeddf honno i gyngor perthnasol a roddwyd gan yr Asiantaeth Safonau Bwyd, ac ar ôl ymgynghori fel sy'n ofynnol gan Erthygl 9 o Reoliad (EC) Rhif 178/2002 Senedd Ewrop a'r Cyngor, sy'n pennu egwyddorion a gofynion cyffredinol cyfraith bwyd, yn sefydlu Awdurdod Diogelwch Bwyd Ewrop ac yn pennu gweithdrefnau o ran materion diogelwch bwyd(3), yn gwneud y Rheoliadau a ganlyn:

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:

Enwi, cymhwyso a chychwyn**Title, application and commencement**

1. Enw'r Rheoliadau hyn yw Rheoliadau Tryptoffan mewn Bwyd (Cymru) 2005; maent yn gymwys i Gymru a deuant i rym ar 11 Tachwedd 2005.

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.

Dehongli**Interpretation**

2.-(1) Yn y Rheoliadau hyn-

2.-(1) In these Regulations-

ystyr "ategolyn bwyd" ("*food supplement*") yw unrhyw fwyd a fwriedir i ychwanegu at ddeiet normal ac sydd-

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

(a) yn ffynhonnell grynodedig o fitamin neu fwyn neu sylwedd arall ag iddi effaith faethol neu ffysiolegol, ar ei phen ei hun neu mewn cyfuniad; a

"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

(b) yn cael ei werthu ar ffurf dogn;

(1) 1990 p.16; amnewidiwyd adran 1(1) a (2) (diffiniad o "food") gan O.S. 2004/2990; diwygiwyd adran 53(2) gan Atodlen 6 i Ddeddf Safonau Bwyd 1999 (1999 p.28) ac O.S. 2004/2990.

(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) Trosglwyddwyd swyddogaethau'r Ysgrifennydd Gwladol o dan Ddeddf Diogelwch Bwyd 1990, i'r graddau y maent yn arferadwy o ran Cymru, i Gynulliad Cenedlaethol Cymru gan Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 1999 (O.S. 1996/672).

(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 Rhif L31, 1.2.2002, t.1. Diwygiwyd y Rheoliad hwnnw ddiwethaf gan Reoliad (EC) Rhif 1642/2003 Senedd Ewrop a'r Cyngor (OJ Rhif L245, 29.9.2003, t.4)

(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)

mae i "awdurdod bwyd" ("*food authority*") yr un ystyr â "food authority" yn adran 5(1A) a (3)(a) a (b) yn Neddf Diogelwch Bwyd 1990;

ystyr "awdurdod iechyd porthladd" ("*port health authority*") o ran unrhyw ardal iechyd porthladd a sefydlwyd drwy orchymyn o dan adran 2(3) o Ddeddf Iechyd y Cyhoedd (Rheoli Clefydau) 1984(a), awdurdod iechyd porthladd ar gyfer yr ardal honno a sefydlwyd gan orchymyn o dan adran 2(4) o'r Ddeddf honno.

ystyr "baban" ("*infant*") yw plentyn o dan ddeuddeg mis oed;

mae i "bwydydd proses sydd wedi'u seilio ar rawn" ("*processed cereal-based food*") a "bwyd babanod" ("*baby food*") yr ystyr a roddir iddynt yn Rheoliadau Bwydydd Proses sydd wedi'u Seilio ar Rawn a Bwydydd Babanod ar gyfer Babanod a Phlant Ifanc (Cymru) 2004(1);

ystyr "Cyfarwyddeb 2001/15/EC" ("*Directive 2001/15/EC*") yw Cyfarwyddeb y Comisiwn 2001/15/EC(2) ar sylweddau y gellir eu hychwanegu at ddibenion maethol penodol mewn bwydydd at ddefnydd maethol neilltuol, fel y'i diwygiwyd gan Gyfarwyddeb y Comisiwn 2004/5/EC(3);

ystyr "y Ddeddf" ("*the Act*") yw Deddf Diogelwch Bwyd 1990;

ystyr "fferyllydd" ("*pharmacist*") yw person sy'n cynnal busnes fferyllool yn gyfreithiol o fewn ystyr adran 69 o Ddeddf Meddyginiaethau 1968(4);

ystyr "fformiwla fabanod" ("*infant formula*") yw bwyd y bwriadwyd ei ddefnyddio'n faethol gan fabanod sydd mewn iechyd da yn ystod pedwar i chwe mis cyntaf eu bywyd ac sydd ar ei ben ei hun yn diwallu anghenion maethol y babanod hynny;

ystyr "fformiwla ddilynol" ("*follow-on formula*") yw bwyd y bwriadwyd ei ddefnyddio'n faethol gan fabanod sydd mewn iechyd da sy'n bedwar mis oed neu drosodd ac mae'n ffurfio'r brif elfen hylif mewn deiet sy'n amrywio'n gynyddol;

"ffurf dogn" ("*dose form*") yw ffurf megis capsïwlau, pastiliau, tabledi, pils, a ffurfiau eraill tebyg, codenni o bowdr, ffiolau o hylif, poteli sy'n gweinyddu diferion, a ffurfiau eraill tebyg o hylifau neu bowdrau a luniwyd i'w cymryd mewn mesurau o unedau bach;

be suffering;

"Directive 2001/15/EC" ("*Cyfarwyddeb 2001/15/EC*") means Commission Directive 2001/15/EC(1) on substances that may be added for specific nutritional purposes in foods for particular nutritional uses, as amended by Commission Directive 2004/5/EC(2);

"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(3);

(1) O.S. 2004/314 (Cy.32).

(2) OJ Rhif L52, 22.2.2001, t.19, fel y mae wedi'i gywiro gan Gywiriad (OJ Rhif L253, 21.9.2001, t.34).

(3) OJ Rhif L14, 21.1.2004, t.19.

(4) 1968 p.67; diwygiwyd adran 69 gan Ddeddf Fferyllywyr (Ffitrwydd i Ymarfer) 1997 (1997 p.19), yr Atodlen, paragraff 5, o ddyddiad sydd i'w bennu.

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

(2) OJ No. L14, 21.1.2004, p.19.

(3) 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.

ystyr "tryptoffan" ("*tryptophan*") yw tryptoffan dehydroadol, tryptoffan chwithdroadol neu dryptoffan rasemig, neu unrhyw halwyn neu beptid a baratowyd o unrhyw un o'r ffurfiau hynny;

ystyr "tystysgrif feddygol briodol" ("*appropriate medical certificate*") yw tystysgrif ysgrifenedig a roddir gan ymarferydd meddygol cofrestredig fod ar berson angen bwyd yr ychwanegwyd tryptoffan ato i drin cyflwr y dadansoddodd yr ymarferydd meddygol cofrestredig fod y person hwnnw'n dioddef oddi wrtho;

mae "ysbyty" ("*hospital*") yn cynnwys clinig, cartref nyrsio neu sefydliad tebyg.

(2) Yn y Rheoliadau hyn o ran cyfeiriadau at ychwanegu tryptoffan at fwyd-

- (a) nid ydynt yn cynnwys achosion lle y mae bwyd nad yw ond yn cynnwys tryptoffan sy'n digwydd yn naturiol ynddo yn cael ei ychwanegu at unrhyw fwyd arall o'r fath neu at fwyd nad yw'n cynnwys tryptoffan;
- (b) ond maent fel arall yn cynnwys achosion lle y cafodd bwyd y cafodd tryptoffan ei ychwanegu ato ei ychwanegu at unrhyw fwyd arall,

ac nid yw cyfeiriadau yn rheoliad 4 a 5 at fwyd sy'n cynnwys tryptoffan yn cynnwys achos lle nad yw'r tryptoffan hwnnw ond yn digwydd yn naturiol yn y bwyd neu mewn cynhwysyn yn y bwyd.

Rhagdybiaeth

3. Os eir yn groes i unrhyw ofynion yn y Rheoliadau hyn o ran unrhyw fwyd a bod y bwyd hwnnw'n rhan o swp, lot neu lwyth o fwyd o'r un dosbarth neu ddisgrifiad, rhagdybir, hyd nes y profir i'r gwrthwyneb, fod yr holl fwyd yn y swp, lot neu lwyth hwnnw yn methu â chydymffurfio â'r gofynion hynny.

Gwaharddiadau

4. Yn ddarostyngedig i reoliad 5 ni chaiff neb -
- (a) ychwanegu tryptoffan at fwyd;
 - (b) gwerthu, neu gynnig ar werth, fwyd sy'n cynnwys tryptoffan
 - (c) arddangos ar werth fwyd sy'n cynnwys tryptoffan.

Eithriadau rhag y gwaharddiadau

5.-(1) Caniateir gwerthu neu gynnig ar werth fwyd sy'n cynnwys tryptoffan-

- (a) gan fferylllydd; neu
- (b) yng nghwrs gweithgareddau ysbyty,

"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(1);

"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.

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,

(1) S.I. 2004/314 (W.32).

i berson y mae tystysgrif feddygol briodol ar ei gyfer neu i rywun sy'n gweithredu ar ran y person hwnnw, a-

- (i) caiff unrhyw berson ychwanegu tryptoffan at fwyd y bwriedir ei werthu yn yr amgylchiadau hynny; a
- (ii) caiff unrhyw berson werthu, neu gynnig ar werth, fwyd sy'n cynnwys tryptoffan er mwyn ei werthu yn yr amgylchiadau hynny.

(2) Ni fydd rheoliad 4 yn gymwys o ran-

- (a) tryptoffan chwithdroadol a ychwanegwyd at unrhyw fformiwla fabanod neu fformiwla ddilynol;
- (b) tryptoffan chwithdroadol a ychwanegwyd at fwyd proses sydd wedi'i seilio ar rawn neu fwyd babanod; neu
- (c) tryptoffan chwithdroadol, ei halwynau sodiwm, potasiwm, calsiwm neu fagneswm neu ei hydroclorid a ychwanegwyd gan gydymffurfio â Chyfarwyddeb 2001/15/EC at unrhyw fwyd at ddefnydd maethol penodol y cyfeirir ato yn yr Atodiad i'r Gyfarwyddeb honno,

os yw'r sylwedd hwnnw a ychwanegir yn cydymffurfio â'r meini prawf purdeb a bennir ar gyfer y sylwedd hwnnw yn Pharmacopoeia Ewrop(1).

(3) Ni fydd rheoliad 4 yn gymwys o ran tryptoffan chwithdroadol a ychwanegwyd at unrhyw ategolyn bwyd-

- (a) os yw'r tryptoffan chwithdroadol yn cydymffurfio â'r meini prawf a bennir ar gyfer y sylwedd hwnnw yn Pharmacopoeia Ewrop; a
- (b) os nad yw'r dogn dyddiol a argymhellir ar gyfer yr ategolyn bwyd hwnnw yn fwy na 220 mg.

Tramgwyddau a chosb

6.-(1) Yn ddarostyngedig i baragraff (2), mae person sy'n mynd yn groes i reoliad 4 yn euog o dramgwydd a bydd yn agored ar gollfarn ddiannod i ddirwy nad yw'n fwy na lefel 5 ar y raddfa safonol.

(2) Nid yw fferyllydd neu berson sy'n gweithredu yng nghws gweithgareddau ysbyty sy'n mynd yn groes i reoliad 4(b) yn unig oherwydd nad yw dogfen sy'n honni ei bod yn dystysgrif feddygol briodol yn ddogfen ddilys yn cyflawni tramgwydd os oedd gan y person hwnnw, ar ôl arfer pob diwydrwydd dyladwy, achos rhesymol dros gredu bod y ddogfen yn dystysgrif feddygol briodol.

(1) Pharmacopoeia Ewrop Pumed Argraffiad, Cyfrol II (2004) Pub. y Gyfarwyddiaeth Ewropeaidd ar gyfer Ansawdd Meddyginaethau, tudalennau 2636 i 2638.

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(1).

(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.

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

Gorfodi

7.-(1) Yn ddarostyngedig i baragraff (2), rhaid i bob awdurdod bwyd orfodi a gweithredu'r Rheoliadau hyn yn ei ardal.

(2) Rhaid i bob awdurdod iechyd porthladd orfodi a gweithredu'r Rheoliadau hyn yn ei ddosbarth o ran bwyd a fewnforiwyd.

Cymhwyso amrywiol ddarpariaethau'r Ddeddf

8. Bydd darpariaethau canlynol y Ddeddf yn gymwys at ddibenion y Rheoliadau hyn gyda'r addasiad bod yn rhaid dehongli unrhyw gyfeiriad yn y darpariaethau hynny at y Ddeddf neu Ran ohoni fel cyfeiriad at y Rheoliadau hyn-

- (a) adran 2 (ystyr estynedig "sale" etc.);
- (b) adran 3 (rhagdybio bod bwyd wedi'i fwriadu i bobl ei fwyta);
- (c) adran 20 (tramgwyddau oherwydd bai person arall);
- (ch) adran 21 (amddiffyniad o ddiwydrwydd dyladwy) fel y mae'n gymwys at ddibenion adran 14 neu 15;
- (d) adran 30(8) (sy'n ymwneud â thystiolaeth ddogfennol);
- (dd) adran 33(1) (rhwystro etc. swyddogion);
- (e) adran 33(2), gyda'r addasiad y bernir bod y cyfeiriad at "any such requirement as is mentioned in subsection (1)(b) above" yn gyfeiriad at unrhyw ofyniad a grybwyllir yn yr is-adran honno fel y'i cymhwysir gan is-baragraff (dd) uchod;
- (f) adran 35(1)(cosbi tramgwyddau)(1) i'r graddau y mae'n berthnasol i dramgwyddau o dan adran 33(1) fel y'i cymhwysir gan baragraff (dd) uchod;
- (ff) adran 35(2) a (3) i'r graddau y mae'n ymwneud â thrangwyddau o dan adran 33(2) fel y'i cymhwysir gan baragraff (e) uchod;
- (g) adran 36 (tramgwyddau gan gyrff corfforaethol);
- (ng) adran 36A (tramgwyddau gan bartneriaethau Albanaidd)(2); ac
- (h) adran 44 (amddiffyn swyddogion sy'n gweithredu'n ddidwyll).

Enforcement

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

(2) Each port health authority must 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 apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part of it must 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" is 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)(1) 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)(2); and
- (l) section 44 (protection of officers acting in good faith).

(1) Diwygiwyd adran 35(1) gan Ddeddf Cyfiawnder Troseddol 2003 (2003 p.44), Atodlen 26, paragraff 42, o ddyddiad sydd i'w bennu.

(2) Mewnosodwyd adran 36A gan Ddeddf Safonau Bwyd 1999 (1999 p.28), Atodlen 5, paragraff 16.

(1) Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c.44), Schedule 26, paragraph 42, from a date to be appointed.

(2) Section 36A was inserted by the Food Standards Act 1999 (1999 c.28), Schedule 5, paragraph 16.

Condemnio bwyd

9. Pan gaiff unrhyw fwyd ei ardystio gan ddadansoddydd bwyd ei fod yn fwyd y mae'n dramgwydd o dan y Rheoliadau hyn i'w werthu, ceir trin y bwyd hwnnw at ddibenion adran 9 o'r Ddeddf (y caniateir i fwyd gael ei atafaelu a'i ddifa ar orchymyn ynad heddwch oddi tani)(1) fel methiant i gydymffurfio â gofynion diogelwch bwyd.

Dirymu

10.-(1) Dirymir Rheoliadau Tryptoffan mewn Bwyd 1990(2) o ran Cymru.

(2) Dirymir rheoliad 10 o Reoliadau Bwyd at Ddefnydd Maethol Neilltuol (Ychwanegu Sylweddau at Ddibenion Maethol Penodol) (Cymru) 2002(3) a rheoliad 14 o Reoliadau Bwydydd Proses sydd wedi'u Seilio ar Rawn a Bwydydd Babanod ar gyfer Babanod a Phlant Ifanc (Cymru) 2004(4).

Llofnodwyd ar ran Cynulliad Cenedlaethol Cymru o dan adran 66(1) o Ddeddf Llywodraeth Cymru 1998(5).

8 Tachwedd 2005

D. Elis-Thomas

Llywydd y Cynulliad Cenedlaethol

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- (1) Diwygiwyd adran 9 ac adran 8 gan O.S. 2004/3279.
 - (2) O.S. 1990/1728, fel y'i diwygiwyd gan O.S. 1990/2486, 2002/2939 (Cy.280), 2004/314 (Cy.32).
 - (3) O.S.2002/2939 (Cy.280) y mae diwygiad iddynt nad ydynt yn gymwys i'r Rheoliadau hyn.
 - (4) O.S. 2004/314 (Cy.32).
 - (5) 1998 p.38.

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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)(1) as failing to comply with food safety requirements.

Revocations

10.-(1) The Tryptophan in Food Regulations 1990(2) are revoked in relation to Wales.

(2) Regulation 10 of the Food for Particular Nutrition Use (Addition of Substances for Specific Nutritional Purposes)(Wales) Regulations 2002(3) and regulation 14 of the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Wales) Regulations 2004(4) are revoked.

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(5).

8 November 2005

The Presiding Officer of the National Assembly

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- (1) Section 9 and section 8 were amended by S.I. 2004/3279.
 - (2) S.I. 1990/1728, amended by S.I. 1990/2486, 2002/2939 (W.280), 2004/314 (W.32).
 - (3) S.I. 2002/2939 (W.280) to which there is an amendment not relevant to these Regulations.
 - (4) S.I. 2004/314 (W.32).
 - (5) 1998 c.38.

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