CYNULLIAD CENEDLAETHOL CYMRU

OFFERYNNAU STATUDOL

2002 Rhif 2939 (Cy.280)

BWYD, CYMRU

Rheoliadau Bwyd at Ddefnydd Maethol Neilltuol (Ychwanegu Sylweddau at Ddibenion Maethol Penodol) (Cymru) 2002

NODYN ESBONIADOL

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

1. Mae'r Rheoliadau hyn yn gweithredu yng Nghymru Gyfarwyddeb y Cyngor 2001/15/EC ar sylweddau y gellir eu hychwanegu at ddibenion maethol penodol mewn bwydydd at ddefnydd maethol neilltuol.

2. Mae'r Rheoliadau hyn yn ymwneud â bwyd ar gyfer y rhan fwyaf o ddefnyddiau maethol neilltuol (ceir diffiniad o "bwyd DMN dynodedig" yn rheoliad 2(1) sy'n eithrio fformwlâu babanod, fformwlâu dilyn ymlaen, bwydydd seiliedig ar rawn a broseswyd a bwydydd babanod a fwriadwyd ar gyfer babanod a phlant ifanc) pan fo sylwedd sy'n dod o fewn un o'r categorïau canlynol wedi cael ei ychwanegu at y bwyd hwnnw at ddiben maethol penodol: fitaminau, mwynau; asidau amino; carnitin a thawrin; niwcelotidau, colin ac inositol. Mae'r Rheoliadau yn gwahardd gwerthu bwydydd o'r fath oni bai bod y sylwedd wedi'i restru o dan y categori perthnasol yn Atodlen 1 neu, yn achos bwydydd at ddibenion meddygol arbennig, wedi'i restru o dan y categori perthnasol yn naill ai Atodlen 1 neu 2. Rhaid bodloni meini prawf perthnasol sy'n ymwneud â phurdeb ar gyfer y sylwedd. (Rheoliad 3(1) i (3)).

NATIONAL ASSEMBLY FOR WALES

STATUTORY INSTRUMENTS

2002 No. 2939 (W.280)

FOOD, WALES

The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations implement in Wales Commission Directive 2001/15/EC on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.

2. These Regulations concern food for most particular nutritional uses (definition of "designated PNU food" in regulation 2(1) which excludes infant formulae, follow-on formulae, processed cereal-based foods and baby foods intended for infants and young children) where there has been added to that food for a specific nutritional purpose a substance falling within one of the following categories : vitamins; minerals; amino acids; carnitine and taurine; nucleotides, choline and inositol. The Regulations prohibit the sale of such food unless the substance is listed under the relevant category in Schedule 1 or, in the case of foods for special medical purposes, is listed under the relevant category in either Schedule 1 or 2. Relevant purity criteria must be met for the substance. (Regulation 3(1) to (3)).

3. Mae'r Rheoliadau hefyd yn gosod cyfyngiadau cyffredinol ar werthu bwydydd DMN dynodedig y defnyddiwyd unrhyw sylweddau at ddibenion maethol penodol wrth eu cyhyrchu (rheoliad 3(4)); ac yn ei gwneud hi'n ofynnol i'r gweithgynhyrchydd neu'r mewnforiwr gyflewni gwybodaeth i'r Asiantaeth Safonau Bwyd os gwneir cais am hynny er mwyn gwirio bod y safonau hynny wedi'u bodloni (rheoliad 4). Mae'r Rheoliadau yn gwahardd y gweithgynhyrchydd neu'r mewnforiwr rhag gwerthu bwydydd DMN dynodedig penodol y mae L-tryptoffan wedi cael ei ychwanegu atynt at ddiben maethol penodol, oni bai bod yr Asiantaeth Safonau Bwyd wedi cael ei hysbysu ymlaen llaw cyn bod bwyd o'r math neilltuol hwnnw yn cael ei farchnata am y tro cyntaf (rheoliad 5).

4. Mae'r Rheoliadau yn gwneud darpariaeth mewn perthynas â chyfrifoldebau ar gyfer gorfodi (rheoliad 6); creu tramgwyddau a chosbau (rheoliad 7) ac yn cymhwyso rhai o ddarpariaethau Deddf Diogelwch Bwyd 1990 (rheoliad 9). Mae'r Rheoliadau hefyd yn cynnig amddiffyniad mewn perthynas ag allforion, yn unol ag Erthyglau 2 a 3 o Gyfarwyddeb y Cyngor 89/397/EEC (OJ Rhif L186, 30.6.89, t.23) ar reolaeth swyddogol bwydydd (rheoliad 8).

5. Mae'r Rheoliadau hefyd yn datgymhwyso'r gwaharddiadau yn Rheoliadau Tryptoffan mewn Bwyd 1990 (o safbwynt eu cymhwyso mewn perthynas â Chymru) i'r graddau y maent yn gwrthdaro â Chyfarwyddeb 2001/15/EC, Erthygl 5 o Gyfarwyddeb y Comisiwn 91/321/EEC (OJ Rhif L175, 4.7.91, t.35) ar fformwlâu babanod a fformwlâu dilyn ymlaen ac Erthygl 5 o Gyfarwyddeb y Comisiwn 96/5/EC (OJ Rhif L49, 28.2.96, t.17) ar fwydydd seiliedig ar rawn a broseswyd a bwydydd babanod ar gyfer babanod a phlant ifanc (rheoliad 10).

6. Paratowyd arfarniad Rheoliadol ar gyfer y Rheoliadau hyn yn unol ag adran 65 o Ddeddf Llywodraeth Cymru 1998 a'i osod yn Llyfrgell Cynulliad Cenedlaethol Cymru. Gellir cael copïau oddi wrth yr Asiantaeth Safonau Bwyd, Llawr 1, Southgate House, Caerdydd CF10 1EN.

3. The Regulations also impose general restrictions on the sale of designated PNU foods in the manufacture of which any substances have been used for specific nutritional purposes (regulation 3(4)); and require the manufacturer or importer to supply the Food Standards Agency with information on request to verify that those restrictions are met (regulation 4). The Regulations prohibit the sale by the manufacturer or importer of certain designated PNU foods to which L-tryptophan has been added for a specific nutitional purpose, unless prior notification has been given to the Food Standards Agency before the first marketing of food of that particular type. (regulation 5).

4. The Regulations make provision as to responsibilities for enforcement (regulation 6); create offences and penalties (regulation 7) and apply certain provisions of the Food Safety Act 1990 (regulation 9). The Regulations provide a defence in relation to exports, in accordance with Articles 2 and 3 of Council Directive 89/397/EEC (OJ No. L186, 30.6.89, p.23) on the official control of foodstuffs (regulation 8).

5. The Regulations also disapply the prohibitions in the Trypophan in Food Regulations 1990 (in their application to Wales) in so far as they conflict with Directive 2001/15/EC, Article 5 of Commission Directive 91/321/EEC (OJ No. L175, 4.7.91, p.35) on infant formulae and follow-on formulae and Article 5 of Commission Directive 96/5/EC (OJ No. L49, 28.2.96, p.17) on processed cereal-based foods and baby foods for infants and young children (regulation 10).

6. A Regulatory appraisal for these Regulations has been prepared pursuant to section 65 of the Government of Wales Act 1998 and placed in the Library of the National Assembly for Wales. Copies may be obtained from the Food Standards Agency, 1st Floor, Southgate House, Cardiff CF10 1EN.

OFFERYNNAU STATUDOL

2002 Rhif 2939 (Cy.280)

BWYD, CYMRU

Rheoliadau Bwyd at Ddefnydd Maethol Neilltuol (Ychwanegu Sylweddau at Ddibenion Maethol Penodol) (Cymru) 2002

Wedi'u gwneud *27 Tachwedd 2002*

Yn dod i rym yn unol â rheoliad 1(2) a (3)

Drwy arfer y pwerau a roddwyd gan adrannau 16(1)(f), 17(1), 26(3) a 48(1) o Ddeddf Diogelwch Bwyd 1990(**a**) ac sydd bellach wedi'u breinio yng Nghynulliad Cenedlaethol Cymru(**b**), mae'r Cynulliad Cenedlaethol ac yntau wedi parchu, yn unol ag adran 48(4A) o'r Ddeddf honno, gyngor perthnasol a roddwyd gan yr Asiantaeth Safonau Bwyd ac ar ôl ymgynghori fel sy'n ofynnol o dan erthygl 9 o Reoliad (EC) Rhif 178/2002 Senedd Ewrop a'r Cyngor(**c**) sy'n pennu egwyddorion cyffredinol a gofynion cyfraith bwyd, yn ogystal â sefydlu Awdurdod Diogelwch Bwyd Ewrop a gosod gweithdrefnau ar gyfer materion sy'n ymwneud â diogelwch bwyd ac yn unol ag adran 48(4) a (4B) o'r Ddedddf honno, yn gwneud y Rheoliadau canlynol:

Enwi, cymhwyso a chychwyn

1.-(1) Enw'r Rheoliadau hyn yw Rheoliadau Bwyd at Ddefnydd Maethol Neilltuol (Ychwanegu Sylweddau at Ddibenion Maethol Penodol) (Cymru) 2002 ac maent yn gymwys i Gymru yn unig.

(2) Daw rheoliadau 1, 5 a 10, a rheoliad 2 a rheoliadau 6 i 9 i'r graddau y maent yn ymwneud â rheoliad 5, i rym ar 31 Rhagfyr 2002.

(a) 1990 p.16.

(b) Trosglwyddwyd swyddogaethau the Secretary of State o dan Ddeddf Diogelwch Bwyd 1990, i'r graddau y maent yn arferadwy mewn perthynas â Chymru, i Gynulliad Cenedlaethol Cymru gan Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 1999 (O.S. 1999/672).

(c) OJ Rhif L31, 1.2.2002, t.1.

STATUTORY INSTRUMENTS

2002 No. 2939 (W.280)

FOOD, WALES

The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002

Made *27th November 2002*

Coming into force

in accorance with regulation 1(2) and (3)

In exercise of the powers conferred by sections 16(1)(f), 17(1), 26(3) and 48(1) of the Food Safety Act 1990(**a**) and now vested in the National Assembly for Wales(**b**), the National Assembly 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(**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 and in accordance with section 48(4) and (4B) of that Act, makes the following Regulations:

Citation, application and commencement

1.-(1) These Regulations may be cited as the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002 and extend to Wales only.

(2) Regulations 1, 5 and 10, and regulations 2 and 6 to 9 in so far as they relate to regulation 5, come into force on 31 December 2002.

(a) 1990 c.16.

(b) 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. 1999/672).

(c) OJ No. L31, 1.2.2002, p.1.

(3) Daw gweddill y Rheoliadau hyn i rym -

(a) ar 31 Rhagfyr 2002 mewn perthynas â bwyd L-tryptoffan; a

(b) mewn unrhyw achos arall ar 1 Ebrill 2004.

Dehongli

2.-(1) Yn y Rheoliadau hyn -

ystyr "bwyd DMN" (*"PNU food"*) yw bwyd at ddefnydd maethol neilltuol -

(a) y mae, oherwydd ei gyfansoddiad arbennig neu y broses o'i gynhyrchu, gwahaniaeth amlwg rhyngddo â bwyd a fwriadwyd i'w fwyta'n arferfol, a

(b) sy'n cael ei werthu mewn modd sy'n dangos a ydyw'n addas ar gyfer y diben maethol penodol honedig;

ystyr "bwyd DMN dynodedig" ("*designated PNU food*") yw unrhyw fwyd DMN heblaw am fformwlâu babanod, fformwlâu dilyn ymlaen, bwydydd seiliedig ar rawn a broseswyd a bwydydd babanod a fwriadwyd ar gyfer babanod a phlant ifanc;

ystyr "bwyd L-tryptoffan" ("*L-tryptophan food*") yw unrhyw fwyd DMN dynodedig sy'n fwyd y mae L-tryptoffan, neu unrhyw un o'i halwynau sodiwm, potasiwm, calsiwm neu fagnesiwm neu ei hydroclorid, wedi'i ychwanegu ato at ddiben maethol penodol;

ystyr "Cyfarwyddeb 89/398" ("*Directive 89/398*") yw Cyfarwyddeb y Cyngor 89/398/EEC(**a**) ar gyd-ddynesiad cyfreithiau Aelod-wladwriaethau sy'n ymwneud â bwydydd a fwriadwyd at ddefnydd maethol neilltuol, fel y'i diwygiwyd gan Gyfarwyddeb 1999/41/EC Senedd Ewrop a'r Cyngor(**b**);

ystyr "Cyfarwyddeb 2001/15" ("*Directive 2001/15*") yw Cyfarwyddeb y Comisiwn 2001/15/EC(**c**) (fel y'i cywiriwyd(**ch**)) ar sylweddau y gellir eu hychwanegu at ddibenion maethol penodol mewn bwydydd at ddefnydd maethol neilltuol;

ystyr "defnydd maethol neilltuol" ("*particular nutritional use*") yw bodloni gofynion maethol neilltuol -

(a) rhai categorïau o bobl y mae eu prosesau treulio, neu eu metaboledd yn afreolus, neu

(b) rhai categorïau o bobl y mae eu cyflwr seicolegol yn golygu ei bod o fudd iddynt fwyta, a hynny dan reolaeth, unrhyw sylwedd mewn bwyd, neu

(a) OJ Rhif L186, 30.6.89, t.27.

(b) OJ Rhif L172, 8.7.1999, t.38.

(c) OJ Rhif L52, 22.2.2001, t.19.

(ch) OJ Rhif L253, 21.9.2001, t.34.

(3) The remainder of these Regulations come into force -

(a) on 31 December 2002 in relation to an L-tryptophan food; and

(b) in any other case on 1st April 2004.

Interpretation

2.-(1) In these Regulations -

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

"designated PNU food" ("*bwyd DMN dynodedig*") means any PNU food other than infant formulae, follow-on formulae, processed cereal-based foods and baby foods intended for infants and young children;

"Directive 89/398"("*Cyfarwyddeb 89/398*") means Council Directive 89/398/EEC(**a**) on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, as amended by Directive 1999/41/EC of the European Parliament and of the Council(**b**);

"Directive 2001/15" ("*Cyfarwyddeb 2001/15*") means Commission Directive 2001/15/EC(**c**) (as corrected(**d**)) on substances that may be added for specific nutritional purposes in foods for particular nutritional uses;

"L - tryptophan food" ("*bwyd L-tryptoffan*") means any designated PNU food being a food to which L-tryptophan, or any of its sodium, potassium, calcium or magnesium salts or its hydrochloride, has been added for a specific nutritional purpose;

"PNU food" ("*bwyd DMN*") means a food for a particular nutritional use which -

(a) owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption, and

(b) is sold in such a way as to indicate its suitability for its claimed particular nutritional purpose;

"particular nutritional use" ("*defnydd maethol neilltuol*") means the fulfilment of the particular nutritional requirements of -

(a) certain categories of persons whose digestive processes are, or whose metabolism is, disturbed, or

(b) certain categories of persons whose physiological condition renders them able to obtain a special benefit from the controlled consumption of any substance in food, or

(a) OJ No. L186, 30.6.89, p.27.

(b) OJ No. L172, 8.7.1999, p.38.

(c) OJ No. L52, 22.2.2001, p.19.

(d) OJ No. L253, 21.9.2001, p.34.

(c) babanod neu bobl ifanc sydd mewn iechyd da; ac

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

mae "gwerthu" ("*sell*") yn cynnwys meddu gyda'r bwriad o werthu a chynnig, amlygu neu hysbysebu gyda'r bwriad o werthu.

(2) Mae i ymadroddion eraill a ddefnyddir yn y Rheoliadau hyn ac yng Nghyfarwyddeb 89/398 neu 2001/15 yr un ystyr yn y Rheoliadau hyn ag sydd iddynt yn y Gyfarwyddeb dan sylw.

(c) infants or young children in good health; and

"sell" ("*gwerthu*") includes possess for sale and offer, expose or advertise for sale.

(2) Other expressions used both in these Regulations and in Directive 89/398 or 2001/15 have the same meaning in these Regulations as they have in the Directive concerned.

Cyfyngiadau ar werthu

3.-(1) Ni chaiff unrhyw berson werthu unrhyw fwyd DMN dynodedig sy'n fwyd y mae sylwedd sy'n dod o fewn un o'r categorïau a grybwyllwyd ym mharagraff (2) wedi cael ei ychwanegu ato at ddiben maethol penodol oni bai bod y sylwedd hwnnw -

(a) yn cael ei restru o dan y categori hwnnw-

(i) yn achos unrhyw fwyd at ddibenion meddygol arbennig, yn Atodlen 1 neu 2; a

(ii) mewn unrhyw achos arall, yn Atodlen 1; a

(b) yn cydymffurfio â'r meini prawf perthnasol ar burdeb y cyfeiriwyd atynt ym mharagraff (3).

(2) At ddibenion paragraff (1), y categorïau yw -

(a) fitaminau,

(b) mwynau,

(c) asidau amino,

(ch) carnitin a thawrin,

(d) niwcleotidau, a

(dd) colin ac inositol.

(3) Y meini prawf perthnasol ar burdeb at ddibenion paragraff (1)(b) yw -

(a) y meini prawf ar burdeb, os o gwbl, a bennir gan ddeddfwriaeth y Gymuned at ddefnyddio'r sylwedd dan sylw wrth gynhyrchu bwyd at ddibenion heblaw am y rhai a gwmpesir gan Gyfarwyddeb 2001/15, neu

(b) os nad oes meini prawf ar burdeb o'r fath, meini prawf ar burdeb a dderbynnir yn gyffredinol ar gyfer y sylwedd dan sylw a argymhellir gan gyrff cenedlaethol.

(4) Ni chaiff unrhyw berson werthu unrhyw fwyd DMN dynodedig y defnyddiwyd unrhyw sylwedd at ddiben maethol penodol wrth ei gynhyrchu oni bai bod y bwyd hwnnw -

(a) yn ddiogel pan gaiff ei ddefnyddio yn unol â chyfarwyddiadau'r gweithgynhyrchydd (os o gwbl); a

(b) yn bodloni gofynion maethol neilltuol y bobl y mae wedi'i fwriadu ar eu cyfer,

Restrictions on sale

3.-(1) No person shall sell any designated PNU food being a food to which a substance falling within one of the categories mentioned in paragraph (2) has been added for a specific nutritional purpose unless that substance -

(a) is listed under that category-

(i) in the case of any food for special medical purposes, in Schedule 1 or 2; and

(ii) in any other case, in Schedule 1; and

(b) complies with the relevant purity criteria referred to in paragraph (3).

(2) For the purposes of paragraph (1), the categories are -

(a) vitamins,

(b) minerals,

(c) amino acids,

(d) carnitine and taurine,

(e) nucleotides, and

(f) choline and inositol.

(3) The relevant purity criteria for the purposes of paragraph (1)(b) are -

(a) the purity criteria, if any, specified by Community legislation for the use of the substance in question in the manufacture of food for purposes other than those covered by Directive 2001/15, or

(b) in the absence of such purity criteria, generally acceptable purity criteria for the substance in question recommended by international bodies.

(4) No person shall sell any designated PNU food in the manufacture of which any substance has been used for a specific nutritional purpose unless that food -

(a) is safe when used in accordance with the manufacturer's instructions (if any); and

(b) fulfils the particular nutritional requirements of the persons for whom it is intended,

fel y caiff ei sefydlu gan ddata gwyddonol a dderbynnir yn gyffredinol.

Gwirio rheoliad 3(4)

4. Bydd gweithgynhyrchydd neu, fel y digwydd, mewnforiwr bwyd DMN dynodedig y defnyddiwyd sylwedd at ddiben maethol penodol wrth ei gynhyrchu yn cyflenwi'r canlynol i'r Asiantaeth Safonau Bwyd os gwneir cais am hynny -

(a) copi o'r gwaith gwyddonol a data sy'n sefydlu bod defnyddio'r sylwedd wrth gynhyrchu'r bwyd hwnnw yn creu bwyd sy'n bodloni'r meini prawf yn rheoliad 3(4), neu

(b) os yw gwaith neu ddata o'r fath wedi'u cynnwys mewn cyhoeddiad sydd ar gael yn rhwydd, cyfeiriad at y cyhoeddiad hwnnw.

Gofyniad i hysbysu

5.- (1) Yn ddarostyngedig i baragraff (2), ni chaiff gweithgynhyrchydd, neu pan fo hynny'n briodol, mewnforiwr unrhyw fwyd hysbysadwy werthu unrhyw fwyd o'r fath oni bai bod y gweithgynhyrchydd, neu pan fo hynny'n briodol, y mewnforiwr, o leiaf 3 mis cyn gosod bwyd o'r math hwnnw ar y farchnad yng Nghymru am y tro cyntaf, wedi hysbysu'r Asiantaeth Safonau Bwyd yn ysgrifenedig drwy anfon model o'r label sydd i'w ddefnyddio ar gyfer y bwyd hwnnw a manylion am gyfansoddiad y bwyd.

(2) Ni fydd paragraff (1) yn gymwys os yw'r gweithgynhyrchydd neu, pan fo hynny'n briodol, y mewnforiwr eisoes wedi hysbysu'r Asiantaeth Safonau Bwyd cyn gosod bwyd o'r math penodol hwnnw ar y farchnad mewn rhan arall o'r Deyrnas Unedig am y tro cyntaf yn unol â darpariaeth gyfatebol sy'n cael effaith yno.

(3) Yn y rheoliad hwn ystyr "bwyd hysbysadwy" ("*notifiable food*") yw unrhyw fwyd L-tryptoffan

(a) sydd wedi'i fwriadu i gael ei ddefnyddio mewn deietau cyfyngu-ar-ynni er mwyn colli pwysau;

(b) sydd wedi'i fwriadu i ddiwallu ymdrech gyhyrol sylweddol, yn arbennig ar gyfer sbortsmyn; neu

(c) sydd ar gyfer pobl sy'n dioddef gan anhwylderau carbohydrad-metaboliaeth (clefyd siwgr).

Gorfodi

6. Bydd pob awdurdod bwyd yn gorfodi ac yn gweithredu'r Rheoliadau hyn yn ei ardal.

as established by generally accepted scientific data.

Verification of regulation 3(4)

4. The manufacturer or, as the case may be, the importer of a designated PNU food in the manufacture of which a substance has been used for a specific nutritional purpose shall supply to the Food Standards Agency on request -

(a) a copy of the scientific work and data establishing that the use of that substance in the manufacture of that food results in a food which meets the criteria in regulation 3(4), or

(b) if such work and data are contained in a publication which is readily available, a reference to that publication.

Notification requirement

5. - (1) Subject to paragraph (2), the manufacturer or, where appropriate, the importer of any notifiable food shall not sell any such food unless at least 3 months before placing food of that particular type on the market in Wales for the first time the manufacturer or, where appropriate, the importer notified the Food Standards Agency in writing by forwarding to it a model of the label to be used for that food and details of the composition of the food.

(2) Paragraph (1) shall not apply if the manufacturer or, where appropriate, the importer has already notified the Food Standards Agency before placing food of that particular type on the market elsewhere in the United Kingdom for the first time in accordance with an equivelent provision having effect there.

(3) In this regulation "notifiable food" ("*bwyd hysbysadwy*") means any L- tryptophan food which is-

(a) intended for use in energy-restricted diets for weight reduction;

(b) intended to meet the expenditure of intense muscular effort, especially for sportsmen; or

(c) for persons suffering from carbohydrate-metabolism disorders (diabetes).

Enforcement

6. Each food authority shall enforce and execute these Regulations in its area.

Tramgwyddau a chosbau

7. Os bydd unrhyw berson -

(a) yn torri rheoliad 3(1) neu (4), neu

(b) yn torri, heb esgus resymol, reoliad 4 neu 5(1),

bydd y person hwnnw yn euog o dramgwydd ac yn agored ar gollfarn ddiannod i ddirwy nad yw'n fwy na lefel 5 ar y raddfa safonol.

Amddiffyniad mewn perthynas ag allforion

8. Mewn unrhyw achos am dramgwydd o dan y Rheoliadau hyn bydd yn amddiffyniad i'r person sy'n cael ei gyhuddo brofi bod y bwyd yr honnir bod y tramgwydd wedi'i gyflawni mewn perthynas ag ef wedi cael ei fwriadu i'w allforio i wlad (ac eithrio Aelod-wladwriaeth) sydd â deddfwriaeth sy'n gyffelyb i'r Rheoliadau hyn a bod y bwyd hwnnw yn cydymffurfio â'r ddeddfwriaeth honno.

Cymhwyso amrywiol ddarpariaethau'r Ddeddf

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

(a) adran 2 (ystyr estynedig "sale" etc.);

(b) adran 3 (rhagdybiaethau fod bwyd wedi'i fwriadu i gael ei fwyta gan bobl);

(c) adran 20 (tramgwyddau o ganlyniad i fai person arall);

(ch) adran 21 (amddiffyniad diwydrwydd dyladwy) fel y mae'n gymwys at ddibenion adran 8, 14 neu 15;

(d) adran 22 (amddiffyniad o gyhoeddi yng nghwrs busnes);

(dd) adran 30(8) (sy'n ymwneud â thystiolaeth ddogfennol);

(e) adran 33(1) (rhwystro etc. swyddogion);

(f) adran 33(2), gyda'r addasiad bod rhaid ystyried 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 baragraff (e) uchod;

(ff) adran 35(1) (cosbi am dramgwyddau) i'r graddau y mae'n ymwneud â thramgwyddau o dan adran 33(1) fel y cânt eu cymhwyso gan baragraff (f);

(g) adran 35(2) a (3) i'r graddau y mae'n ymwneud â thramgwyddau o dan adran 33(2) fel y'i cymhwysir gan baragraff (f) uchod;

(ng) adran 36 (tramgwyddau gan gyrff corfforaethol); ac

Offences and penalties

7. If any person -

(a) contravenes regulation 3(1) or (4), or

(b) without reasonable excuse contravenes regulation 4 or 5(1),

that person shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Defence in relation to exports

8. In any proceedings for an offence under these Regulations it shall be a defence for the person charged to prove that the food in respect of which the offence is alleged to have been committed was intended for export to a country (other than a member State) which has legislation analogous to these Regulations and that the food complies with that legislation.

Application of various provisions of the Act

9. 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 is 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 8, 14 or 15;

(e) section 22 (defence of publication in the course of business);

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

(g) section 33(1) (obstruction etc. of officers);

(h) 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 (g) above;

(i) section 35(1) (punishment of offences) in so far as it relates to offences under section 33(1) as applied by paragraph (g) above;

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

(k) section 36 (offences by bodies corporate); and

(h) adran 44 (amddifyn swyddogion sy'n gweithredu yn ddidwyll).

Diwygio Rheoliadau Tryptoffan mewn Bwyd 1990

10.-(1) Caiff Rheoliadau Tryptoffan mewn Bwyd 1990(**a**) eu diwygio (i'r graddau y maent yn ymestyn i Gymru) yn unol â pharagraff (2).

(2) Yn rheoliad 2 (gwaharddiad ar werthu, etc. bwyd sy'n cynnwys tryptoffan) -

(a) ym mharagraffau (1) a (2) yn lle'r geiriau "Subject to paragraph (4)" rhoddir y geiriau "Subject to paragraphs (4) and (4A)";

(b) ym mharagraff (3) mewnosodir ar y dechrau y geiriau "Subject to paragraph (4A) of this regulation,";

(c) ar ôl paragraff (4) mewnosodir y paragraff canlynol -

"(4A) Paragraphs (1) to (3) of this regulation 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 to any designated PNU food for a specific nutritional purpose in compliance with Commission Directive 2001/15/EC(**b**) (as corrected(**c**)) on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.";

(ch) ym mharagraff (7) -

(i) ar ôl y diffiniad o "appropriate medical certificate" mewnosodir y diffiniad canlynol -

""designated PNU food" has the meaning assigned to it by the Food for Particular Nutritional Uses (Addition of Substances for Particular Nutritional Purposes) (Wales) Regulations 2002;";

(ii) ar ôl y diffiniad o "hospital" hepgorir y gair "and" a mewnosodir y diffiniadau canlynol -

(a) O.S. 1990/1728, y mae diwygiad iddo nad yw'n berthnasol i'r Rheoliadau hyn.

(b) OJ Rhif L52, 22.2.2001, t.19.

(c) OJ Rhif L253, 21.9.2001, t.34.

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

Amendment of the Tryptophan in Food Regulations 1990

10.-(1) The Tryptophan in Food Regulations 1990(**a**) shall be amended (in so far as they extend to Wales) in accordance with paragraph (2).

(2) In regulation 2 (prohibition on sale, etc. of food containing tryptophan) -

(a) in paragraphs (1) and (2) for the words "Subject to paragraph (4)" there shall be substituted the words "Subject to paragraphs (4) and (4A)";

(b) in paragraph (3) there shall be inserted at the beginning the words "Subject to paragraph (4A) of this regulation,";

(c) after paragraph (4) there shall be inserted the following paragraph -

"(4A) Paragraphs (1) to (3) of this regulation 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 to any designated PNU food for a specific nutritional purpose in compliance with Commission Directive 2001/15/EC(**b**) (as corrected(**c**)) on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.";

(d) in paragraph (7) -

(i) after the definition of "appropriate medical certificate" there shall be inserted the following definition -

""designated PNU food" has the meaning assigned to it by the Food for Particular Nutritional Uses (Addition of Substances for Particular Nutritional Purposes) (Wales) Regulations 2002;";

(ii) after the definition of "hospital" the word "and" shall be omitted and there shall be inserted the following definitions -

(a) S.I. 1990/1728, to which there is an amendment not relevant to these Regulations.

(b) OJ No. L52, 22.2.2001, p.19.

(c) OJ No. L253, 21.9.2001, p.34.

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

"processed cereal-based food" and "baby food" have the meaning assigned to them by the Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations 1997(**b**); and".

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

"processed cereal-based food" and "baby food" have the meaning assigned to them by the Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations 1997(**b**); and".

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

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

27 Tachwedd 2002

27th November 2002

D. Elis-Thomas

Llywydd y Cynulliad Cenedlaethol

The Presiding Officer of the National Assembly

(a) O.S. 1995/77, y mae diwygiadau iddo nad ydynt yn berthnasol i'r Rheoliadau hyn.

(b) O.S. 1997/2042, y mae diwygiadau iddo nad ydynt yn berthnasol i'r Rheoliadau hyn.

(c) 1998 p.38.

(a) S.I. 1995/77, to which there are amendments not relevant to these Regulations.

(b) S.I. 1997/2042, to which there are amendments not relevant to these Regulations.

(c) 1998 c.38.

ATODLEN 1

Rheoliad 3(1)(a)

SYLWEDDAU Y GELLIR EU HYCHWANEGU AT DDIBENION MAETHOL PENODOL MEWN BWYDYDD DMN DYNODEDIG

Categori 1. Fitaminau

VITAMIN A:

- retinol
- retinyl acetate
- retinyl palmitate
- beta-carotene

VITAMIN D :

- cholecalciferol
- ergocalciferol

VITAMIN E :

- D-alpha-tocopherol
- DL-alpha-tocopherol
- D-alpha-tocopheryl acetate
- DL-alpha-tocopheryl acetate
- D-alpha-tocopheryl acid succinate

VITAMIN K :

- phylloquinone (phytomenadione)

VITAMIN B1 :

- thiamin hydrochloride
- thiamin mononitrate

VITAMIN B2 :

- riboflavin
- riboflavin 5'-phosphate, sodium

SCHEDULE 1

Regulation 3(1)(a)

SUBSTANCES WHICH MAY BE ADDED FOR SPECIFIC NUTRITIONAL PURPOSES IN DESIGNATED PNU FOODS

Category 1. Vitamins

VITAMIN A:

- retinol
- retinyl acetate
- retinyl palmitate
- beta-carotene

VITAMIN D :

- cholecalciferol
- ergocalciferol

VITAMIN E :

- D-alpha-tocopherol
- DL-alpha-tocopherol
- D-alpha-tocopheryl acetate
- DL-alpha-tocopheryl acetate
- D-alpha-tocopheryl acid succinate

VITAMIN K :

- phylloquinone (phytomenadione)

VITAMIN B1 :

- thiamin hydrochloride
- thiamin mononitrate

VITAMIN B2 :

- riboflavin
- riboflavin 5'-phosphate, sodium

NIACIN :

- nicotinic acid
- nicotinamide

PANTOTHENIC ACID :

- D-pantothenate, calcium
- D-pantothenate, sodium
- dexpanthenol

VITAMIN B6 :

- pyridoxine hydrochloride
- pyridoxine 5'-phosphate
- pyridoxine dipalmitate

FOLIC ACID :

- pteroylmonoglutamic acid

VITAMIN B12 :

- cyanocobalamin
- hydroxocobalamin

BIOTIN :

- D-biotin

VITAMIN C :

- L-ascorbic acid
- sodium-L-ascorbate
- calcium-L-ascorbate
- potassium-L-ascorbate
- L-ascorbyl 6-palmitate

Categori 2. Mwynau

CALCIUM :

- carbonate
- chloride
- salts of citric acid

NIACIN :

- nicotinic acid
- nicotinamide

PANTOTHENIC ACID :

- D-pantothenate, calcium
- D-pantothenate, sodium
- dexpanthenol

VITAMIN B6 :

- pyridoxine hydrochloride
- pyridoxine 5'-phosphate
- pyridoxine dipalmitate

FOLIC ACID :

- pteroylmonoglutamic acid

VITAMIN B12 :

- cyanocobalamin
- hydroxocobalamin

BIOTIN :

- D-biotin

VITAMIN C :

- L-ascorbic acid
- sodium-L-ascorbate
- calcium-L-ascorbate
- potassium-L-ascorbate
- L-ascorbyl 6-palmitate

Category 2. Minerals

CALCIUM :

- carbonate
- chloride
- salts of citric acid

- gluconate
- glycerophosphate
- lactate
- salts of orthophosphoric acid
- hydroxide
- oxide

MAGNESIUM :

- acetate
- carbonate
- chloride
- salts of citric acid
- gluconate
- glycerophosphate
- salts of orthophosphoric acid
- lactate
- hydroxide
- oxide
- sulphate

IRON :

- ferrous carbonate
- ferrous citrate
- ferric ammonium citrate
- ferrous gluconate
- ferrous fumarate
- ferric sodium diphosphate
- ferrous lactate
- ferrous sulphate
- ferric diphosphate (ferric pyrophosphate)
- ferric saccharate
- elemental iron (carbonyl + electrolytic + hydrogen reduced)

COPPER :

- cupric carbonate
- cupric citrate

- gluconate
- glycerophosphate
- lactate
- salts of orthophosphoric acid
- hydroxide
- oxide

MAGNESIUM :

- acetate
- carbonate
- chloride
- salts of citric acid
- gluconate
- glycerophosphate
- salts of orthophosphoric acid
- lactate
- hydroxide
- oxide
- sulphate

IRON :

- ferrous carbonate
- ferrous citrate
- ferric ammonium citrate
- ferrous gluconate
- ferrous fumarate
- ferric sodium diphosphate
- ferrous lactate
- ferrous sulphate
- ferric diphosphate (ferric pyrophosphate)
- ferric saccharate
- elemental iron (carbonyl + electrolytic + hydrogen reduced)

COPPER :

- cupric carbonate
- cupric citrate

- cupric gluconate
- cupric sulphate
- copper lysine complex

IODINE :
- potassium iodide
- potassium iodate
- sodium iodide
- sodium iodate

ZINC :
- acetate
- chloride
- citrate
- gluconate
- lactate
- oxide
- carbonate
- sulphate

MANGANESE :
- carbonate
- chloride
- citrate
- gluconate
- glycerophosphate
- sulphate

SODIUM :
- bicarbonate
- carbonate
- chloride
- citrate
- gluconate
- lactate
- hydroxide
- salts of orthophosphoric acid

- cupric gluconate
- cupric sulphate
- copper lysine complex

IODINE :
- potassium iodide
- potassium iodate
- sodium iodide
- sodium iodate

ZINC :
- acetate
- chloride
- citrate
- gluconate
- lactate
- oxide
- carbonate
- sulphate

MANGANESE :
- carbonate
- chloride
- citrate
- gluconate
- glycerophosphate
- sulphate

SODIUM :
- bicarbonate
- carbonate
- chloride
- citrate
- gluconate
- lactate
- hydroxide
- salts of orthophosphoric acid

POTASSIUM :

- bicarbonate
- carbonate
- chloride
- citrate
- gluconate
- glycerophosphate
- lactate
- hydroxide
- salts of orthophosphoric acid

SELENIUM :

- sodium selenate
- sodium hydrogen selentine
- sodium selenite

CHROMIUM (III) and their hexahydrates :

- chloride
- sulphate

MOLYBDENUM (VI) :

- ammonium molybdate
- sodium molybdate

FLUORINE :

- potassium fluoride
- sodium fluoride

Categori 3. Asidau amino

- L-alanine
- L-arginine
- L-cysteine
- Cystine
- L-histidine
- L-glutamic acid
- L-glutamine
- L-isoleucine

POTASSIUM :

- bicarbonate
- carbonate
- chloride
- citrate
- gluconate
- glycerophosphate
- lactate
- hydroxide
- salts of orthophosphoric acid

SELENIUM :

- sodium selenate
- sodium hydrogen selentine
- sodium selenite

CHROMIUM (III) and their hexahydrates :

- chloride
- sulphate

MOLYBDENUM (VI) :

- ammonium molybdate
- sodium molybdate

FLUORINE :

- potassium fluoride
- sodium fluoride

Category 3. Amino acids

- L-alanine
- L-arginine
- L-cysteine
- Cystine
- L-histidine
- L-glutamic acid
- L-glutamine
- L-isoleucine

- L-leucine
- L-lysine
- L-lysine acetate
- L-methionine
- L-ornithine
- L-phenylalanine
- L-threonine
- L-tryptophan
- L-tyrosine
- L-valine

Ar gyfer asidau amino, i'r graddau y bo hynny'n gymwys caniateir defnyddio hefyd eu halwynau sodiwm, potasiwm, calsiwm a magnesiwm yn ogystal â'u hydrocloridau

Categori 4. Carnitin a thawrin

- L-carnitine
- L-carnitine hydrochloride
- taurine

Categori 5. Niwcleotidau

- adenosine 5'-phosphoric acid (AMP)
- sodium salts of AMP
- cytidine 5'-monophosphoric acid (CMP)
- sodium salts of CMP
- guanosine 5'-phosphoric acid (GMP)
- sodium salts of GMP
- insosine 5'-phosphoric acid (IMP)
- sodium salts of IMP
- uridine 5'-phosphoric acid (UMP)
- sodium salts of UMP

Categori 6. Colin ac inositol

- choline
- choline chloride
- choline bitartrate
- choline citrate
- inositol

- L-leucine
- L-lysine
- L-lysine acetate
- L-methionine
- L-ornithine
- L-phenylalanine
- L-threonine
- L-tryptophan
- L-tyrosine
- L-valine

For amino acids, as far as applicable, also the sodium, potassium, calcium and magnesium salts as well as their hydrochlorides may be used

Category 4. Carnitine and taurine

- L-carnitine
- L-carnitine hydrochloride
- taurine

Category 5. Nucleotides

- adenosine 5'-phosphoric acid (AMP)
- sodium salts of AMP
- cytidine 5'-monophosphoric acid (CMP)
- sodium salts of CMP
- guanosine 5'-phosphoric acid (GMP)
- sodium salts of GMP
- insosine 5'-phosphoric acid (IMP)
- sodium salts of IMP
- uridine 5'-phosphoric acid (UMP)
- sodium salts of UMP

Category 6. Choline and inositol

- choline
- choline chloride
- choline bitartrate
- choline citrate
- inositol

ATODLEN 2

Rheoliad 3(1)(a)

SYLWEDDAU YCHWANEGOL Y GELLIR EU HYCHWANEGU AT DDIBENION MAETHOL PENODOL MEWN BWYDYDD AT DDIBENION MEDDYGOL ARBENNIG

Categori 3. Asidau amino

- L-aspartic acid
- L-citrulline
- glycine
- L-proline

SCHEDULE 2

Regulation 3(1)(a)

ADDITIONAL SUBSTANCES WHICH MAY BE ADDED FOR SPECIFIC NUTRITIONAL PURPOSES IN FOODS FOR SPECIAL MEDICAL PURPOSES

Category 3. Amino acids

- L-aspartic acid
- L-citrulline
- glycine
- L-proline

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