CYNULLIAD CENEDLAETHOL CYMRU

OFFERYNNAU STATUDOL

2004 Rhif 1012 (Cy.109)

BWYD, CYMRU

Rheoliadau Bwyd at Ddefnydd Maethol Neilltuol (Ychwanegu Sylweddau at Ddibenion Maethol Penodol) (Cymru) (Diwygio) 2004

NODYN ESBONIADOL

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

1. Mae'r Rheoliadau hyn, sy'n gymwys i Gymru, yn diwygio Rheoliadau Bwyd at Ddefnydd Maethol Neilltuol (Ychwanegu Sylweddau at Ddibenion Maethol Penodol) (Cymru) 2002 ("y prif Reoliadau").

2. Mae'r Rheoliadau hyn yn gweithredu -

(a) Cyfarwyddeb y Comisiwn 2004/5/EC (OJ Rhif L.14, 21.1.2004, t.19) sy'n diwygio Cyfarwyddeb 2001/15/EC er mwyn iddi gynnwys sylweddau penodol yn yr Atodiad; a

(b) Cyfarwyddeb y Comisiwn 2004/6/EC (OJ Rhif L.15, 21.1.2004, t.31) sy'n rhanddirymu Cyfarwyddeb 2001/15/EC er mwyn gohirio cymhwyso'r gwaharddiad ar fasnachu i gynhyrchion penodol.

3. Mae'r prif Reoliadau'n gymwys i fwyd ar gyfer y rhan fwyaf o ddefnydd maethol neilltuol (diffiniad o "fwydydd DMN dynodedig" yn rheoliad 2(1) o'r Rheoliadau hynny). 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; niwcleotidau; colin ac inositol, mae'r Rheoliadau hynny (yn y mwyafrif o achosion o 1 Ebrill 2004) yn gwahardd gwerthu bwyd o'r fath onid yw'r sylwedd wedi'i restru o dan y categori perthnasol yn Atodlen 1 neu, yn achos bwydydd at ddibenion meddygol arbennig, yn Atodlen 1 neu 2.

NATIONAL ASSEMBLY FOR WALES

STATUTORY INSTRUMENTS

2004 No. 1012 (W.109)

FOOD, WALES

The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) (Amendment) Regulations 2004

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations, which apply in Wales, amend the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002 ("the principal Regulations").

2. These Regulations implement -

(a) Commission Directive 2004/5/EC (OJ No. L.14, 21.1.2004, p.19) amending Directive 2001/15/EC to include certain substances in the Annex; and

(b) Commission Directive 2004/6/EC (OJ No. L.15, 22.1.2004, p.31) derogating from Directive 2001/15/EC to postpone the application of the prohibition of trade to certain products.

3. The principal Regulations apply to food for most particular nutritional uses (definition of "designated PNU foods" in regulation 2(1) of those Regulations). 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, those Regulations prohibit (in most cases from 1st April 2004) 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, Schedule 1 or 2.

4. Mae'r Rheoliadau hyn -

(a) hyd 1 Ionawr 2007, yn ddarostyngedig i amodau, yn caniatáu gwerthu bwydydd DMN dynodedig yr ychwanegwyd atynt sylwedd a restrir yn Atodlen 3 newydd i'r prif Reoliadau (rheoliadau 4(b) a 7 ac Atodlen 2);

(b) yn ychwanegu at y rhestr o sylweddau yng nghategori mwynau ac yng nghategori carnitin a thawrin sylwedd arall y gellir ei ychwanegu at ddibenion maethol penodol mewn bwydydd DMN dynodedig (rheoliad 5);

(c) yn ychwanegu at y rhestr o sylweddau yng nghategori asidau amino chwe sylwedd y gellir eu hychwanegu at ddibenion maethol penodol mewn bwydydd at ddibenion meddygol penodol (rheoliad 6 ac Atodlen 1); yn gosod amod ar ei ddefnyddio yn achos un o'r sylweddau hyn (rheoliad 4(a) ac Atodlen 1); ac wrth weithredu'r Atodiad i Gyfarwyddeb 2001/15/EC (OJ Rhif L52, 22.2.2001, t.19) yn darparu y gellir defnyddio yn lle asidau amino hefyd halwynau sodiwm, potasiwm, calsiwm a magnesiwm, yn ogystal â'u hydrocloridau (Atodlen 1);

(ch) diweddaru'r diffiniad o "Cyfarwyddeb 2001/15" (rheoliad 3).

5. Mae arfarniad rheoliadol yn unol ag adran 65 o Ddeddf Llywodraeth Cymru 1998 wedi'i baratoi a'i osod yn Llyfrgell Cynulliad Cenedlaethol Cymru ynghyd â Nodyn Trosi yn nodi sut y trosir prif elfennau Cyfarwyddebau 2004/5/EC a 2004/6/EC yn y Rheoliadau hyn. Gellir cael copïau oddi wrth yr Asiantaeth Safonau Bwyd, Llawr 11, Southgate House, Caerdydd, CF10 1EW.

4. These Regulations -

(a) allow until 1st January 2007, subject to conditions, the sale of designated PNU foods to which there has been added a substance listed in new Schedule 3 to the principal Regulations (regulations 4(b) and 7 and Schedule 2);

(b) add another substance to the list of substances in the category minerals and in the category carnitine and taurine which may be added for specific nutritional purposes in designated PNU foods (regulation 5);

(c) add six substances to the list of substances in the category amino acids which may be added for specific nutritional purposes in foods for specific medical purposes (regulation 6 and Schedule 1); impose a condition of use in the case of one of these substances (regulation 4(a) and Schedule 1); and in implementation of the Annex to Directive 2001/15/EC (OJ No. L52, 22.2.2001, p.19) provide that for amino acids also the sodium, potassium, calcium and magnesium salts, as well as their hydrochlorides may be used (Schedule 1);

(d) update the definition of "Directive 2001/15" (regulation 3).

5. A regulatory appraisal pursuant to section 65 of the Government of Wales Act 1998 has been prepared and placed in the Library of the National Assembly for Wales together with a Transposition Note setting out how the main elements of Directives 2004/5/EC and 2004/6/EC are transposed in these Regulations. Copies may be obtained from the Food Standards Agency, 11th Floor, Southgate House, Cardiff, CF10 1EW.

2004 Rhif 1012 (Cy.109)

BWYD, CYMRU

Rheoliadau Bwyd at Ddefnydd Maethol Neilltuol (Ychwanegu Sylweddau at Ddibenion Maethol Penodol) (Cymru) (Diwygio) 2004

Wedi'u gwneud 31 Mawrth 2004

Yn dod i rym 1 Ebrill 2004

Drwy arfer y pwerau a roddwyd iddo gan adrannau 16(1)(f), 17(1), 26(3) a 48(1) o Ddeddf Diogelwch Bwyd 1990(**a**) ac a freinir ynddo bellach(**b**), mae Cynulliad Cenedlaethol Cymru, 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 gan Erthygl 9 o Reoliad (EC) Rhif 178/2002 Senedd Ewrop a'r Cyngor (**c**) sy'n pennu egwyddorion cyffredinol a gofynion cyfraith fwyd, yn sefydlu Awdurdod Diogelwch Bwyd Ewrop ac yn 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, cychwyn a dehongli

1.-(1) Enw'r Rheoliadau hyn yw Rheoliadau Bwyd at Ddefnydd Maethol Neilltuol (Ychwanegu Sylweddau at Ddibenion Maethol Penodol) (Cymru) (Diwygio) 2004.

(2) Mae'r Rheoliadau hyn yn dod i rym ar 1 Ebrill 2004.

(a) 1990 p. 16.

(b) Trosglwyddwyd Swyddogaethau'r Ysgrifennydd Gwladol 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) fel y'i darllenir ynghyd ag adran 40(3) o Ddeddf 1999.

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

2004 No. 1012 (W.109)

FOOD, WALES

The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) (Amendment) Regulations 2004

Made 31st March 2004

Coming into force 1st April 2004

The National Assembly for Wales, 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 it(**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 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:

Title, commencement and interpretation

1.-(1) These Regulations may be cited as the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) (Amendment) Regulations 2004.

(2) These Regulations come into force on 1st April 2004.

(a) 1990 c. 16.

(b) Functions of the Secretary of State 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.

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

(3) Yn y Rheoliadau hyn ystyr "y prif Reoliadau" "the principal Regulations" yw Rheoliadau Bwyd at Ddefnydd Maethol Neilltuol (Ychwanegu Sylweddau at Ddibenion Maethol Penodol) (Cymru) 2002(**a**).

Diwygio'r prif Reoliadau

2. Caiff y prif Reoliadau eu diwygio yn unol â rheoliadau 3 i 7.

3. Yn rheoliad 2(1) (dehongli), yn y diffiniad o "Cyfarwyddeb 2001/15" mewnosoder ar y diwedd y geiriau ", fel y'i diwygiwyd gan Gyfarwyddeb y Comisiwn 2004/5/EC(**b**) ac fel y'i darllenir gyda Chyfarwyddeb y Comisiwn 2004/6/EC(**c**) yn rhanddirymu Cyfarwyddeb 2001/15/EC er mwyn gohirio cymhwyso'r gwaharddiad ar fasnachu i gynhyrchion penodol".

4. Yn rheoliad 3 (cyfyngiadau ar werthu) -

(a) yn lle paragraff (1) rhodder y paragraff canlynol -

"(1) Yn ddarostyngedig i baragraff (5), ni chaiff neb werthu unrhyw fwyd DMN dynodedig, sef bwyd yr ychwanegwyd ato at ddiben maethol penodol sylwedd sy'n dod o fewn un o'r categorïau a grybwyllir ym mharagraff (2) -

(a) onid yw'r sylwedd hwnnw'n 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;

(b) onid yw'r sylwedd hwnnw'n bodloni'r meini prawf perthnasol sy'n ymwneud â phurdeb ac y cyfeirir atynt ym mharagraff (3); a

(c) yn achos sylwedd a restrir yn Atodlen 2, oni fodlonir yr amodau ar ei ddefnyddio (os o gwbl) a nodir yn yr Atodlen honno sy'n ymwneud â'r sylwedd hwnnw"; a

(b) mewnosoder ar ddiwedd y paragraff canlynol -

"(5) Ni fydd y cyfyngiadau ym mharagraff (1) yn gymwys nes 1 Ionawr 2007 yn achos sylwedd sy'n dod oddi mewn i un o'r categorïau a grybwyllir ym mharagraff (2) ac a restrir o dan y categori hwnnw yn Atodlen 3-

(a) os nad yw Awdurdod Diogelwch Bwyd Ewrop wedi rhoi barn anffafriol mewn cysylltiad â defnyddio'r sylwedd hwnnw wrth weithgynhyrchu unrhyw fwyd DMN dynodedig; a

(3) In these Regulations "the principal Regulations" means the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002(**a**).

Amendment of the principal Regulations

2. The principal Regulations shall be amended in accordance with regulations 3 to 7.

3. In regulation 2(1) (interpretation), in the definition of "Directive 2001/15" there shall be inserted at the end the words ", as amended by Commission Directive 2004/5/EC(**b**) and as read with Commission Directive 2004/6/EC(**c**) derogating from Directive 2001/15/EC to postpone the application of the prohibition of trade to certain products".

4. In regulation 3 (restrictions on sale) -

(a) for paragraph (1) there shall be substituted the following paragraph -

"(1) Subject to paragraph (5), 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 -

(a) that substance 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;

(b) that substance complies with the relevant purity criteria referred to in paragraph (3); and

(c) in the case of a substance listed in Schedule 2, the conditions of use (if any) set out in that Schedule relating to that substance are met."; and

(b) there shall be inserted at the end the following paragraph -

"(5) The restrictions in paragraph (1) shall not apply until 1st January 2007 in the case of a substance falling within one of the categories mentioned in paragraph (2) and listed under that category in Schedule 3 if -

(a) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance in the manufacture of any designated PNU food; and

(a) O.S. 2002/2939 (Cy 280).

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

(c) OJ Rhif L15, 22.1.2004, t.31.

(a) S.I. 2002/2939 (W 280).

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

(c) OJ No. L15, 22.1.2004, p.31.

(b) os defnyddiwyd y sylwedd hwnnw wrth weithgynhyrchu bwyd at ddefnydd maethol neilltuol oedd ar werth yn y Gymuned Ewropeaidd ar 11 Chwefror 2004.".

5. Yn Atodlen 1 (sylweddau y gellir eu hychwanegu at ddibenion maethol penodol mewn bwydydd DMN dynodedig) -

(a) mewnosoder yng Nghategori 2 (Mwynau) o dan y pennawd "CALCIUM" ar ôl y cofnod "- oxide", y cofnod "- sulphate"; a

(b) mewnosoder yng Nghategori 4 (Carnitin a thawrin) ar ôl y cofnod "L-carnitine hydrochloride" y cofnod "L-carnitin-L-tartrate".

6. Yn lle Atodlen 2 (sylweddau ychwanegol y gellir eu hychwanegu at ddibenion maethol penodol mewn bwydydd at ddibenion meddygol arbennig) rhodder cynnwys Atodlen 1 i'r Rheoliadau hyn.

7. Ar ôl Atodlen 2 mewnosoder fel Atodlen 3 gynnwys Atodlen 2 i'r Rheoliadau hyn.

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

31 Mawrth 2004

D. Elis-Thomas

Llywydd y Cynulliad Cenedlaethol

(a) 1998 p.38.

(b) that substance was used in the manufacture of a food for a particular nutritional use which was on sale in the European Community on 11th February 2004.".

5. In Schedule 1 (substances which may be added for specific nutritional purposes in designated PNU foods) -

(a) there shall be inserted in Category 2 (Minerals) under the heading "CALCIUM" after the entry "- oxide", the entry "- sulphate"; and

(b) there shall be inserted in Category 4 (Carnitine and taurine) after the entry "L-carnitine hydrochloride" the entry "L-carnitine-L-tartrate".

6. For Schedule 2 (additional substances which may be added for specific nutritional purposes in foods for special medical purposes) there shall be substituted the contents of Schedule 1 to these Regulations.

7. After Schedule 2 there shall be inserted as Schedule 3 the contents of Schedule 2 to these Regulations.

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

31st March 2004

The Presiding Officer of the National Assembly

(a) 1998 c.38.

ATODLEN 1

Rheoliad 6

ATODLEN 2 DDIWYGIEDIG I'W RHOI YN Y PRIF REOLIADAU

"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

Sylweddau	*Amodau defnyddio*
L-arginine-L-aspartate	
L-aspartic acid	
L-citrulline	
Glycine	
L-lysine-L-aspartate	
L-lysine-L-glutamate	
L-proline	
L-serine	
N-acetyl-L-cysteine	
N-acetyl-L-methionine	Rhaid peidio â'i ddefnyddio ond mewn bwydydd a fwriedir ar gyfer pobl dros flwydd oed.

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."

SCHEDULE 1

Regulation 6

REVISED SCHEDULE 2 TO BE SUBSTITUTED IN THE PRINCIPAL REGULATIONS

"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

Substance	*Conditions of use*
L-arginine-L-aspartate	
L-aspartic acid	
L-citrulline	
Glycine	
L-lysine-L-aspartate	
L-lysine-L-glutamate	
L-proline	
L-serine	
N-acetyl-L-cysteine	
N-acetyl-L-methionine	Shall not be used except in foods intended for persons over 1 year of age.

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

ATODLEN 2

Rheoliad 7

ATODLEN 3 NEWYDD I'W MEWNOSOD YN Y PRIF REOLIADAU

"ATODLEN 3

Rheoliad 3(5)

SYLWEDDAU Y GELLIR EU HYCHWANEGU AT DDIBENION MAETHOL PENODOL MEWN BWYDYDD DMN DYNODEDIG YN UNOL Â'R RHANDDIRYMIAD YN RHEOLIAD 3(5)

Categori 1. Fitaminau

VITAMIN E:

- D-alpha tocopheryl polyethylene glycol 1000 succinate

Categori 2. Mwynau

BORON:

- boric acid
- sodium borate

CALCIUM:

- amino acid chelate
- pidolate

MAGNESIUM:

- amino acid chelate
- pidolate

IRON:

- ferrous hydroxide
- ferrous pidolate
- amino acid chelate

COPPER:

- amino acid chelate

ZINC:

- amino acid chelate

MANGANESE:

- amino acid chelate

SELENIUM:

- enriched yeast

CHROMIUM:

- amino acid chelate"

SCHEDULE 2

Regulation 7

NEW SCHEDULE 3 TO BE INSERTED IN THE PRINCIPAL REGULATIONS

"SCHEDULE 3

Regulation 3(5)

SUBSTANCES WHICH MAY BE ADDED FOR SPECIFIC NUTRITIONAL PURPOSES IN DESIGNATED PNU FOODS IN ACCORDANCE WITH THE DEROGATION IN REGULATION 3(5)

Category 1. Vitamins

VITAMIN E:

- D-alpha tocopheryl polyethylene glycol 1000 succinate

Category 2. Minerals

BORON:

- boric acid
- sodium borate

CALCIUM:

- amino acid chelate
- pidolate

MAGNESIUM:

- amino acid chelate
- pidolate

IRON:

- ferrous hydroxide
- ferrous pidolate
- amino acid chelate

COPPER:

- amino acid chelate

ZINC:

- amino acid chelate

MANGANESE:

- amino acid chelate

SELENIUM:

- enriched yeast

CHROMIUM:

- amino acid chelate"

OFFERYNNAU STATUDOL

2004 Rhif 1012 (Cy.109)

BWYD, CYMRU

Rheoliadau Bwyd at Ddefnydd Maethol Neilltuol (Ychwanegu Sylweddau at Ddibenion Maethol Penodol) (Cymru) (Diwygio) 2004

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2004 No. 1012 (W.109)

FOOD, WALES

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