



OFFERYNNAU STATUDOL
CYMRU

WELSH
STATUTORY INSTRUMENTS

2007 Rhif 2753 (Cy.232)

2007 No. 2753 (W.232)

BWYD, CYMRU

FOOD, WALES

**Rheoliadau Bwyd at Ddefnydd
Maethol Neilltuol (Diwygiadau
Amrywiol) (Cymru) 2007**

**The Food for Particular Nutritional
Uses (Miscellaneous Amendments)
(Wales) Regulations 2007**

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, sy'n gymwys o ran Cymru, yn diwygio'r Rheoliadau a enwir yn y paragraffau canlynol yn y modd a ddisgrifir yn y paragraffau hynny.

1. These Regulations, which apply in relation to Wales, amend the Regulations identified in the following paragraphs in the manner described in those paragraphs.

2. Mae'r Rheoliadau hyn yn diwygio Rheoliadau Fformiwlâ Fabanod a Fformiwlâ Ddilynol 1995 (O.S. 1995/77, fel y'i diwygiwyd, "Rheoliadau 1995") i'r graddau y maent yn gymwys o ran Cymru i ddarparu ar gyfer gweithredu a gorfodi Rheoliad y Comisiwn (EC) Rhif 1609/2006 sy'n awdurdodi rhoi ar y farchnad fformiwlâ fabanod a seilir ar hydrolysadau o brotein maidd sy'n dod o brotein llaeth buwch am gyfnod o ddwy flynedd (OJ Rhif L299, 28.10.2006, t.9). Maent yn diwygio Rheoliadau 1995 i ddarparu nad ystyrir bod person wedi mynd yn groes i'r darpariaethau sydd yn rheoliad 2 i Rheoliadau 1995 neu wedi methu cydymffurfio â hwy os yw'r gwerthiant, a fyddai fel arall wedi ffurfio toriad yn y darpariaethau hynny neu fethiant i gydymffurfio â hwy ac felly'n dramgwydd, yn werthiant o fformiwlâ babanod sy'n dod o fewn y rhanddirymiad a osodir yn Rheoliad y Comisiwn (EC) Rhif 1609/2006 (rheoliad 2(2)).

2. These Regulations amend the Infant Formula and Follow-on Formula Regulations 1995 (S.I. 1995/77, as amended, "the 1995 Regulations") in so far as they apply in relation to Wales to provide for the execution and enforcement of Commission Regulation (EC) No. 1609/2006 authorising the placing on the market of infant formula based on hydrolysates of whey protein derived from cows' milk protein for a two-year period (OJ No. L299, 28.10.2006, p.9). They amend the 1995 Regulations to provide that a person will not be considered to have contravened or failed to comply with the provisions contained in regulation 2 of the 1995 Regulations where the sale which would otherwise have constituted a contravention of or a failure to comply with those provisions and thus an offence is the sale of an infant formula falling within the derogation set out in Commission Regulation (EC) No. 1609/2006 (regulation 2(2)).

3. Mae'r Rheoliadau hyn yn diwygio Rheoliadau Bwydydd y Bwriedir eu Defnyddio mewn Deietau Cyfyngu-ar-ynni er mwyn Colli Pwysau 1997 (O.S. 1997/2182, fel y'i diwygiwyd, "Rheoliadau 1997") i'r graddau y maent yn gymwys o ran Cymru i weithredu Cyfarwydddeb y Comisiwn 2007/29/EC sy'n diwygio Cyfarwydddeb 96/8/EC ynghylch labelu, hysbysebu neu gyflwyno bwydydd a fwriedir ar gyfer deietau cyfyngu-ar-ynni er mwyn colli pwysau (OJ Rhif L139, 31.5.2007, t.22). Maent yn diwygio Rheoliadau 1997 i ddarparu ar gyfer tynnu'r gwaharddiad ar werthu

3. These Regulations amend the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 (S.I. 1997/2182, as amended, "the 1997 Regulations") in so far as they apply in relation to Wales to implement Commission Directive 2007/29/EC amending Directive 96/8/EC as regards labelling, advertising or presenting foods intended for use in energy-restricted diets for weight reduction (OJ No. L139, 31.5.2007, p.22). They amend the 1997 Regulations to provide for the removal of the prohibition on selling certain foods where the

bwydydd penodol lle y mae'r labelu, yr hysbysebu neu'r cyflwyno yn cyfeirio at leihad yn yr ystyr o newyn neu gynydd yn yr ystyr o syrffed bwyd (rheoliad 3(2)).

4. Mae'r Rheoliadau hyn yn diwygio Rheoliadau Bwyd Meddygol (Cymru) 2000 (O.S. 2000/1866 (Cy.125), fel y'i diwygiwyd, "Rheoliadau 2000") i weithredu Cyfarwyddeb y Comisiwn 2006/82/EC sy'n addasu Cyfarwyddeb 91/321/EEC ar fformiwlâu babanod a fformiwlâu dilynol a Chyfarwyddeb 1999/21/EC ar fwyd deietegol at ddibenion meddygol arbennig, oherwydd ymaelodaeth Bwlgaria a Rwmania (OJ Rhif L362, 20.12.2006, t.94). Maent yn diwygio Rheoliadau 2000 drwy amnewid diffiniad diwygiedig o "y Gyfarwyddeb" (i gymryd ystyriaeth o Gyfarwyddeb y Comisiwn 2006/82/EC) yn lle'r diffiniad presennol o "y Gyfarwyddeb" yn rheoliad 2 (dehongli) (rheoliad 4(2)).

5. Mae'r Rheoliadau hyn yn diwygio Rheoliadau Bwyd at Ddefnydd Maethol Neilltuol (Ychwanegu Sylweddau at Ddibenion Maethol Penodol) (Cymru) 2002 (O.S. 2002/2939 (Cy.280), fel y'i diwygiwyd, "Rheoliadau 2002") i weithredu Cyfarwyddeb y Comisiwn 2007/26/EC sy'n diwygio Cyfarwyddeb 2004/6/EC i ymestyn ei gyfnod cymhwyso (OJ Rhif L118, 8.5.2007, t.5). Maent yn diwygio Rheoliadau 2002 i ddarparu na fydd cyfyngiadau penodol sydd yn y Rheoliadau hynny yn gymwys ar gyfer sylweddau penodol tan 1 Ionawr 2010 (rheoliad 5(2)).

6. Mae'r Rheoliadau hyn yn diwygio Rheoliadau Bwydydd Proses sydd wedi'u Seilio ar Rawn a Bwydydd Babanod ar gyfer Babanod a Phlant Ifanc (Cymru) 2004 (O.S. 2004/314 (Cy.32), fel y'i diwygiwyd, "Rheoliadau 2004") i weithredu Cyfarwyddeb y Comisiwn 2006/125/EC ar fwydydd proses sydd wedi'u seilio ar rawn a bwydydd babanod ar gyfer babanod a phlant ifanc (OJ Rhif L339, 6.12.2006, t.16). Maent yn diwygio Rheoliadau 2004 drwy amnewid diffiniad diwygiedig o "y Gyfarwyddeb" (fel ei fod bellach yn cyfeirio at Gyfarwyddeb y Comisiwn 2006/125/EC) yn lle'r diffiniad presennol o "y Gyfarwyddeb" ym mharagraff (1) o reoliad 2 (dehongli) (rheoliad 6(2)).

7. Mae asesiad effaith rheoleiddiol llawn o'r effaith y bydd yr offeryn hwn yn ei gael ar gostau busnes a'r sector gwirfoddol ar gael gan yr Asiantaeth Safonau Bwyd, Llawr 11, Southgate House, Wood Street, Caerdydd, CF10 1EW.

labelling, advertising or presentation of that food refers to a reduction in the sense of hunger or an increase in the sense of satiety (regulation 3(2)).

4. These Regulations amend the Medical Food (Wales) Regulations 2000 (S.I. 2000/1866 (W.125), as amended, "the 2000 Regulations") to implement Commission Directive 2006/82/EC adapting Directive 91/321/EEC on infant formulae and follow-on formulae and Directive 1999/21/EC on dietary food for special medical purposes, by reason of the accession of Bulgaria and Romania (OJ No. L362, 20.12.2006, p.94). They amend the 2000 Regulations by substituting a revised definition of "the Directive" (to take account of Commission Directive 2006/82/EC) for the existing definition of "the Directive" in regulation 2 (interpretation) (regulation 4(2)).

5. These Regulations amend the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002 (S.I. 2002/2939 (W.280), as amended, "the 2002 Regulations") to implement Commission Directive 2007/26/EC amending Directive 2004/6/EC to extend its period of application (OJ No. L118, 8.5.2007, p.5). They amend the 2002 Regulations to provide that certain restrictions contained in those Regulations will not apply to certain substances until 1st January 2010 (regulation 5(2)).

6. These Regulations amend the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Wales) Regulations 2004 (S.I. 2004/314 (W.32), as amended, "the 2004 Regulations") to implement Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children (OJ No. L339, 6.12.2006, p.16). They amend the 2004 Regulations by substituting a revised definition of the "the Directive" (so that it now refers to Commission Directive 2006/125/EC) for the existing definition of "the Directive" in paragraph (1) of regulation 2 (interpretation) (regulation 6(2)).

7. A full regulatory impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Food Standards Agency, 11th Floor, Southgate House, Cardiff, CF10 1EW.

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Gwnaed 18 Medi 2007

Made 18 September 2007

*Gosodwyd gerbron
Cynulliad Cenedlaethol Cymru* 19 Medi 2007

*Laid before the National
Assembly for Wales* 19 September 2007

Yn dod i rym 15 Hydref 2007

Coming into force 15 October 2007

Mae Gweinidogion Cymru'n gwneud y Rheoliadau canlynol drwy arfer y pwerau a roddwyd gan adrannau 17(1) a (2), 26(1)(a) a 48(1) o Ddeddf Diogelwch Bwyd 1990(1).

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 17(1) and (2), 26(1)(a) and 48(1) of the Food Safety Act 1990(1).

Yn unol ag adran 48(4A) o Ddeddf Diogelwch Bwyd 1990, mae Gweinidogion Cymru wedi rhoi sylw i gyngor perthnasol a roddwyd gan yr Asiantaeth Safonau Bwyd.

In accordance with section 48(4A) of the Food Safety Act 1990, the Welsh Ministers have had regard to relevant advice given by the Food Standards Agency.

Fel sy'n ofynnol gan Erthygl 9 o Reoliad (EC) Rhif 178/2002 Senedd Ewrop a'r Cyngor, sy'n pennu egwyddorion cyffredinol a gofynion cyfraith bwyd, ac yn sefydlu Awdurdod Diogelwch Bwyd Ewrop ac yn pennu gweithdrefnau o ran materion diogelwch bwyd(2), cafwyd ymgynghori agored a thryloyw â'r cyhoedd yn ystod cyfnod paratoi a gwerthuso'r Rheoliadau hyn.

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(2), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Enwi, cymhwyso a chychwyn

1. Enw'r Rheoliadau hyn yw Rheoliadau Bwyd at Ddefnydd Maethol Neilltuol (Diwygiadau Amrywiol) (Cymru) 2007; maent yn gymwys o ran Cymru a deuant i rym ar 15 Hydref 2007.

Title, application and commencement

1. The title of these Regulations is the Food for Particular Nutritional Uses (Miscellaneous Amendments) (Wales) Regulations 2007; they apply in relation to Wales and come into force on 15 October 2007.

(1) 1990 p.16. Trosglwyddwyd swyddogaethau'r Ysgrifennydd Gwladol, i'r graddau y maent yn arferadwy o ran Cymru, i Gynulliad Cenedlaethol Cymru gan Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 1999, O.S. 1999/672. Trosglwyddwyd y swyddogaethau hynny wedyn i Weinidogion Cymru gan adran 162 o Ddeddf Llywodraeth Cymru 2006 a pharagraff 30 o Atodlen 11 iddi (p.32).

(2) OJ Rhif L31, 1.2.2002, t.1 fel y'i diwygiwyd ddiwethaf gan Reoliad y Comisiwn (EC) Rhif 575/2006 (OJ Rhif L100, 8.4.2006, t.3).

(1) 1990 c.16. 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. Those functions were transferred to Welsh Ministers by section 162 of and paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c.32).

(2) OJ No. L31, 1.2.2002, p.1, as last amended by Commission Regulation (EC) No. 575/2006 (OJ No. L100, 8.4.2006, p.3).

Diwygio Rheoliadau Fformiwla Fabanod a Fformiwla Ddilynol 1995

2.-(1) Diwygir Rheoliadau Fformiwla Fabanod a Fformiwla Ddilynol 1995(1) yn unol â pharagraff (2) i'r graddau y maent yn gymwys o ran Cymru.

(2) Yn rheoliad 22 (tramgwyddau a gorfodi)-

- (a) ym mharagraff (1) mewnosoder ar y dechrau y geiriau "Subject to paragraph (2B),"; a
- (b) yn syth ar ôl paragraff (2A) ychwaneger y paragraff canlynol-

"(2B) A person shall not be considered to have contravened or failed to comply with the provisions contained in regulation 2 where the sale which would otherwise have constituted a contravention of or a failure to comply with those provisions is the sale of an infant formula falling within the derogation set out in Article 1 of Commission Regulation (EC) No. 1609/2006 authorising the placing on the market of infant formulae based on hydrolysates of whey protein derived from cows' milk protein for a two-year period(2).".

Diwygio Rheoliadau Bwydydd y Bwriedir eu Defnyddio mewn Deietau Cyfyngu-ar-ynni er mwyn Colli Pwysau 1997

3.-(1) Diwygir Rheoliadau Bwydydd y Bwriedir eu Defnyddio mewn Deietau Cyfyngu-ar-ynni er mwyn Colli Pwysau 1997(3) yn unol â pharagraff (2) i'r graddau y maent yn gymwys o ran Cymru.

(2) Yn rheoliad 4 (labelu, hysbysebu a chyflwyno) hepgorer y geiriau "or to a reduction in the sense of hunger or an increase in the sense of satiety".

Diwygio Rheoliadau Bwyd Meddygol (Cymru) 2000

4.-(1) Diwygir Rheoliadau Bwyd Meddygol (Cymru) 2000(4) yn unol â pharagraff (2).

(2) Yn rheoliad 2 (dehongli), yn lle'r diffiniad o "y Gyfarwydddeb" ("*the Directive*") rhodder y diffiniad canlynol-

Amendment of the Infant Formula and Follow-on Formula Regulations 1995

2.-(1) The Infant Formula and Follow-on Formula Regulations 1995(1) are amended in accordance with paragraph (2) in so far as they apply in relation to Wales.

(2) In regulation 22 (offences and enforcement)-

- (a) in paragraph (1), insert at the beginning the words "Subject to paragraph (2B),"; and
- (b) immediately after paragraph (2A), add the following paragraph-

"(2B) A person shall not be considered to have contravened or failed to comply with the provisions contained in regulation 2 where the sale which would otherwise have constituted a contravention of or a failure to comply with those provisions is the sale of an infant formula falling within the derogation set out in Article 1 of Commission Regulation (EC) No. 1609/2006 authorising the placing on the market of infant formulae based on hydrolysates of whey protein derived from cows' milk protein for a two-year period(2).".

Amendment of the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997

3.-(1) The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997(3) are amended in accordance with paragraph (2) in so far as they apply in relation to Wales.

(2) In regulation 4 (labelling, advertising and presentation) omit the words "or to a reduction in the sense of hunger or an increase in the sense of satiety".

Amendment of the Medical Food (Wales) Regulations 2000

4.-(1) The Medical Food (Wales) Regulations 2000(4) are amended in accordance with paragraph (2).

(2) In regulation 2 (interpretation), for the definition of "the Directive" ("*y Gyfarwydddeb*") substitute the following definition-

(1) O.S. 1995/77, y mae diwygiadau iddo nad ydynt yn berthnasol i'r Rheoliadau hyn.
(2) OJ Rhif L299, 28.10.2006, t.9.
(3) O.S. 1997/2182, y mae diwygiad iddo nad yw'n berthnasol i'r Rheoliadau hyn.
(4) O.S. 2000/1866 (Cy.125).

(1) S.I. 1995/77, to which there are amendments not relevant to these Regulations.
(2) OJ No. L299, 28.10.2006, p.9.
(3) S.I. 1997/2182, to which there is an amendment not relevant to these Regulations.
(4) S.I. 2000/1866 (W.125).

"ystyr "y Gyfarwyddeb" ("*the Directive*") yw Cyfarwyddeb y Comisiwn 1999/21/EC ar fwydydd deietegol at ddibenion meddygol arbennig(1) fel y'i diwygiwyd gan y Ddeddf ynghylch amodau ymaelodaeth y Weriniaeth Tsiec, Gweriniaeth Estonia, Gweriniaeth Cyprus, Gweriniaeth Latfia, Gweriniaeth Lithwania, Gweriniaeth Hwngari, Gweriniaeth Malta, Gweriniaeth Gwlad Pwyl, Gweriniaeth Slofenia a Gweriniaeth Slofacia, a chan addasiadau i'r Cytuniadau sy'n sail i'r Undeb Ewropeaidd(2) a Chyfarwyddeb y Comisiwn 2006/82/EC sy'n addasu Cyfarwyddeb 91/321 ar fformiwlâu babanod a fformiwlâu dilynol a Chyfarwyddeb 1999/21/EC ar fwydydd deietegol at ddibenion meddygol arbennig, oherwydd ymaelodaeth Bwlgaria a Rwmania(3);".

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

5.-(1) Diwygir Rheoliadau Bwyd at Ddefnydd Maethol Neilltuol (Ychwanegu Sylweddau at Ddibenion Maethol Penodol) (Cymru) 2002(4) yn unol â pharagraff (2).

(2) Ym mharagraff (5) o reoliad 3 (cyfyngiadau ar werthu) yn lle'r geiriau "1 Ionawr 2007" rhodder y geiriau "1 Ionawr 2010".

Diwygio Rheoliadau Bwydydd Proses sydd wedi'u Seilio ar Rawn a Bwydydd Babanod ar gyfer Babanod a Phlant Ifanc (Cymru) 2004

6.-(1) Diwygir Rheoliadau Bwydydd Proses sydd wedi'u Seilio ar Rawn a Bwydydd Babanod ar gyfer Babanod a Phlant Ifanc (Cymru) 2004(5) yn unol â pharagraff (2).

(2) Ym mharagraff (1) o reoliad 2 (dehongli), yn lle'r diffiniad o "y Gyfarwyddeb" ("*the Directive*") rhodder y diffiniad canlynol-

"ystyr "y Gyfarwyddeb" ("*the Directive*") yw Cyfarwyddeb y Comisiwn 2006/125/EC ar fwydydd proses sydd wedi'u seilio ar rawn a bwydydd babanod ar gyfer babanod a phlant ifanc(6);".

"the Directive" ("*y Gyfarwyddeb*") means Commission Directive 1999/21/EC on dietary foods for special medical purposes(1) as amended by the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded(2) and Commission Directive 2006/82/EC adapting Directive 91/321 on infant formulae and follow-on formulae and Directive 1999/21/EC on dietary foods for special medical purposes, by reason of the accession of Bulgaria and Romania(3);".

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

5.-(1) The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002(4) are amended in accordance with paragraph (2).

(2) In paragraph (5) of regulation 3 (restrictions on sale) for the words "1st January 2007" substitute the words "1st January 2010".

Amendment of the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Wales) Regulations 2004

6.-(1) The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Wales) Regulations 2004(5) are amended in accordance with paragraph (2).

(2) In paragraph (1) of regulation 2 (interpretation), for the definition of "the Directive" ("*y Gyfarwyddeb*") substitute the following definition -

"the Directive" ("*y Gyfarwyddeb*") means Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children(6);".

(1) OJ Rhif L91, 7.4.1999, t.29, fel y'i darllenir gyda'r Corrigendwm yn OJ Rhif L2, 5.1.2000, t.79.

(2) OJ Rhif L236, 23.9.2003, t.33.

(3) OJ Rhif L362, 20.12.2006, t.94.

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

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

(6) OJ Rhif L339, 6.12.2006, t.16.

(1) OJ No. L91, 7.4.1999, p.29, as read with the Corrigendum at OJ No. L2, 5.1.2000, p.79.

(2) OJ No. L236, 23.9.2003, p.33.

(3) OJ No. L362, 20.12.2006, p.94.

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

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

(6) OJ No. L339, 6.12.2006, p.16.

O dan awdurdod y Gweinidog dros Iechyd a
Gwasanaethau Cymdeithasol, un o Weinidogion
Cymru

Under authority of the Minister for Health and Social
Services, one of the Welsh Ministers

18 Medi 2007

18 September 2007

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