



OFFERYNNAU STATUDOL
CYMRU

WELSH
STATUTORY INSTRUMENTS

2007 Rhif 3573 (Cy.316)

2007 No. 3573 (W.316)

BWYD, CYMRU

FOOD, WALES

Rheoliadau Fformiwla Fabanod a
Fformiwla Ddilynol (Cymru) 2007

The Infant Formula and Follow-on
Formula (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 rhoi ei heffaith i Gyfarwyddeb y Comisiwn 2006/141/EC ar fformiwla fabanod a fformiwla ddilynol ac yn diwygio Cyfarwyddeb 1999/21/EC (OJ Rhif L401 20.12.2006, t.1) a Chyfarwyddeb y Cyngor 92/52/EEC ar fformiwla babanod a fformiwla dilynol a fwriedir ar gyfer eu hallforio i drydydd gwledydd (OJ Rhif L179, 1.7.1992, t.129).

1. These Regulations, which apply in relation to Wales, give effect to Commission Directive 2006/141/EC on infant formula and follow-on formula and amending Directive 1999/21/EC (OJ No. L401, 20.12.2006, p.1) and Council Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries (OJ No. L179, 1.7.1992, p.129).

2. Mae'r Rheoliadau hyn yn darparu at ddiben a grybwyllir yn adran 2(2) o Ddeddf y Cymunedau Ewropeaidd 1972 (1972 p.68) ac mae cyfeiriadau at yr Atodiad i Gyfarwyddeb 2006/141/EC i'w dehongli fel cyfeiriadau at yr Atodiad hwnnw fel y'i diwygiwyd o bryd i'w gilydd (rheoliad 2(6)).

2. These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 (1972 c.68) and references to Annex to Directive 2006/141/EC are to be construed as references to that Annex as amended from time to time (regulation 2(6)).

3. Mae'r Rheoliadau hyn—

3. These Regulations—

- (a) yn gwahardd marchnata fformiwla fabanod a fformiwla ddilynol sy'n mynd yn groes i reoliadau penodedig neu'n methu â chydymffurfio â hwy (rheoliad 3);
- (b) yn gwahardd marchnata neu gynrychioli fel arall fod cynnyrch yn addas ar ei ben ei hun i fodloni gofynion maethol babanod normal iach yn ystod misoedd cyntaf eu bywyd hyd nes y cyflwynir bwydo ategol priodol oni bai bod y cynnyrch hwnnw yn fformiwla fabanod (rheoliad 4);
- (c) yn darparu bod rhaid i fformiwla fabanod a fformiwla ddilynol beidio â chynnwys cymaint o unrhyw sylweddau ag i beryglu iechyd babanod a phlant ifanc (rheoliad 5);
- (ch) yn darparu bod rhaid i fformiwla fabanod fod wedi'i gweithgynhyrchu o ffynonellau protein

- (a) prohibit marketing of infant formula and follow-on formula which contravenes or fails to comply with specified regulations (regulation 3);
- (b) prohibit marketing or otherwise representing a product as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding unless that product is infant formula (regulation 4);
- (c) provide that infant formula and follow-on formula must not contain any substance in such quantity as to endanger the health of infants and young children (regulation 5);
- (d) provide that infant formula must be manufactured from specified protein sources

- penodol a chynhwysion bwyd addas eraill (rheoliad 6);
- (d) yn darparu bod rhaid i fformiwla ddilynol fod wedi'i gweithgynhyrchu o ffynonellau protein penodol a chynhwysion bwyd addas eraill (rheoliad 7);
- (dd) yn darparu bod rhaid i fformiwla fabanod gydymffurfio â meini prawf cyfansoddiadol penodedig (rheoliad 8);
- (e) yn darparu bod rhaid i fformiwla ddilynol gydymffurfio â meini prawf cyfansoddiadol penodedig (rheoliad 9);
- (f) yn darparu na fydd gofyn gwneud dim ond ychwanegu dŵr ati er mwyn gwneud fformiwla babanod neu fformiwla ddilynol yn barod i'w defnyddio (rheoliad 10);
- (ff) yn darparu bod rhaid i'r defnydd o gynhwysion bwyd mewn fformiwla fabanod a fformiwla ddilynol gadw at waharddiadau a therfynau penodedig (rheoliad 11);
- (g) yn darparu mai dim ond sylweddau penodedig a gaiff eu defnyddio wrth weithgynhyrchu fformiwla fabanod a fformiwla ddilynol er mwyn bodloni gofynion penodedig Cyfarwyddeb 2006/141/EC a bod rhaid i'r sylweddau hynny fodloni meini prawf purdeb penodedig (rheoliad 12);
- (ng) yn gwahardd gweithredydd busnes bwyd rhag gosod fformiwla fabanod ar y farchnad nad yw eto wedi'i gosod ar y farchnad yn y Deyrnas Unedig oni bai bod y gweithredydd busnes bwyd hwnnw wedi rhoi hysbysiad ymlaen llaw i'r Asiantaeth Safonau Bwyd (rheoliad 13);
- (h) yn darparu na chaiff fformiwla fabanod a fformiwla ddilynol gynnwys gweddillion plaleiddiaid uwchlaw lefelau penodedig (rheoliad 14);
- (i) yn darparu mai dim ond o dan enwau penodol y caiff fformiwla fabanod ei gwerthu (rheoliad 15);
- (j) yn darparu mai dim ond o dan enwau penodol y caiff fformiwla ddilynol ei gwerthu (rheoliad 16);
- (l) yn darparu ar gyfer labelu fformiwla fabanod (rheoliad 17);
- (ll) yn darparu ar gyfer labelu fformiwla ddilynol (rheoliad 18);
- (m) yn darparu bod rhaid labelu fformiwla fabanod a fformiwla ddilynol mewn modd sy'n gwahaniaethu'n glir rhwng y cyfryw gynhyrchion er mwyn osgoi unrhyw risg o ddryswch rhyngddynt (rheoliad 19);
- and other suitable food ingredients (regulation 6);
- (e) provide that follow-on formula must be manufactured from specified protein sources and other suitable food ingredients (regulation 7);
- (f) provide that infant formula must comply with specified compositional criteria (regulation 8);
- (g) provide that follow-on formula must comply with specified compositional criteria (regulation 9);
- (h) provide that in order to make infant formula or follow-on formula ready for use nothing more must be required than the addition of water (regulation 10);
- (i) provide that the use of food ingredients in infant formula and follow-on formula must observe specified prohibitions and limitations (regulation 11);
- (j) provide that only specified substances may be used in the manufacture of infant formula and follow-on formula in order to satisfy specified requirements of Directive 2006/141/EC and that those substances must meet specified purity criteria (regulation 12);
- (k) prohibit a food business operator placing an infant formula on the market that has not yet been placed on the market in the United Kingdom unless that food business operator has given prior notice to the Food Standards Agency (regulation 13);
- (l) provide that infant formula and follow-on formula may not contain pesticide residues above specified levels (regulation 14);
- (m) provide that infant formula may only be sold under certain names (regulation 15);
- (n) provide that follow-on formula may only be sold under certain names (regulation 16);
- (o) provide for the labelling of infant formula (regulation 17);
- (p) provide for the labelling of follow-on formula (regulation 18);
- (q) provide that infant formula and follow-on formula must be labelled to make a clear distinction between such products so as to avoid any risk of confusion between them (regulation 19);

- (n) yn cymhwyso darpariaethau rheoliadau penodedig i gyflwyno fformiwla fabanod a fformiwla ddilynol (rheoliad 20);
- (o) yn gwahardd hysbysebu fformiwla fabanod ac eithrio mewn cyhoeddiadau penodedig oni bai bod yr hysbyseb yn cydymffurfio â darpariaethau rheoliadau penodedig (rheoliad 21(1));
- (p) yn gosod cyfyngiadau ar gynnwys hysbysebion am fformiwla fabanod (rheoliad 21(2) a (3));
- (ph) yn gwahardd hysbysebu fformiwla ddilynol os yw'r hysbyseb yn mynd yn groes i reoliadau penodedig neu'n methu â chydymffurfio â'u darpariaethau. (rheoliad 22);
- (r) yn gosod cyfyngiadau ar hybu fformiwla fabanod (rheoliad 23);
- (rh) yn gosod cyfyngiadau ar gynhyrchu neu gyhoeddi deunydd at ddibenion gwybodaeth neu addysg sy'n ymwneud â bwydo babanod ac y bwriedir iddo gyrraedd menywod beichiog a mamau babanod a mamau plant bach (rheoliad 24(1), (2) a (3));
- (s) yn gwahardd cynhyrchwyr neu ddsbarthwyr fformiwla fabanod rhag gwneud rhodd o gyfarpar na deunyddiau at ddibenion gwybodaeth neu addysg oni bai bod amodau penodol wedi'u bodloni (rheoliad 24(4));
- (t) yn gosod cyfyngiadau ar yr hyn y gall corff neu sefydliad ei wneud gyda fformiwla fabanod y mae wedi ei chael heb dalu amdani neu am bris gostyngol (rheoliad 25);
- (th) yn gwahardd allforio i drydedd wlad fformiwla fabanod sy'n groes i reoliadau penodedig neu i safon ryngwladol benodedig neu i Reoliadau Bwyd (Marcio Lotiau) 1996 (O.S. 1996/1502) neu'n methu â chydymffurfio â hwy (rheoliad 26(1));
- (u) yn gwahardd allforio i drydedd wlad gynnyrch a gynrychiolir fel cynnyrch sy'n addas ar ei ben ei hun i fodloni gofynion maethol babanod normal iach yn ystod pedwar i chwe mis cyntaf eu bywyd oni bai bod y cynnyrch hwnnw yn fformiwla fabanod (rheoliad 26(2));
- (w) yn gwahardd allforio i drydedd wlad fformiwla ddilynol sy'n groes i reoliadau penodedig neu i safon ryngwladol benodedig neu i Reoliadau Bwyd (Marcio Lotiau) 1996 neu'n methu â chydymffurfio â hwy (rheoliad 27);
- (y) yn darparu bod person sy'n mynd yn groes i reoliadau penodedig neu'n methu â chydymffurfio â hwy yn euog o dramgwydd ac yn darparu cosb am fynd yn groes iddynt neu am fethu â chydymffurfio â hwy (rheoliad 28(1));
- (r) apply the provisions of specified regulations to the presentation of infant formula and follow-on formula (regulation 20);
- (s) prohibit advertising of infant formula except in specified publications unless the advertisement complies with the provisions of specified regulations (regulation 21(1));
- (t) impose restrictions on the content of advertisements for infant formula (regulation 21(2) and (3));
- (u) prohibit advertising of follow-on formula where the advertisement contravenes or fails to comply with the provisions of specified regulations (regulation 22);
- (v) impose restrictions on the promotion of infant formula (regulation 23);
- (w) impose restrictions on the production or publication of informational or educational material dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children (regulation 24(1), (2) and (3));
- (x) prohibit donation of informational or educational equipment or materials by manufacturers or distributors of infant formula unless certain conditions are met (regulation 24(4));
- (y) impose restrictions on what an institution or organisation may do with infant formula that it has received free of charge or at a reduced rate (regulation 25);
- (z) prohibit export to a third country of infant formula which contravenes or fails to comply with specified regulations, a specified international standard or the Food (Lot Marking) Regulations (S.I. 1996/1502) (regulation 26(1));
- (aa) prohibit export to a third country of a product represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life unless that product is infant formula (regulation 26(2));
- (bb) prohibit export to a third country of follow-on formula which contravenes or fails to comply with specified regulations, a specified international standard or the Food (Lot Marketing) Regulations 1996 (regulation 27);
- (cc) provide that a person who contravenes or fails to comply with specified regulations is guilty of an offence and provide a penalty for contravening or failing to comply with those regulations (regulation 28(1));

- (aa) yn darparu bod rhaid i bob awdurdod bwyd orfodi a gweithredu'r Rheoliadau hyn o fewn ei ardal (rheoliad 28(2));
- (bb) yn cymhwyso darpariaethau penodol o Ddeddf Diogelwch Bwyd 1990 (1990 p.16) gydag addasiadau (rheoliad 29);
- (cc) yn diwygio Rheoliadau Bwyd Meddygol (Cymru) 2000 (O.S. 2000/1866 (Cy. 25)) (rheoliad 30); ac
- (chch) yn dirymu Rheoliadau Fformiwla Fabanod a Fformiwla Ddilynol (O.S. 1995/77) i'r graddau y maent yn gymwys i Gymru (mae O.S. 1995/77 yn gymwys i'r cyfan o Brydain Fawr) ac yn darparu trefniadau trosiannol o ran O.S. 1995/77 (rheoliad 31) .

4. Paratowyd asesiad effaith rheoleiddiol llawn ar yr effaith y bydd yr offeryn hwn yn ei gael. Gellir cael copïau gan yr Asiantaeth Safonau Bwyd, Llawr 11, Southgate House, Wood Street, Caerdydd, CF10 1EW.

- (dd) provide that each food authority must enforce and execute these Regulations within its area (regulation 28(2));
- (ee) apply specified provisions of the Food Safety Act 1990 (1990 c.16) with modifications (regulation 29);
- (ff) amend the Medical Food (Wales) Regulations (S.I. 2000/1866 (W.25)) (regulation 30); and
- (gg) revoke the Infant Formula and Follow-on Formula Regulations (S.I. 1995/77) in so far as they apply in relation to Wales (S.I. 1995/77 applies in relation to the whole of Great Britain) and provide transitional arrangements with regard to S.I. 1995/77 (regulation 31).

4. A full regulatory impact assessment of the effect that this instrument will have has been prepared. Copies may be obtained from the Food Standards Agency, 11th Floor, Southgate House, Wood Street, Cardiff, CF10 1EW.

2007 Rhif 3573 (Cy.316)

BWYD, CYMRU

**Rheoliadau Fformiwla Fabanod a
Fformiwla Ddilynol (Cymru) 2007**

Gwnaed 18 Rhagfyr 2007

*Gosodwyd gerbron Cynulliad
Cenedlaethol Cymru* 20 Rhagfyr 2007

Yn dod i rym yn unol â rheoliad 1

CYNNWYS

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2007 No. 3573 (W.316)

FOOD, WALES

**The Infant Formula and Follow-on
Formula (Wales) Regulations 2007**

Made 18 December 2007

*Laid before the National
Assembly for Wales* 20 December 2007

*Coming into force in accordance with
regulation 1*

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Mae Gweinidogion Cymru yn gwneud y Rheoliadau a ganlyn ac eithrio rheoliadau 2(6) a 24 drwy arfer y pwerau a roddwyd gan adrannau 16(1)(e), 17(1), 26(1)(a) a (3) a 48(1) o Ddeddf Diogelwch Bwyd 1990(1).

The Welsh Ministers make the following Regulations apart from regulations 2(6) and 24 in exercise of the powers conferred by sections 16(1)(e), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(1).

Mae Gweinidogion Cymru yn gwneud rheoliadau 2(6) a 24 drwy arfer y pwerau a roddwyd gan adran 2(2) o Ddeddf y Cymunedau Ewropeaidd 1972 a pharagraff 1A o Atodlen 2 iddi(2).

The Welsh Ministers make regulations 2(6) and 24 in exercise of the powers conferred by section 2(2) of and paragraph 1A of Schedule 2 to the European Communities Act 1972(2).

(1) 1990 p.16. Amnewidiwyd adran 1(1) a (2) (y diffiniad o "food") gan O.S. 2004/2990. Diwygiwyd adrannau 17 a 48 gan baragraffau 12 a 21 yn eu trefn o Atodlen 5 i Ddeddf Safonau Bwyd 1999 (1999 p.28), "Deddf 1999". Diwygiwyd adran 48 hefyd gan O.S. 2004/2990. Diwygiwyd adran 26(3) gan Atodlen 6 i Ddeddf 1999.

(2) 1972 p.68. O ran Cymru, cafodd y swyddogaethau a arferid gynt gan "the Ministers" (sef, o ran Cymru a Lloegr ac yn gweithredu ar y cyd, y Gweinidog dros Amaethyddiaeth, Pysgodfeydd a Bwyd a'r Ysgrifenyddion Gwladol â'r cyfrifoldeb yn eu trefn dros iechyd yn Lloegr a bwyd ac iechyd yng Nghymru ac o ran yr Alban, yr Ysgrifenydd Gwladol eu trosglwyddo i Gynulliad Cenedlaethol Cymru gan O.S. 1999/672 fel y'i darllenir gydag adran 40(3) o Ddeddf 1999, ac a drosglwyddwyd wedi hynny i Weinidogion Cymru gan adrannau 58 a 59 o Ddeddf Llywodraeth Cymru 2006 a pharagraff 30 o Atodlen 11 iddi (p.32).

(1) 1990 c.16. Section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), "the 1999 Act". Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act.

(2) 1972 c.68. In relation to Wales, the functions formerly exercised by "the Ministers" (being, in relation to England and Wales and acted jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act and thereafter transferred to the Welsh Ministers by sections 58 and 59 of and paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c.32).

Mae Gweinidogion Cymru wedi'u dynodi at ddibenion adran 2(2) o Ddeddf y Cymunedau Ewropeaidd 1972 o ran mesurau sy'n ymwneud â bwyd (gan gynnwys diodydd) gan gynnwys cynhyrchu sylfaenol o ran bwyd(1).

Mae'r Rheoliadau hyn yn gwneud darpariaeth at ddiben a grybwyllir yn adran 2(2) o Ddeddf y Cymunedau Ewropeaidd 1972 ac mae'n ymddangos i Weinidogion Cymru ei bod yn hwylus i ddehongli unrhyw gyfeiriad at Atodiad i Reoliad y Comisiwn 2006/141/EC ar fformiwlâu babanod a fformiwlâu dilynol ac sy'n diwygio Cyfarwyddeb 1999/21/EC(2) fel cyfeiriad at yr Atodiad hwnnw fel y'i diwygiwyd o bryd i'w gilydd.

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

Fel sy'n ofynnol gan Erthygl 9 o Reoliad (EC) Rhif 178/2002 Senedd Ewrop a'r Cyngor, sy'n gosod egwyddorion a gofynion cyffredinol cyfraith bwyd, yn sefydlu Awdurdod Diogelwch Bwyd Ewrop ac yn gosod gweithdrefnau o ran materion diogelwch bwyd(3) cafwyd ymgynghori agored a thryloyw â'r cyhoedd yn ystod cyfnod paratoi a gwerthuso'r Rheoliadau hyn.

Enwi, cychwyn a chymhwysu

1.–(1) Enw'r Rheoliadau hyn yw Rheoliadau Fformiwlâ Fabanod a Fformiwlâ Ddilynol (Cymru) 2007.

(2) Mae'r Rheoliadau hyn yn dod i rym—

(a) yn achos rheoliad 31(2), ar 1 Ionawr 2010; a

(b) fel arall, ar 11 Ionawr 2008.

(3) Mae'r Rheoliadau hyn yn gymwys o ran Cymru.

Dehongli

2.–(1) Yn y Rheoliadau hyn—

ystyr "yr Asiantaeth" ("*the Agency*") yw'r Asiantaeth Safonau Bwyd;

mae i "awdurdod bwyd" yr ystyr a roddir i "*food authority*" yn rhinwedd adran 5(1A) o'r Ddeddf;

The Welsh Ministers have been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to food (including drink) including the primary production of food(1).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Welsh Ministers that it is expedient for any reference to an Annex to Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC(2) to be construed as a reference to that Annex as amended from time to time.

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.

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

Title, commencement and application

1.–(1) The title of these Regulations is the Infant Formula and Follow-on Formula (Wales) Regulations 2007.

(2) These Regulations come into force—

(a) in the case of regulation 31(2), on 1 January 2010; and

(b) otherwise, on 11 January 2008.

(3) These Regulations apply in relation to Wales.

Interpretation

2.–(1) In these Regulations—

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

"the Agency" ("*yr Asiantaeth*") means the Food Standards Agency;

(1) O.S. 2005/1971.

(2) OJ Rhif L401, 30.12.2006, t.1.

(3) OJ Rhif L31, 1.2.2002, t.1, fel y'i diwygiwyd ddiwethaf gan Reoliad y Comisiwn (EC) Rhif 575/2006 sy'n diwygio Rheoliad (EC) Rhif 178/2002 Senedd Ewrop a'r Cyngor o ran nifer ac enwau Paneli Gwyddonol parhaol Awdurdod Diogelwch Bwyd Ewrop (OJ Rhif L100, 8.4.2006, t.3).

(1) S.I. 2005/1971.

(2) OJ No. L401, 30.12.2006, p.1.

(3) OJ No. L31, 1.2.2002, p.1, as last amended by Commission Regulation (EC) No. 575/2006 amending Regulation (EC) No. 178/2002 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the European Food Safety Authority (OJ No. L100, 8.4.2006, p.3).

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

ystyr "y Gyfarwyddeb" ("*the Directive*") yw Cyfarwyddeb y Comisiwn 2006/141/EC ar fformiwlâu babanod a fformiwlâu dilynol ac sy'n diwygio Cyfarwyddeb 1999/21/EC; ac

ystyr "system gofal iechyd" ("*health care system*") yw cyrff neu sefydliadau sy'n ymwneud, yn uniongyrchol neu'n anuniongyrchol, â gofal iechyd i famau, babanod a menywod beichiog, ac mae'n cynnwys meithrinfeydd neu sefydliadau gofal plant a gweithwyr iechyd mewn practis preifat.

(2) Yn ddarostyngedig i baragraff (3), mae i unrhyw ymadrodd a ddefnyddir yn y Rheoliadau hyn, ac eithrio un a ddiffinnir ym mharagraff (1), ac y defnyddir yr ymadrodd Saesneg cyfatebol yn y Rheoliadau hyn ac yn y Ddeddf yr ystyr a roddir i'r ymadrodd Saesneg cyfatebol hwnnw yn y Ddeddf.

(3) Er gwaethaf paragraff (2), mae i unrhyw ymadrodd a ddefnyddir yn y Rheoliadau hyn ac y defnyddir yr ymadrodd Saesneg cyfatebol yn y Gyfarwyddeb yr ystyr a roddir i'r ymadrodd Saesneg cyfatebol hwnnw yn y Gyfarwyddeb.

(4) Pan fo unrhyw swyddogaethau o dan y Ddeddf yn cael eu neilltuo—

- (a) drwy orchymyn o dan adran 2 neu 7 o Ddeddf Iechyd y Cyhoedd (Rheoli Clefydau) 1984(1), i awdurdod iechyd porthladd; neu
- (b) drwy orchymyn o dan adran 6 o Ddeddf Iechyd y Cyhoedd 1936(2), i gyd-fwrdd ar gyfer dosbarth unedig;

mae unrhyw gyfeiriad yn y Rheoliadau hyn at awdurdod bwyd i'w ddehongli, i'r graddau y mae'n ymwneud â'r swyddogaethau hynny, fel cyfeiriad at yr awdurdod y maent wedi'u neilltuo felly iddo.

(5) Yn y Rheoliadau hyn mae unrhyw gyfeiriad at Atodiad â rhif yn gyfeiriad at yr Atodiad sy'n dwyn y rhif hwnnw yn y Gyfarwyddeb.

(6) Yn y Rheoliadau hyn mae unrhyw gyfeiriad at Atodiad i'r Gyfarwyddeb yn gyfeiriad at yr Atodiad hwnnw fel y'i diwygiwyd o bryd i'w gilydd.

Gwaharddiad ar farchnata fformiwlâ fabanod neu fformiwlâ ddilynol oni fo amodau penodol wedi'u bodloni

3.-(1) Ni chaiff unrhyw berson farchnata fformiwlâ fabanod sy'n mynd yn groes i neu'n methu â chydymffurfio â rheoliad 5, 6, 8, 10, 11, 12, 14(1), (2) neu (3), 15, 17 neu 19.

"the Directive" ("*y Gyfarwyddeb*") means Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC;

"food authority" ("*awdurdod bwyd*") has the meaning that it bears by virtue of section 5(1A) of the Act; and

"health care system" ("*system gofal iechyd*") means institutions or organisations engaged, directly or indirectly, in health care for mothers, infants and pregnant women, including nurseries or child-care institutions and health workers in private practice.

(2) Subject to paragraph (3), any expression other than one defined in paragraph (1) that is used both in these Regulations and in the Act has the meaning that it bears in the Act.

(3) Notwithstanding paragraph (2), any expression used both in these Regulations and in the Directive has the meaning that it bears in the Directive.

(4) Where any functions under the Act are assigned—

- (a) by an order under section 2 or 7 of the Public Health (Control of Disease) Act 1984(1), to a port health authority; or
- (b) by an order under section 6 of the Public Health Act 1936(2), to a joint board for a united district,

any reference in these Regulations to a food authority is to be construed, so far as relating to those functions, as a reference to the authority to whom they are so assigned.

(5) In these Regulations any reference to a numbered Annex is a reference to the Annex bearing that number in the Directive.

(6) In these Regulations any reference to an Annex to the Directive is a reference to that Annex as amended from time to time.

Prohibition on the marketing of infant formula or follow-on formula unless certain conditions are met

3.-(1) No person may market infant formula which contravenes or fails to comply with regulation 5, 6, 8, 10, 11, 12, 14(1), (2) or (3), 15, 17 or 19.

(1) 1984 p.22; amnewidiwyd adran 7(3)(d) gan baragraff 27 o Atodlen 3 i Ddeddf Diogelwch Bwyd 1990 (1990 p.16).

(2) 1936 p.49; mae adran 6 i'w darllen gyda pharagraff 1 o Atodlen 3 i Ddeddf Diogelwch Bwyd 1990.

(1) 1984 c.22; section 7(3)(d) was substituted by paragraph 27 of Schedule 3 to the Food Safety Act 1990 (1990 c.16).

(2) 1936 c.49; section 6 is to be read with paragraph 1 of Schedule 3 to the Food Safety Act 1990.

(2) Ni chaiff unrhyw berson farchnata fformiwla ddilynol sy'n mynd yn groes i neu'n methu â chydymffurfio â rheoliad 5, 7, 9, 10, 11, 12, 14(1), (2) neu (3), 16, 18 neu 19.

Gwaharddiad ar farchnata cynhyrchion ac eithrio fformiwla fabanod ar gyfer babanod normal iach

4. Ni chaiff unrhyw berson farchnata neu gynrychioli fel arall fod cynnyrch yn addas ar ei ben ei hun i fodloni gofynion maethol babanod normal iach yn ystod misoedd cyntaf eu bywyd hyd nes y cyflwynir bwydo ategol priodol oni bai bod y cynnyrch hwnnw yn fformiwla fabanod.

Cymaint o sylweddau ag i beryglu iechyd babanod a phlant ifanc

5. Rhaid i fformiwla fabanod a fformiwla ddilynol beidio â chynnwys unrhyw cymaint o unrhyw sylwedd ag i beryglu iechyd babanod a phlant ifanc.

Ffynonellau protein a chynhwysion bwyd eraill sy'n addas i fabanod o'u genedigaeth (fformiwla fabanod)

6.–(1) Rhaid i fformiwla fabanod fod wedi'i gweithgynhyrchu—

- (a) o'r ffynonellau protein a bennir ym mhwynt 2 o Atodiad I; a
- (b) o gynhwysion bwyd eraill y cafodd eu haddasrwydd at ddefnydd maethol penodol gan fabanod o'u genedigaeth ei sefydlu drwy ddata gwyddonol a dderbynir yn gyffredinol ac a gafodd ei ddangos yn unol â pharagraff (2).

(2) Rhaid i addasrwydd gael ei ddangos drwy adolygiad systematig o'r data sydd ar gael sy'n ymwneud â'r buddiant a ddisgwylir ac ag ystyriaethau diogelwch yn ogystal â thrwy astudiaethau priodol, pan fo angen hynny, a wnaed gan ddilyn canllawiau arbenigol sy'n dderbynir yn gyffredinol ar lunio a chynnal astudiaethau o'r fath.

Ffynonellau protein a chynhwysion bwyd eraill sy'n addas i fabanod dros chwe mis oed (fformiwla ddilynol)

7. Rhaid i fformiwla ddilynol fod wedi'i gweithgynhyrchu—

- (a) o'r adnoddau protein a bennir ym mhwynt 2 o Atodiad II; a
- (b) o gynhwysion bwyd eraill y cafodd eu haddasrwydd at ddefnydd maethol penodol gan fabanod dros chwe mis oed ei sefydlu drwy ddata gwyddonol a dderbynir yn gyffredinol ac a gafodd ei ddangos yn unol â rheoliad 6(2).

(2) No person may market follow-on formula which contravenes or fails to comply with regulation 5, 7, 9, 10, 11, 12, 14(1), (2) or (3), 16, 18 or 19.

Prohibition on the marketing of products other than infant formula for normal health infants

4. No person may market or otherwise represent a product as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding unless that product is infant formula.

Substances in such quantity as to endanger the health of infants and young children

5. Infant formula and follow-on formula must not contain any substance in such quantity as to endanger the health of infants and young children.

Protein sources and other food ingredients suitable for infants from birth (infant formula)

6.–(1) Infant formula must be manufactured from—

- (a) the protein sources specified in point 2 of Annex I; and
- (b) other food ingredients the suitability of which for particular nutritional use by infants from birth has been established by generally accepted scientific data and demonstrated in accordance with paragraph (2).

(2) Suitability must be demonstrated through systematic review of the available data relating to the expected benefits and safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

Protein sources and other food ingredients suitable for infants aged over six months (follow-on formula)

7. Follow-on formula must be manufactured from—

- (a) the protein sources specified in point 2 of Annex II; and
- (b) other food ingredients the suitability of which for particular nutritional use by infants aged over six months has been established by generally accepted scientific data and demonstrated in accordance with regulation 6(2).

Meini prawf cyfansoddiadol ar gyfer fformiwla fabanod

8.–(1) Yn ddarostyngedig i baragraffau (2) a (3), rhaid i fformiwla fabanod gydymffurfio â'r meini prawf cyfansoddiadol a osodir yn Atodiad I gan gymryd ystyriaeth o'r manylebau yn Atodiad V.

(2) Yn achos fformiwla fabanod sydd wedi'i gweithgynhyrchu o'r proteinau llaeth gwartheg a bennir ym mhwynt 2.1 o Atodiad I sydd â'u cynnwys protein rhwng y lleiafswm a 0.5g/100kJ (2g/100 kcal) rhaid i addasrwydd y fformiwla fabanod ar ei phen ei hun fodloni gofynion maethol babanod normal iach yn ystod misoedd cyntaf eu bywyd hyd nes y cyflwynir bwydo ategol priodol gael ei ddangos drwy astudiaethau priodol a wnaed gan ddilyn canllawiau arbenigol sy'n dderbyniol yn gyffredinol ar lunio a chynnal astudiaethau o'r fath.

(3) Yn achos fformiwla fabanod sydd wedi'i gweithgynhyrchu o'r hydrolysatau protein hynny a bennir ym mhwynt 2.2 o Atodiad I â'u cynnwys protein rhwng y lleiafswm a 0.56g/100kJ (2.25g/100 kcal)–

- (a) rhaid i addasrwydd y fformiwla fabanod ar ei phen ei hun fodloni gofynion maethol babanod normal iach yn ystod misoedd cyntaf eu bywyd hyd nes y cyflwynir bwydo ategol priodol gael ei ddangos drwy astudiaethau priodol a wnaed gan ddilyn canllawiau arbenigol sy'n dderbyniol yn gyffredinol ar lunio a chynnal astudiaethau o'r fath; a
- (b) rhaid i'r fformiwla fabanod fod yn unol â'r manylebau priodol a osodir yn Atodiad VI.

Meini prawf cyfansoddiadol ar gyfer fformiwla ddilynol

9. Rhaid i fformiwla ddilynol gydymffurfio â'r meini prawf cyfansoddiadol a osodir yn Atodiad II gan gymryd ystyriaeth o'r manylebau a osodir yn Atodiad V.

Ychwanegu dŵr (fformiwla fabanod a fformiwla ddilynol)

10. Er mwyn gwneud fformiwla fabanod neu fformiwla ddilynol yn barod i'w defnyddio ni fydd gofyn gwneud dim ond ychwanegu dŵr ati.

Gwaharddiadau a therfynau ar y defnydd o gynhwysion bwyd (fformiwla fabanod a fformiwla ddilynol)

11. Rhaid cadw at y gwaharddiadau a'r terfynau ar y defnydd o gynhwysion bwyd mewn fformiwla fabanod a fformiwla ddilynol a osodir yn eu trefn yn Atodiadau I a II.

Compositional criteria for infant formula

8.–(1) Subject to paragraphs (2) and (3), infant formula must comply with the compositional criteria set out in Annex I taking into account the specifications in Annex V.

(2) In the case of infant formula manufactured from those cows' milk proteins specified in point 2.1 of Annex I with a protein content between the minimum and 0.5g/100kJ (2g/100 kcal) the suitability of the infant formula for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding must be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

(3) In the case of infant formula manufactured from those protein hydrolysates specified in point 2.2 of Annex I with a protein content between the minimum and 0.56g/100kJ (2.25g/100 kcal)–

- (a) the suitability of the infant formula for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding must be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies; and
- (b) the infant formula must be in accordance with the appropriate specifications set out in Annex VI.

Compositional criteria for follow-on formula

9. Follow-on formula must comply with the compositional criteria set out in Annex II taking account the specifications set out in Annex V.

Addition of water (infant formula and follow-on formula)

10. In order to make infant formula or follow-on formula ready for use nothing more must be required than the addition of water.

Prohibitions and limitations on the use of food ingredients (infant formula and follow-on formula)

11. The prohibitions and limitations on the use of food ingredients in infant formula and follow-on formula set out respectively in Annexes I and II must be observed.

Sylweddau rhestredig a'u meini prawf purdeb (fformiwla fabanod a fformiwla ddilynol)

12.–(1) Dim ond y sylweddau a restrir yn Atodiad III y ceir eu defnyddio wrth weithgynhyrchu fformiwla fabanod a fformiwla ddilynol er mwyn bodloni gofynion Atodiadau I a II yn eu trefn ar–

- (a) sylweddau mwynol;
- (b) fitaminau;
- (c) asidau amino a chyfansoddion nitrogen eraill; ac
- (ch) sylweddau eraill sydd â diben maethol penodol.

(2) Rhaid i sylweddau a ddefnyddir i weithgynhyrchu fformiwla fabanod a fformiwla ddilynol yn unol â pharagraff (1) fodloni'r meini prawf purdeb perthnasol.

(3) Y meini prawf purdeb perthnasol at ddibenion paragraff (2) yw–

- (a) y meini prawf ar gyfer sylweddau, fel y darperir ar eu cyfer yn neddfwriaeth y Gymuned ynghylch y defnydd o sylweddau a restrir yn Atodiad III, wrth weithgynhyrchu bwydydd at ddibenion ac eithrio'r rheini a gwmpesir gan y Gyfarwyddeb; a
- (b) yn absenoldeb meini prawf purdeb o'r fath, meini prawf purdeb sy'n dderbyniol yn gyffredinol a argymhellir gan gyrff rhyngwladol.

Hysbysiad o fformiwla fabanod

13. Ni chaiff unrhyw weithredydd busnes bwyd osod fformiwla fabanod ar y farchnad nad yw eto wedi'i gosod ar y farchnad yn y Deyrnas Unedig oni bai bod y gweithredydd busnes bwyd hwnnw wedi rhoi hysbysiad i'r Asiantaeth drwy anfon ati fodol o'r label a ddefnyddir ar gyfer y cynnyrch.

Gweddillion pleiddiaid (fformiwla fabanod a fformiwla ddilynol)

14.–(1) Yn ddarostyngedig i baragraffau (2) a (3), ni chaiff fformiwla fabanod na fformiwla ddilynol gynnwys lefelau uwch na 0.01 mg/kg o weddillion pleiddiaid unigol.

(2) Ni chaiff fformiwla fabanod na fformiwla ddilynol gynnwys lefelau uwch na 0.003 mg/kg o unrhyw weddillion pleiddiaid a restrir yn Nhabl 1 neu yn Nhabl 2 o Atodiad VIII.

(3) Ni chaiff fformiwla fabanod na fformiwla ddilynol gynnwys lefelau uwch o unrhyw weddillion pleiddiaid a restrir yn Atodiad IX nac uchafswm lefel y gweddillion a restrir yn yr Atodiad hwnnw.

(4) Mae'r lefelau y cyfeirir atynt ym mharagraffau (1) i (3) yn gynnwys o ran fformiwla fabanod neu

Listed substances and their purity criteria (infant formula and follow-on formula)

12.–(1) Only the substances listed in Annex III may be used in the manufacture of infant formula and follow-on formula in order to satisfy the requirements of Annexes I and II respectively on–

- (a) mineral substances;
- (b) vitamins;
- (c) amino acids and other nitrogen compounds; and
- (d) other substances having a particular nutritional purpose.

(2) Substances used in the manufacture of infant formula and follow-on formula pursuant to paragraph (1) must meet the relevant purity criteria.

(3) The relevant purity criteria for the purposes of paragraph (2) are–

- (a) the purity criteria for substances, as provided for in Community legislation concerning the use of substances listed in Annex III, in the manufacture of foodstuffs for purposes other than those covered by the Directive; and
- (b) in the absence of such purity criteria, generally acceptable purity criteria recommended by international bodies.

Notification of infant formula

13. No food business operator may place an infant formula on the market that has not yet been placed on the market in the United Kingdom unless he or she has given prior notice to the Agency by forwarding to it a model of the label used for the product.

Pesticide residues (infant formula and follow-on formula)

14.–(1) Subject to paragraphs (2) and (3), infant formula and follow-on formula may not contain residues of individual pesticides at levels exceeding 0.01 mg/kg.

(2) Infant formula and follow-on formula may not contain any residue of a pesticide listed in Table 1 or Table 2 of Annex VIII at a level exceeding 0.003 mg/kg.

(3) Infant formula and follow-on formula may not contain any residue of a pesticide listed in Annex IX at a level exceeding the maximum residue level specified in that Annex.

(4) The levels referred to in paragraphs (1) to (3) apply in relation to infant formula or follow-on

fformiwla ddilydol—

- (a) a weithgynhyrchwyd i fod yn barod i'w bwyta; neu
- (b) os nad yw wedi'i weithgynhyrchu ar gyfer hynny, fel y mae wedi'i hailgyfansoddi yn ôl cyfarwyddyd y gweithgynhyrchydd.

(5) Rhaid i ddulliau dadansoddi ar gyfer pennu lefelau gweddillion plaleiddiaid at ddibenion y rheoliad hwn fod yn ddulliau wedi'u safoni sy'n dderbyniol yn gyffredinol.

Enwi fformiwla fabanod

15. Ni cheir gwerthu fformiwla fabanod onis gwerthir o dan yr enw—

- (a) yn achos cynnyrch nad yw wedi ei weithgynhyrchu yn gyfan gwbl o broteinâu llaeth gwartheg, yr enw "infant formula"; neu
- (b) yn achos cynnyrch sydd wedi ei weithgynhyrchu yn gyfan gwbl o broteinâu llaeth gwartheg, yr enw "infant milk";

Enwi fformiwla ddilydol

16. Ni cheir gwerthu fformiwla ddilydol onis gwerthir o dan yr enw—

- (a) yn achos cynnyrch nad yw wedi'i weithgynhyrchu yn gyfan gwbl o broteinâu llaeth gwartheg, yr enw "follow-on formula"; neu
- (b) yn achos cynnyrch sydd wedi'i weithgynhyrchu yn gyfan gwbl o broteinâu llaeth gwartheg, yr enw "follow-on milk".

Labelu fformiwla fabanod

17.—(1) Ni cheir gwerthu fformiwla fabanod oni bai bod y labelu arno yn dangos y manylion a ganlyn—

- (a) datganiad i'r perwyl fod y cynnyrch yn addas i'w ddefnyddio at ddiben maethol penodol gan fabanod o'u genedigaeth pan nad ydynt yn cael eu bwydo ar y fron;
- (b) y gwerth egni sydd ar gael, wedi'i fynegi mewn kJ a kcal a'r cynnwys o broteinâu, carbohydradau a lipidau, wedi'i fynegi ar ffurf rifyddegol, ym mhob 100ml o'r cynnyrch sy'n barod i'w ddefnyddio;
- (c) pa faint ar gyfartaledd o bob sylwedd mwynol ac o bob fitamin a grybwyllir yn Atodiad I ac, os yw'n gymwys, o golîn, inositol a charnitîn, wedi'i fynegi ar ffurf rifyddegol, sydd ym mhob 100ml o'r cynnyrch sy'n barod i'w ddefnyddio;
- (ch) cyfarwyddiadau ar gyfer paratoi, storio a chael gwared â'r cynnyrch yn briodol a rhybudd rhag peryglon posibl i iechyd o'i baratoi a'i storio yn amhriodol; a

formula—

- (a) manufactured as ready for consumption; or
- (b) if it is not so manufactured, as reconstituted according to the manufacturer's instructions.

(5) Analytical methods for determining levels of pesticide residues for the purposes of this regulation must be generally acceptable standardised methods.

Naming of infant formula

15. Infant formula may not be sold unless it is sold under the name—

- (a) in the case of a product which is not manufactured entirely from cows' milk proteins, the name "infant formula"; or
- (b) in the case of a product which is manufactured entirely from cows' milk proteins, the name "infant milk".

Naming of follow-on formula

16. Follow-on formula may not be sold unless it is sold under the name—

- (a) in the case of a product which is not manufactured entirely from cows' milk proteins, the name "follow-on formula"; or
- (b) in the case of a product which is manufactured entirely from cows' milk proteins, the name "follow-on milk".

Labelling of infant formula

17.—(1) Infant formula may not be sold unless the labelling bears the following particulars—

- (a) a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast fed;
- (b) the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100ml of the product ready for use;
- (c) the average quantity of each mineral substance and of each vitamin mentioned in Annex I and, where applicable, of choline, inositol and carnitine, expressed in numerical form, per 100ml of the product ready for use;
- (d) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage; and

(d) y geiriau "Important Notice", neu eiriau cyfatebol iddynt yn cael eu dilyn yn union gan—

- (i) datganiad ynghylch rhagoriaeth bwydo ar y fron, a
- (ii) datganiad yn argymhell mai dim ond wedi cael cyngor gan bersonau annibynnol sydd â chymwysterau mewn meddygaeth, maethiad neu fferylliaeth, neu weithwyr proffesiynol eraill sy'n gyfrifol am ofal mamau a gofal plant i wneud hynny y dylid defnyddio'r cynnyrch.

(2) Rhaid i labelu fformiwla fabanod—

- (a) fod wedi'i lunio i roi'r wybodaeth angenrheidiol ynghylch y defnydd priodol o'r cynnyrch mewn modd nad yw'n annog menywod i beidio â bwydo ar y fron; a
- (b) peidio â chynnwys y termau "humanised", "maternalised", "adapted" nac unrhyw derm cyffelyb.

(3) Ni chaiff fformiwla fabanod gynnwys—

- (a) unrhyw lun o faban; na
- (b) unrhyw lun arall a ddichon ddelfrydu defnyddio'r cynnyrch,

ond caiff gynnwys delweddau graffig er mwyn adnabod y cynnyrch yn rhwydd neu er mwyn dangos dulliau paratoi.

(4) Dim ond dan yr amodau isod y caiff labelu fformiwla fabanod ddwyn honiadau o ran maeth ac iechyd—

- (a) mae'r hyn a honnir wedi'i restru yng nghlofn gyntaf Atodiad IV ac wedi'i fynegi yn y termau a osodir yno; a
- (b) mae'r amod a bennir yn yr ail glofn i Atodiad IV mewn perthynas â'r honiad perthnasol a wneir yn y glofn gyntaf wedi'i fodloni.

(5) Caiff labelu fformiwla fabanod ddwyn manylion o ba faint ar gyfartaledd o'r maetholion a grybwyllir yn Atodiad III, pan nad yw gwybodaeth o'r fath yn ofynnol gan baragraff (1)(c), wedi'i fynegi ar ffurf rifyddegol, sydd ym mhob 100ml o'r cynnyrch sy'n barod i'w ddefnyddio.

Labelu fformiwla ddilynol

18.—(1) Ni cheir gwerthu fformiwla ddilynol oni bai bod y labelu arno yn dangos y manylion a ganlyn—

- (a) datganiad i'r perwyl—
 - (i) mai dim ond i'w ddefnyddio at ddiben maethol penodol gan fabanod dros chwe mis oed y mae'r cynnyrch yn addas,
 - (ii) na ddylai fod yn ddim ond rhan o ddeiet amrywiol,
 - (iii) nad yw i gael ei ddefnyddio yn lle llaeth y

(e) the words "Important Notice" or their equivalent immediately followed by—

- (i) a statement concerning the superiority of breast feeding, and
- (ii) a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care.

(2) The labelling of infant formula must—

- (a) be designed to provide the necessary information about the appropriate use of the product so as not to discourage breast feeding; and
- (b) not contain the terms "humanised", "maternalised", "adapted" or any similar term.

(3) The labelling of an infant formula may not include—

- (a) any picture of an infant; or
- (b) any other picture or text which may idealise the use of the product,

but may include graphic representations for easy identification of the product or for illustrating methods of preparation.

(4) The labelling of an infant formula may bear nutrition and health claims only when—

- (a) the claim is listed in the first column of Annex IV and is expressed in the terms set out there; and
- (b) the condition specified in the second column of Annex IV in relation to the relevant claim made in the first column is satisfied.

(5) The labelling of an infant formula may bear particulars of the average quantity of nutrients mentioned in Annex III when such information is not required by paragraph (1)(c), expressed in numerical form, per 100 ml of the product ready for use.

Labelling of follow-on formula

18.—(1) Follow-on formula may not be sold unless the labelling bears the following particulars—

- (a) a statement to the effect that—
 - (i) the product is suitable only for particular nutritional use by infants over the age of six months,
 - (ii) it should form only part of a diversified diet,
 - (iii) it is not to be used as a substitute for breast

fron yn ystod chwe mis cyntaf bywyd y baban, a

(iv) mai dim ond wedi cael cyngor gan bersonau annibynnol sydd â chymwysterau mewn meddygaeth, maethiad neu fferylliaeth, neu weithwyr proffesiynol eraill sy'n gyfrifol am ofal mamau a gofal plant i wneud hynny y dylid gwneud y penderfyniad i ddechrau bwydo ategol, gan gynnwys unrhyw benderfyniad o ran gwneud eithriad i'r egwyddor o beidio â defnyddio fformiwla ddilynol cyn chwe mis oed, a hynny ar sail anghenion twf a datblygiad penodol y baban dan sylw;

(b) y gwerth egni sydd ar gael, wedi'i fynegi mewn kJ a kcal a'r cynnwys o broteinau, carbohydradau a lipidau, wedi'i fynegi ar ffurf rifyddegol, ym mhob 100ml o'r cynnyrch sy'n barod i'w ddefnyddio;

(c) pa faint ar gyfartaledd o bob sylwedd mwynol ac o bob fitamin a grybwyllir yn Atodiad II ac, os yw'n gymwys, o golîn, inositol a charnitîn, wedi'i fynegi ar ffurf rifyddegol, sydd ym mhob 100ml o'r cynnyrch sy'n barod i'w ddefnyddio;

(ch) cyfarwyddiadau ar gyfer paratoi, storio a chael gwared â'r cynnyrch yn briodol a rhybudd rhag peryglon posibl i iechyd o'i baratoi a'i storio yn amhriodol.

(2) Rhaid i labelu fformiwla ddilynol—

(a) fod wedi'i lunio i roi'r wybodaeth angenrheidiol ynghylch y defnydd priodol o'r cynnyrch mewn modd nad yw'n annog menywod i beidio â bwydo ar y fron; a

(b) peidio â chynnwys y termau "humanised", "maternalised", "adapted" nac unrhyw derm cyffelyb.

(3) Caiff labelu fformiwla ddilynol ddwyn manylion—

(a) o ba faint ar gyfartaledd o'r maetholion a grybwyllir yn Atodiad III, pan nad yw gwybodaeth o'r fath yn ofynnol gan baragraff (1)(c), wedi'i fynegi ar ffurf rifyddegol, sydd ym mhob 100ml o'r cynnyrch sy'n barod i'w ddefnyddio; a

(b) yn ychwanegol at wybodaeth rifyddegol, gwybodaeth ar fitaminau a mwynau sydd wedi'u cynnwys yn Atodiad VII, wedi'i mynegi fel canran o'r gwerthoedd cyfeiriadol a roddir yn yr Atodiad hwnnw, am bob 100ml o'r cynnyrch sy'n barod i'w ddefnyddio.

Osgoi'r perygl o ddryswch rhwng fformiwla fabanod a fformiwla ddilynol

19. Rhaid labelu fformiwla fabanod a fformiwla ddilynol mewn modd sy'n galluogi defnyddwyr i

milk during the first six months of life, and

(iv) the decision to begin complementary feeding, including any decision as to making an exception to the principle of not using follow-on formula before six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal or child care, based on the individual infant's specific growth and development needs;

(b) the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100ml of the product ready for use;

(c) the average quantity of each mineral substance and of each vitamin mentioned in Annex II and, where applicable, of choline, inositol and carnitine, expressed in numerical form, per 100ml of the product ready for use;

(d) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.

(2) The labelling of follow-on formula must—

(a) be designed to provide the necessary information about the appropriate use of the product so as not to discourage breast feeding; and

(b) not contain the terms "humanised", "maternalised", "adapted" or any similar term.

(3) The labelling of a follow-on formula may bear particulars of—

(a) the average quantity of nutrients mentioned in Annex III when such information is not required by paragraph (1)(c), expressed in numerical form, per 100 ml of the product ready for use; and

(b) in addition to numerical information, information on vitamins and minerals included in Annex VII, expressed as a percentage of the reference values given in that Annex, per 100 ml of the product ready for use.

Avoidance of the risk of confusion between infant formula and follow-on formula

19. Infant formula and follow-on formula must be labelled in such a way that it enables consumers to

wahaniaethu'n glir rhwng y cyfryw gynhyrchion er mwyn osgoi unrhyw risg o ddrwsych rhwng fformiwla fabanod a fformiwla ddilynol.

Cyflwyno (fformiwla fabanod a fformiwla ddilynol)

20.–(1) Mae darpariaethau rheoliadau 17(1)(d), (2), (3) a (4) a 19 hefyd yn gymwys o ran cyflwyno fformiwla fabanod.

(2) Mae darpariaethau rheoliadau 18(2) a 19 hefyd yn gymwys o ran cyflwyno fformiwla ddilynol.

(3) At ddibenion y rheoliad hwn mae "cyflwyno" yn cynnwys siâp, gwedd neu ddull pacio'r cynhyrchion dan sylw, y deunyddiau pacio a ddefnyddiwyd, y ffordd y cawsant eu trefnu a'r man lle maent yn cael eu harddangos.

Cyfyngiadau ar hysbysebu fformiwla fabanod

21.–(1) Ni chaiff unrhyw berson hysbysebu fformiwla fabanod–

- (a) ac eithrio–
 - (i) mewn cyhoeddiad gwyddonol, neu
 - (ii) at ddibenion masnach cyn y cyfnod manwerthu, mewn cyhoeddiad a fwriedir ar gyfer darllenwyr gwahanol i'r cyhoedd yn gyffredinol; ac
- (b) oni bai bod yr hysbyseb yn cydymffurfio â darpariaethau rheoliad 17(1)(d) (2), (3) a (4), rheoliad 19 a pharagraff (2) a (3).

(2) Ni chaiff hysbysebion ar gyfer fformiwla fabanod gynnwys ond gwybodaeth o natur wyddonol a ffeithiol.

(3) Ni chaiff yr wybodaeth mewn hysbysebion ar gyfer fformiwla fabanod awgrymu neu greu cred fod bwydo â photel yn cyfateb i neu'n rhagori ar fwydo ar y fron.

Cyfyngiadau ar hysbysebu fformiwla ddilynol

22. Ni chaiff unrhyw berson hysbysebu fformiwla ddilynol os yw'r hysbyseb yn mynd yn groes i neu'n methu â chydymffurfio â darpariaethau rheoliad 18(2) neu 19.

Cyfyngiadau ar hybu fformiwla fabanod

23.–(1) Yn unrhyw fan lle gwerthir fformiwla fabanod drwy ei manwerthu ni chaiff unrhyw berson–

- (a) hysbysebu unrhyw fformiwla fabanod;
- (b) gwneud unrhyw arddangosiad arbennig o fformiwla fabanod sydd wedi'i llunio i hybu gwerthiant;
- (c) wneud rhodd–

make a clear distinction between such products so as to avoid any risk of confusion between infant formula and follow-on formula.

Presentation (infant formula and follow-on formula)

20.–(1) The provisions of regulations 17(1)(e), (2), (3) and (4) and 19 also apply in relation to the presentation of an infant formula.

(2) The provisions of regulations 18(2) and 19 also apply in relation to the presentation of a follow-on formula.

(3) For the purposes of this regulation "presentation" includes the shape, appearance or packaging of the products concerned, the packaging materials used, the way in which they are arranged and the setting in which they are displayed.

Restrictions on advertising infant formula

21.–(1) No person may advertise infant formula–

- (a) except–
 - (i) in a scientific publication, or
 - (ii) for the purposes of trade prior to the retail stage, in a publication of which the intended readership is other than the general public; and
- (b) unless the advertisement complies with the provisions of regulation 17(1)(e), (2), (3) and (4), regulation 19 and paragraph (2) and (3).

(2) Advertisements for infant formula may only contain information of a scientific and factual nature.

(3) Information in advertisements for infant formula may not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.

Restrictions on advertising follow-on formula

22. No person may advertise follow-on formula where the advertisement contravenes or fails to comply with the provisions of regulation 18(2) or 19.

Restrictions on the promotion of infant formula

23.–(1) No person may at any place where any infant formula is sold by retail–

- (a) advertise any infant formula;
- (b) make any special display of an infant formula designed to promote sales;
- (c) give away–

- (i) o unrhyw fformiwla fabanod fel sampl am ddim, nac
- (ii) o unrhyw gwpon y gellir ei ddefnyddio i brynu fformiwla fabanod ar ddisgownt;
- (ch) hybu gwerthiant fformiwla fabanod drwy breimymau, gwerthiannau arbennig, gwerthiannau islaw cost neu werthiannau rhwym; na
- (d) ymwneud ag unrhyw weithgaredd hyrwyddol arall i gymell gwerthiant o fformiwla fabanod.

(2) Ni chaiff unrhyw weithgynhyrchydd na dosbarthwr fformiwla fabanod roi unrhyw fformiwla fabanod am ddim neu am bris gostyngol neu ar ddisgownt er mwyn ei hyrwyddo, na rhoi unrhyw rodd gyda'r bwriad o hyrwyddo gwerthiant fformiwla fabanod—

- (a) i'r cyhoedd yn gyffredinol;
- (b) i fenywod beichiog;
- (c) i famau; nac
- (ch) i aelodau o deuluoedd personau a grybwyllir yn is-baragraffau (b) ac (c),

naill ai yn uniongyrchol neu'n anuniongyrchol drwy'r system gofal iechyd neu drwy weithwyr iechyd.

Darparu deunydd at ddibenion gwybodaeth ac addysg yn ymwneud â bwydo babanod

24.–(1) Ni chaiff unrhyw berson gynhyrchu na chyhoeddi deunydd at ddibenion gwybodaeth neu addysg, p'un ai ar ffurf ysgrifenedig neu glyweledol, sy'n ymwneud â bwydo babanod ac y bwriedir iddo gyrraedd menywod beichiog a mamau babanod a mamau plant bach onid yw'r deunydd hwnnw'n cynnwys gwybodaeth glir ar bob un o'r pwyntiau a ganlyn—

- (a) manteision a rhagoriaeth bwydo ar y fron;
- (b) maethiad y fam;
- (c) paratoi ar gyfer a chynnal bwydo ar y fron;
- (ch) effaith negyddol bosibl cyflwyno bwydo rhannol â photel ar fwydo ar y fron;
- (d) anhawster newid y penderfyniad i beidio â bwydo ar y fron; ac
- (dd) os oes angen, y defnydd priodol o fformiwla fabanod.

(2) Pan fydd y deunydd y cyfeirir ato ym mharagraff (1) yn cynnwys gwybodaeth ynghylch y defnydd o fformiwla fabanod rhaid iddo gynnwys gwybodaeth ynghylch—

- (a) y goblygiadau cymdeithasol ac ariannol o'i ddefnyddio;
- (b) y peryglon bosibl i iechyd oddi wrth fwydydd neu ddulliau bwydo amhriodol; ac
- (c) y peryglon bosibl i iechyd oddi wrth

- (i) any infant formula as a free sample, or
- (ii) any coupon which may be used to purchase an infant formula at a discount;
- (d) promote the sale of an infant formula by means of premiums, special sales, loss-leaders or tie-in sales; or
- (e) undertake any other promotional activity to induce the sale of an infant formula.

(2) No manufacturer or distributor of any infant formula may provide for promotional purposes any infant formula free or at a reduced or discounted price, or any gift designed to promote the sale of an infant formula, to—

- (a) the general public;
- (b) pregnant women;
- (c) mothers; or
- (d) members of the families of persons mentioned in sub-paragraphs (b) and (c),

either directly, or indirectly through the health care system or health workers.

Provision of informational and educational material dealing with the feeding of infants

24.–(1) No person may produce or publish any informational or educational material, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, unless that material includes clear information on all the following points—

- (a) the benefits and superiority of breast-feeding;
- (b) maternal nutrition;
- (c) the preparation for and the maintenance of breast-feeding;
- (d) the possible negative effect on breast-feeding of introducing partial bottle-feeding;
- (e) the difficulty of reversing the decision not to breast-feed; and
- (f) where needed, the proper use of an infant formula.

(2) When the material referred to in paragraph (1) contains information about the use of an infant formula it must include information about—

- (a) the social and financial implications of its use;
- (b) the health hazards of inappropriate foods or feeding methods; and
- (c) the health hazards of improper use of infant

ddefnyddio fformiwla fabanod yn amhriodol.

(3) Pan fydd y deunydd y cyfeirir ato ym mharagraff (1) yn cynnwys gwybodaeth ynghylch y defnyddio o fformiwla fabanod rhaid iddo beidio â defnyddio unrhyw ddarluniau a ddichon ddelfrydu defnyddio fformiwla fabanod.

(4) Ni chaiff unrhyw weithgynhyrhydd neu ddsbarthwr fformiwla fabanod wneud rhodd o unrhyw gyfarpar na deunyddiau at bwrpas addysg neu wybodaeth ac eithrio yn unol â'r amodau a ganlyn—

- (a) rhaid bod y rhodd wedi ei rhoi ar ôl cael cais amdani gan y sawl sy'n bwriadu ei derbyn;
- (b) rhaid bod y rhodd wedi ei rhoi gydag awdurdod ysgrifenedig Gweinidogion Cymru neu'n unol â chanllawiau a luniwyd gan Weinidogion Cymru;
- (c) rhaid peidio â marcio na labelu'r cyfarpar na'r deunyddiau gydag enw brand perchnogaethol o fformiwla fabanod; ac
- (ch) dim ond drwy'r system gofal iechyd y ceir dosbarthu'r cyfarpar neu'r deunyddiau.

Fformiwla fabanod ddi-dâl neu am bris gostyngol

25. Rhaid i gorff neu sefydliad sy'n cael unrhyw fformiwla fabanod heb dalu amdani neu am bris gostyngol—

- (a) os yw'r fformiwla fabanod honno i gael ei defnyddio o fewn y corff neu'r sefydliad hwnnw, ei defnyddio yn unig ar gyfer babanod y mae'n rhaid eu bwydo ar fformiwla fabanod a dim ond cyhyd ag y mae hynny'n angenrheidiol i'r babanod hynny; neu
- (b) os yw'r fformiwla fabanod honno i gael ei dosbarthu y tu allan i'r corff neu'r sefydliad hwnnw, ei dosbarthu yn unig ar gyfer babanod y mae'n rhaid eu bwydo ar fformiwla fabanod a dim ond cyhyd ag y mae hynny'n angenrheidiol i'r babanod hynny.

Allforio fformiwla fabanod i drydydd gwledydd

26.—(1) Ni chaiff unrhyw berson allforio i drydedd wlad unrhyw fformiwla fabanod sy'n mynd yn groes i neu'n methu â chydymffurfio â—

- (a) rheoliad 5, 6, 8, 10, 11, 12, 14(1), (2) neu (3), 17 neu 19;
- (b) safonau Codex ar gyfer fformiwla fabanod a sefydlwyd gan y Codex Alimentarius(1);
- (c) Rheoliadau Bwyd (Marcio Lotiau) 1996(2).

formula.

(3) When the material referred to in paragraph (1) contains information about the use of an infant formula it must not use any pictures which may idealise the use of infant formula.

(4) No manufacturer or distributor of an infant formula may make a donation of any informational or educational equipment or materials except in accordance with the following conditions—

- (a) the donation must be made following a request by the intended recipient;
- (b) the donation must be made with the written authority of the Welsh Ministers or in accordance with guidelines drawn up by the Welsh Ministers;
- (c) the equipment and materials must not be marked or labelled with the name of a proprietary brand of infant formula; and
- (d) the equipment or materials may be distributed only through the health care system.

Free or reduced rate infant formula

25. An institution or organisation which receives any infant formula free or at a reduced rate must—

- (a) if that infant formula is for use in the institution or organisation, only use it for infants who have to be fed on infant formula and only for as long as required by those infants; or
- (b) if that infant formula is for distribution outside the institution or organisation, only distribute it to those infants who have to be fed on infant formula and only for as long as required by those infants.

Export of infant formula to third countries

26.—(1) No person may export to a third country any infant formula which contravenes or fails to comply with—

- (a) regulation 5, 6, 8, 10, 11, 12, 14(1), (2) or (3), 17 or 19;
- (b) the Codex Standard for Infant Formula established by the Codex Alimentarius(1);
- (c) the Food (Lot Marking) Regulations 1996(2).

(1) Codex Stan 72-1981, cyfrol 4, Codex Alimentarius, 1981.

(2) O.S. 1996/1502.

(1) Codex Stan 72-1981, volume 4, Codex Alimentarius, 1981.

(2) S.I. 1996/1502.

(2) Ni chaiff unrhyw berson allforio i drydedd wlad gynnyrch a gynrychiolir fel cynnyrch sydd yn addas ar ei ben ei hun i fodloni gofynion maethol babanod normal iach yn ystod pedwar i chwe mis cyntaf eu bywyd oni bai bod y cynnyrch hwnnw yn fformiwla fabanod.

Allforio fformiwla ddilynol i drydydd gwledydd

27. Ni chaiff unrhyw berson allforio i drydedd wlad unrhyw fformiwla ddilynol sy'n mynd yn groes i neu'n methu â chydymffurfio â–

- (a) rheoliad 5, 7, 9, 10, 12, 14(1), (2) neu (3), 18 neu 19;
- (b) safonau Codex ar gyfer fformiwla ddilynol a sefydlwyd gan y Codex Alimentarius(1);
- (c) Rheoliadau Bwyd (Marcio Lotiau) 1996.

Tramgwyddau a gorfodi

28.–(1) Os oes unrhyw berson yn mynd yn groes i neu'n methu â chydymffurfio â rheoliad 3, 4, 13, 21(1), 22, 23, 24, 25, 26 neu 27 bydd y person hwnnw yn euog o dramgwydd ac yn agored o'i gollfarnu'n ddiannod i ddirwy heb fod yn uwch na lefel 5 ar y raddfa safonol.

(2) Rhaid i bob awdurdod bwyd orfodi a gweithredu'r Rheoliadau hyn o fewn ei ardal.

Cymhwyso amryfal adrannau o Ddeddf Diogelwch Bwyd 1990

29. Mae darpariaethau canlynol y Ddeddf yn gymwys ar gyfer dibenion y Rheoliadau hyn gyda'r addasiad bod unrhyw gyfeiriad yn y darpariaethau hynny at y Ddeddf neu at Ran ohoni i'w ddehongli fel cyfeiriad at y Rheoliadau hyn–

- (a) adran 3 (rhagdybiaethau bod bwyd wedi'i fwriadu i'w fwyta gan bobl);
- (b) adran 20 (tramgwyddau oherwydd bai person arall);
- (c) adran 21 (amddiffyniad diwydrwydd dyladwy)(2), gyda'r addasiadau bod is-adrannau (2) i (4) i fod yn gymwys mewn perthynas â thramgwydd o dan reoliad 28 sy'n mynd yn groes i reoliad 3, 4 neu 13 neu'n methu â chydymffurfio â hwy fel y maent yn gymwys mewn perthynas â thramgwydd o dan adran 14 neu 15 ac yn is-adran (4)(b) dylid barnu bod y cyfeiriadau at "sale or intended sale" yn gyfeiriadau at "marketing or as the case may be placing on the market";
- (ch) adran 30(8) (sy'n ymwneud â thystiolaeth ddogfennol);

(2) No person may export to a third country a product represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life unless that product is infant formula.

Export of follow-on formula to third countries

27. No person may export to a third country any follow-on formula which contravenes or fails to comply with–

- (a) regulation 5, 7, 9, 10, 12, 14(1), (2) or (3), 18 or 19;
- (b) the Codex Standard for Follow-up Formula established by the Codex Alimentarius(1);
- (c) the Food (Lot Marking) Regulations 1996.

Offences and enforcement

28.–(1) If any person contravenes or fails to comply with regulation 3, 4, 13, 21(1), 22, 23, 24, 25, 26 or 27 he or she will be guilty of an offence and will be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(2) Each food authority must enforce and execute these Regulations within its area.

Application of various sections of the Food Safety Act 1990

29. 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 thereof is to be construed as a reference to these Regulations–

- (a) section 3 (presumptions that food intended for human consumption);
- (b) section 20 (offences due to fault of another person);
- (c) section 21 (defence of due diligence)(2), with the modifications that subsections (2) to (4) are to apply in relation to an offence under regulation 28 consisting of a contravention of or failure to comply with regulation 3, 4 or 13 as they apply in relation to an offence under section 14 or 15 and that in subsection (4)(b) the references to "sale or intended sale" should be deemed to be references to "marketing or as the case may be placing on the market";
- (d) section 30(8) (which relates to documentary evidence);

(1) Codex Stan 156-1987, cyfrol 4, Codex Alimentarius, 1987.

(2) Diwygiwyd adran gan O.S. 2004/3279.

(1) Codex Stan 156-1987, volume 4, Codex Alimentarius, 1987.

(2) Section 21 was amended by S.I. 2004/3279.

- (d) adran 33(1) (rhwystro etc. swyddogion);
- (dd) 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 o'r fath ag a grybwyllir yn adran 33(1)(b) fel y'i cymhwysir gan is-baragraff (d);
- (e) adran 35(1) (cosbi tramgwyddau)(1), i'r graddau y mae'n ymwneud â thramgwyddau o dan adran 33(1) fel y'i cymhwysir gan baragraff (d);
- (f) adran 35(2) a (3)(2), i'r graddau y mae'n ymwneud â thramgwyddau o dan adran 33(2) fel y'i cymhwysir gan baragraff (dd);
- (ff) adran 36 (tramgwyddau gan gyrff corfforaethol);
- (g) adran 36A (tramgwyddau gan bartneriaethau Albanaidd)(3); ac
- (ng) adran 44 (amddiffyn swyddogion sy'n gweithredu yn ddiwyll).

- (e) section 33(1) (obstruction etc. of officers);
- (f) section 33(2), with the modification that the reference to "any such requirement as is mentioned in subsection (1)(b) above" is to be deemed to be a reference to any such requirement as is mentioned in section 33(1)(b) as applied by sub-paragraph (e);
- (g) section 35(1) (punishment of offences)(1), in so far as it relates to offences under section 33(1) as applied by sub-paragraph (e);
- (h) section 35(2) and (3)(2), in so far as it relates to offences under section 33(2) as applied by sub-paragraph (f);
- (i) section 36 (offences by bodies corporate);
- (j) section 36A (offences by Scottish partnerships)(3); and
- (k) section 44 (protection of officers acting in good faith).

Diwygio Rheoliadau Bwyd Meddygol (Cymru) 2000

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

(2) Yn rheoliad 2 (dehongli), yn lle'r diffiniad o "y Gyfarwyddeb" rhodder y diffiniad canlynol

"ystyr "y Gyfarwyddeb" (*"the Directive"*) yw Cyfarwyddeb y Comisiwn 1999/21/EC ar fwydydd deietegol at ddibenion meddygol arbennig(5) fel y'i diwygiwyd gan—

yr Act sy'n ymwneud ag 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'r addasiadau i'r Cytuniadau y mae'r Undeb Ewropeaidd wedi'i seilio arnynt(6);

Cyfarwyddeb y Comisiwn 2006/82/EC sy'n addasu Cyfarwyddeb 91/321 ar fformwlâu babanod a fformwlâu dilynol a Chyfarwyddeb 1999/21/EC ar fwydydd deietegol at ddibenion meddygol arbennig, oherwydd ymaelodaeth Bwlgaria a Romania(7); a

Amendment of the Medical Food (Wales) Regulations 2000

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

(2) In regulation 2 (interpretation), for the definition "the Directive" substitute the following definition—

"the Directive" (*"y Gyfarwyddeb"*) means Commission Directive 1999/21/EC on dietary foods for special medical purposes(5) 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(6);

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(7); and

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

(2) Diwygiwyd adran 35(3) gan O.S. 2004/3279.

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

(4) O.S. 2000/1866 (Cy.25).

(5) OJ Rhif L91, 7.4.99, t.29.

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

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

(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 35(3) was amended by S.I. 2004/3279.

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

(4) S.I. 2000/1866 (W.25).

(5) OJ No. L91, 7.4.99, p.29.

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

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

Cyfarwyddeb y Comisiwn 2006/141 ar fformiwlâu babanod a fformiwlâu dilynol ac sy'n diwygio Cyfarwyddeb 1991/21/EC."

Commission Directive 2006/141 on infant formulae and follow-on formulae and amending Directive 1991/21/EC."

Dirymu a threfniadau trosiannol

31.–(1) Dirymir rheoliadau 4, 5, 6, 7, 13, 14, 14A, 15, 16, 17, 18, 19, 20 a 21 o Reoliadau 1995 i'r graddau y maent yn gymwys o ran Cymru.

(2) Dirymir Rheoliadau 1995 i'r graddau y maent yn gymwys o ran Cymru.

(3) Ni fydd unrhyw berson yn cyflawni tramgwydd o dan reoliad 28(1) sy'n mynd yn groes i'r canlynol neu'n methu â chydymffurfio â'r canlynol–

(a) rheoliad 3(1)

- (i) os yw'r weithred a fyddai fel arall yn ffurfio'r tramgwydd yn farchnata fformiwlâ fabanod sy'n mynd yn groes i neu'n methu â chydymffurfio â rheoliad 5,6, 8, 10, 11, 12 neu 14(1), (2) neu (3), a
- (ii) os nad oes tramgwydd o dan reoliad 22(1) o Reoliadau 1995 sy'n mynd yn groes i neu'n methu â chydymffurfio â rheoliad (2)(a)(i) neu (ii) o'r Rheoliadau hynny;

(b) rheoliad 3(2)–

- (i) os yw'r weithred a fyddai fel arall yn ffurfio'r tramgwydd yn farchnata fformiwlâ ddilynol sy'n mynd yn groes i neu'n methu â chydymffurfio â rheoliad 5, 7, 9, 10, 11, 12, neu 14(1), (2) neu (3), a
- (ii) os nad oes tramgwydd o dan reoliad 22(1) o Reoliadau 1995 sy'n mynd yn groes i neu'n methu â chydymffurfio ag unrhyw un o'r darpariaethau a geir yn rheoliad 3(a) neu (b) o'r Rheoliadau hynny; neu

(c) rheoliad 4, pan nad oes unrhyw dramgwydd o dan reoliad 22(1) o Reoliadau 1995 sy'n mynd yn groes i neu'n methu â chydymffurfio â rheoliad 2(b)(i) neu (ii) o'r Rheoliadau hynny.

(4) Diwygir Rheoliadau 1995 i'r graddau y maent yn gymwys o ran Cymru yn unol â pharagraff (5).

(5) Ychwanegir y paragraff canlynol ar ddiwedd rheoliad 22 (tramgwyddau a gorfodi) o Reoliadau 1995–

"(4) No person commits an offence under paragraph (1) consisting of a contravention of or a failure to comply with–

- (a) regulation 2(a)(i) or (ii), where there is no offence under regulation 3(1) of the of the 2007 Regulations consisting of a contravention of or a failure to comply with regulation 5, 6, 8, 10, 11, 12 or 14(1), (2) or (3) of those Regulations;

Revocation and transitional arrangements

31.–(1) Regulations 4, 5, 6, 7, 13, 14, 14A, 15, 16, 17, 18, 19, 20 and 21 of the 1995 Regulations are revoked in so far as they apply in relation to Wales.

(2) The 1995 Regulations are revoked in so far as they apply in relation to Wales.

(3) No person commits an offence under regulation 28(1) consisting of a contravention of or a failure to comply with–

(a) regulation 3(1) where–

- (i) the action that would otherwise constitute the offence consists of marketing infant formula which contravenes or fails to comply with regulation 5,6, 8, 10, 11, 12 or 14(1), (2) or (3), and
- (ii) there is no offence under regulation 22(1) of the 1995 Regulations consisting of a contravention of or a failure to comply with regulation (2)(a)(i) or (ii) of those Regulations;

(b) regulation 3(2), where–

- (i) the action that would otherwise constitute the offence consists of marketing follow-on formula which contravenes or fails to comply with regulation 5, 7, 9, 10, 11, 12, or 14(1), (2) or (3), and
- (ii) there is no offence under regulation 22(1) of the 1995 Regulations consisting of a contravention of or a failure to comply with regulation 3(a) or (b) of those Regulations; or

(c) regulation 4, where there is no offence under regulation 22(1) of the 1995 Regulations consisting of a contravention of or a failure to comply with regulation 2(b)(i) or (ii) of those Regulations.

(4) The 1995 Regulations are amended in so far as they apply in relation to Wales in accordance with paragraph (5).

(5) The following paragraph is added at the end of regulation 22 (offences and enforcement) of the 1995 Regulations–

"(4) No person commits an offence under paragraph (1) consisting of a contravention of or a failure to comply with–

- (a) regulation 2(a)(i) or (ii), where there is no offence under regulation 3(1) of the of the 2007 Regulations consisting of a contravention of or a failure to comply with regulation 5, 6, 8, 10, 11, 12 or 14(1), (2) or (3) of those Regulations;

- (b) regulation 2(b)(i) or (ii), where there is no offence under regulation 4 of the 2007 Regulations; or
- (c) regulation 3(a) or (b), where there is no offence under regulation 3(2) of the 2007 Regulations consisting of a contravention of or a failure to comply with regulation 5, 7, 9, 10, 11, 12 or 14(1), (2) or (3) of those Regulations.

(5) In this regulation "the 2007 Regulations" means the Infant Formula and Follow-on Formula (Wales) Regulations 2007."

(6) Yn y rheoliad hwn ystyr "Rheoliadau 1995" yw Rheoliadau Fformiwla Fabanod a Fformiwla Ddilynol 1995(1).

- (b) regulation 2(b)(i) or (ii), where there is no offence under regulation 4 of the 2007 Regulations; or
- (c) regulation 3(a) or (b), where there is no offence under regulation 3(2) of the 2007 Regulations consisting of a contravention of or a failure to comply with regulation 5, 7, 9, 10, 11, 12 or 14(1), (2) or (3) of those Regulations.

(5) In this regulation "the 2007 Regulations" means the Infant Formula and Follow-on Formula (Wales) Regulations 2007."

(6) In this regulation "the 1995 Regulations" means the Infant Formula and Follow-on Formula Regulations 1995(1).

G. Thomas

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 Rhagfyr 2007

18 December 2007

(1) O.S. 1995/77, fel y'i diwygiwyd gan O.S. 1997/451, O.S.2001/1690 (Cy.120) ac O.S. 2004/313 (Cy.31).

(1) S.I. 1995/77, amended by S.I. 1997/451, S.I. 2001/1690 (W.120) and S.I. 2004/313 (W.31).

OFFERYNNAU STATUDOL
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2007 Rhif 3573 (Cy.316)

BWYD, CYMRU

Rheoliadau Fformiwla Fabanod a
Fformiwla Ddilynol (Cymru) 2007

WELSH
STATUTORY INSTRUMENTS

2007 No. 3573 (W.316)

FOOD, WALES

The Infant Formula and Follow-on
Formula (Wales) Regulations 2007

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