



CYNULLIAD CENEDLAETHOL CYMRU

NATIONAL ASSEMBLY FOR WALES

OFFERYNNAU STATUDOL

STATUTORY INSTRUMENTS

2004 Rhif 313 (Cy.31)

2004 No. 313 (W.31)

BWYD, CYMRU

FOOD, WALES

**Rheoliadau Fformwla Fabanod a
Fformwla Ddilynol (Diwygio)
(Cymru) 2004**

**The Infant Formula and Follow-on
Formula (Amendment) (Wales)
Regulations 2004**

NODYN ESBONIADOL

EXPLANATORY NOTE

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

(This note is not part of the Regulations)

1. Mae'r Rheoliadau hyn yn diwygio Rheoliadau Fformwla Fabanod a Fformwla Ddilynol 1995, fel y'u diwygiwyd ("Rheoliadau 1995"), mewn perthynas â Chymru. Mae Rheoliadau 1995 yn gymwys i Brydain Fawr. Mae'r Rheoliadau hyn yn gweithredu ar gyfer Cymru Gyfarwyddeb y Comisiwn 2003/14/EC (OJ Rhif 41, 14.2.2003, t.37) sy'n diwygio Cyfarwyddeb 91/321/EEC (OJ Rhif L175, 4.7.91, t.35) ar fformwlâu babanod a fformwlâu dilynol. Mae'r Rheoliadau yn dod i rym ar 6 Mawrth 2005.

1. These Regulations amend the Infant Formula and Follow-on Formula Regulations 1995, as amended ("the 1995 Regulations"), in relation to Wales. The 1995 Regulations extend to Great Britain. These Regulations implement for Wales Commission Directive 2003/14/EC (OJ No.L41, 14.2.2003, p.37) amending Directive 91/321/EEC (OJ No.L175, 4.7.91, p.35) on infant formulae and follow-on formulae. The Regulations come into force on 6th March 2005.

2. Er mwyn gweithredu Cyfarwyddeb 2003/14/EC mae'r Rheoliadau -

2. In implementation of Directive 2003/14/EC the Regulations -

(a) yn gwahardd gwerthu, neu allforio i drydydd gwledydd, fformwlâu babanod neu fformwlâu dilynol sy'n cynnwys gweddillion pleiddiaid uwchlaw lefelau penodol. Mae lefelau gwahanol wedi'u pennu yn dibynnu ar y pleiddiad o dan sylw (rheoliadau 4, 5, 7 a 10 a'r Atodlen); a

(a) prohibit the sale, or export to third countries, of infant formulae or follow-on formulae containing pesticide residues above certain levels. Different levels are set depending on the pesticide in question (regulations 4, 5, 7 and 10 and Schedule); and

(b) yn gwneud rhai diwygiadau canlyniadol (rheoliadau 3 a 6).

(b) make some consequential amendments (regulations 3 and 6).

3. Er mwyn gweithredu brawddeg olaf Erthygl 6(2) o Gyfarwyddeb 91/321/EEC fel y'i hamnewidiwyd gan Gyfarwyddeb y Comisiwn 1999/50/EC, mae darpariaeth yn cael ei gwneud ynglŷn â dulliau dadansoddiadol ar gyfer penderfynu lefelau gweddillion pleiddiaid (rheoliad 7).

3. In implementation of the final sentence of Article 6(2) of Directive 91/321/EEC as substituted by Commission Directive 1999/50/EC, provision is made as to analytical methods for determining levels of pesticide residues (regulation 7).

4. Mae'r Rheoliadau hefyd -

4. The Regulations also -

(a) yn rhoi rôl ym maes gofodi i awdurdodau

(a) give port health authorities a role in

iechyd porthladdoedd (rheoliad 8); a

- (b) yn gwneud rhai newidiadau technegol i'r ddarpariaeth sy'n cymhwyso darpariaethau amrywiol Deddf Diogelwch Bwyd 1990 (rheoliad 9).

5. Mae arfarniad rheoliadol wedi'i baratoi a'i roi yn Llyfrgell Cynulliad Cenedlaethol Cymru ynghyd â Nodyn Trosi sy'n nodi sut mae prif elfennau Cyfarwyddeb 2003/14/EC yn cael eu trosi yn y Rheoliadau hyn. Gellir cael copïau oddi wrth yr Asiantaeth Safonau Bwyd, Llawr 11, Southgate House, Wood Street, Caerdydd, CF10 1EW.

enforcement (regulation 8); and

- (b) make some technical changes to the provision applying various provisions of the Food Safety Act 1990 (regulation 9).

5. A regulatory appraisal has been prepared and placed in the Library of the National Assembly for Wales together with a Transposition Note setting out how the main elements of Directive 2003/14/EC are transposed in these Regulations. Copies may be obtained from the Food Standards Agency, 11th Floor, Southgate House, Wood Street, Cardiff, CF10 1EW.

2004 Rhif 313 (Cy.31)**2004 No. 313 (W.31)****BWYD, CYMRU****FOOD, WALES****Rheoliadau Fformwla Fabanod a Fformwla Ddilynol (Diwygio) (Cymru) 2004****The Infant Formula and Follow-on Formula (Amendment) (Wales) Regulations 2004***Wedi'u gwneud* 10 Chwefror 2004*Made* 10th February 2004*Yn dod i rym* 6 Mawrth 2005*Coming into force* 6th March 2005

Mae Cynulliad Cenedlaethol Cymru, drwy arfer y pwerau a roddwyd iddo gan adrannau 6(4), 16(1)(a) ac (f), (17)(1), 26(1) a (3) a 48(1) o Ddeddf Diogelwch Bwyd 1990(a) ac sydd bellach wedi'u breinio ynddo(b), ar ôl rhoi sylw yn unol ag adran 48(4A) o'r Ddeddf honno i gyngor perthnasol a roddwyd gan yr Asiantaeth Safonau Bwyd ac ar ôl ymgynghori yn unol ag Erthygl 9 o Reoliad (EC) Rhif 178/2002 Senedd Ewrop a'r Cyngor(c) sy'n pennu egwyddorion a gofynion cyffredinol cyfraith fwyd, yn sefydlu Awdurdod Diogelwch Bwyd Ewrop ac yn pennu gweithdrefnau o ran materion diogelwch bwyd, ac yn unol ag adran 48(4) a (4B) o'r Ddeddf honno, yn gwneud y Rheoliadau canlynol:

The National Assembly for Wales, in exercise of the powers conferred by sections 6(4), 16(1)(a) and (f), 17(1), 26(1) and (3) and 48(1) of the Food Safety Act 1990(a) and now vested in it(b), having had regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency and after consultation both as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council(c) laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety and in accordance with section 48(4) and (4B) of that Act, makes the following Regulations:

Enwi, cymhwyso a chychwyn

1. Enw'r Rheoliadau hyn yw Rheoliadau Fformwla Fabanod a Fformwla Ddilynol (Diwygio) (Cymru) 2004; maent yn gymwys i Gymru yn unig a deuant i rym ar 6 Mawrth 2005.

Title, application and commencement

1. These Regulations may be cited as the Infant Formula and Follow-on Formula (Amendment) (Wales) Regulations 2004; they apply in relation to Wales only and come into force on 6th March 2005.

Diwygio Rheoliadau Fformwla Fabanod a Fformwla Ddilynol 1995

2. Diwygir Rheoliadau Fformwla Fabanod a Fformwla Ddilynol 1995(ch) (i'r graddau y maent yn gymwys i Gymru) yn unol â rheoliadau 3 i 10.

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

2. The Infant Formula and Follow-on Formula Regulations 1995(d) shall be amended (in so far as they apply in relation to Wales) in accordance with regulations 3 to 10.

(a) 1990 p.16.

(b) Trosglwyddwyd swyddogaethau a oedd gynt yn arferadwy gan "the Secretary of State" i'r graddau yr oeddent yn arferadwy mewn perthynas â Chymru, i Gynulliad Cenedlaethol Cymru gan Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 1999 (O.S. 1999/672), o'i ddarllen ynghyd ag adran 40(3) o Ddeddf Safonau Bwyd 1999 (1999 p.28).

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

(ch) O.S. 1995/77; O.S.2001/1690 yw'r offeryn diwygio perthnasol yw (Cy.120).

(a) 1990 c.16.

(b) Functions formerly exercisable by "the Secretary of State" so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672), as read with section 40(3) of the Food Standards Act 1999 (1999 c.28).

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

(d) S.I. 1995/77; the relevant amending instrument is S.I. 2001/1690 (W.120).

3. Yn rheoliad 1(2) (dehongli), yn y diffiniad o "the Directive", yn lle'r geiriau "Commission Directive 1999/50/EC" rhowch y geiriau "Commission Directive 2003/14/EC(a)".

4. Yn rheoliadau 2(ii) a 3(b) (amodau ar gyfer gwerthu fformwlâu babanod a fformwlâu dilynol), yn lle'r ymadrodd "regulation 12" rhowch yr ymadrodd "regulations 12 and 12A".

5. Yn rheoliadau 5(1)(a) a 6(1)(a) (allforio fformwlâu babanod a fformwlâu dilynol i drydydd gwledydd), yn lle'r ymadrodd "11 and 12" rhowch yr ymadrodd ", 11, 12 and 12A".

6. Yn rheoliadau 8(2) a 9(2) (cyfansoddiad fformwlâu babanod a fformwlâu dilynol), hepgorwch y geiriau o "and it shall not" hyd at y diwedd.

7. Ar ôl rheoliad 12 (cyfansoddiad fformwlâu babanod a fformwlâu dilynol) mewnosodwch y rheoliad canlynol -

"12A.-(1) No infant formula or follow-on formula shall contain -

- (a) any pesticide residue of a pesticide specified in Schedule 7A; or
- (b) any omethoate, where it is a metabolite of a pesticide not specified in Schedule 7A, or any product resulting from degradation or reaction of that metabolite,

at a level exceeding 0.003 mg/kg.

(2) No infant formula or follow-on formula shall contain any pesticide residue of a pesticide specified in column 1 of Schedule 7B at a level exceeding that specified in column 2 of that Schedule in relation to that pesticide.

(3) No infant formula or follow-on formula shall contain any pesticide residue of any individual pesticide which is not specified in Schedule 7A or column 1 of Schedule 7B at a level exceeding 0.01 mg/kg.

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

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

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

8. Yn rheoliad 22 (tramgwyddau a gorfodi) -

- (a) ym mharagraff (2) mewnosodwch ar y dechrau y geiriau "Except where paragraph (2A) below applies,";
- (b) ar ôl paragraff (2) mewnosodwch y paragraff

3. In regulation 1(2) (interpretation), in the definition of "the Directive", for the words "Commission Directive 1999/50/EC" there shall be substituted the words "Commission Directive 2003/14/EC(a)".

4. In regulations 2(ii) and 3(b) (conditions for the sale of infant formulae and follow-on formulae), for the expression "regulation 12" there shall be substituted the expression "regulations 12 and 12A".

5. In regulations 5(1)(a) and 6(1)(a) (export of infant formulae and follow-on formulae to third countries), for the expression "11 and 12" there shall be substituted the expression ", 11, 12 and 12A".

6. In regulations 8(2) and 9(2) (composition of infant formulae and follow-on formulae), the words from "and it shall not" to the end shall be omitted.

7. After regulation 12 (composition of infant formulae and follow-on formulae) there shall be inserted the following regulation -

"12A.-(1) No infant formula or follow-on formula shall contain -

- (a) any pesticide residue of a pesticide specified in Schedule 7A; or
- (b) any omethoate, where it is a metabolite of a pesticide not specified in Schedule 7A, or any product resulting from degradation or reaction of that metabolite,

at a level exceeding 0.003 mg/kg.

(2) No infant formula or follow-on formula shall contain any pesticide residue of a pesticide specified in column 1 of Schedule 7B at a level exceeding that specified in column 2 of that Schedule in relation to that pesticide.

(3) No infant formula or follow-on formula shall contain any pesticide residue of any individual pesticide which is not specified in Schedule 7A or column 1 of Schedule 7B at a level exceeding 0.01 mg/kg.

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

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

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

8. In regulation 22 (offences and enforcement) -

- (a) in paragraph (2) there shall be inserted at the beginning the words "Except where paragraph (2A) below applies,";
- (b) after paragraph (2) there shall be inserted the

(a) OJ Rhif L41, 14.2.2003, t.37.

(a) OJ No. L41, 14.2.2003, p.37.

canlynol -

"(2A) Each port health authority shall enforce and execute these Regulations in its district in relation to imported food."

9. Yn lle rheoliad 23 (cymhwyso darpariaethau Deddf Diogelwch Bwyd 1990) rhowch y rheoliad canlynol -

"Application of various provisions of the Act

23. The following provisions of the Act shall apply for the purposes of these Regulations (except regulation 21) with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to these Regulations (except regulation 21) -

- (a) section 2 (extended meaning of "sale" etc.);
- (b) section 3 (presumptions that food is intended for human consumption);
- (c) section 20 (offences due to fault of another person);
- (d) section 21 (defence of due diligence) as it applies for the purposes of section 8, 14 or 15;
- (e) section 30(8) (which relates to documentary evidence);
- (f) section 33(1) (obstruction etc. of officers);
- (g) section 33(2), with the modification that the reference to "any such requirement as is mentioned in subsection (1)(b) above" shall be deemed to be a reference to any such requirement as is mentioned in that subsection as applied by paragraph (f) above;
- (h) section 35(1) (punishment of offences) in so far as it relates to offences under section 33(1) as applied by paragraph (f) above;
- (i) section 35(2) and (3) in so far as it relates to offences under section 33(2) as applied by paragraph (g) above;
- (j) section 36 (offences by bodies corporate); and
- (k) section 44 (protection of officers acting in good faith)."

10. Ar ôl Atodlen 7 (yr elfennau mwynol mewn llaeth buchod) mewnosodwch fel Atodlenni 7A a 7B gynnwys yr Atodlen i'r Rheoliadau hyn.

following paragraph -

"(2A) Each port health authority shall enforce and execute these Regulations in its district in relation to imported food."

9. For regulation 23 (application of provisions of the Food Safety Act 1990) there shall be substituted the following regulation -

"Application of various provisions of the Act

23. The following provisions of the Act shall apply for the purposes of these Regulations (except regulation 21) with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to these Regulations (except regulation 21) -

- (a) section 2 (extended meaning of "sale" etc.);
- (b) section 3 (presumptions that food is intended for human consumption);
- (c) section 20 (offences due to fault of another person);
- (d) section 21 (defence of due diligence) as it applies for the purposes of section 8, 14 or 15;
- (e) section 30(8) (which relates to documentary evidence);
- (f) section 33(1) (obstruction etc. of officers);
- (g) section 33(2), with the modification that the reference to "any such requirement as is mentioned in subsection (1)(b) above" shall be deemed to be a reference to any such requirement as is mentioned in that subsection as applied by paragraph (f) above;
- (h) section 35(1) (punishment of offences) in so far as it relates to offences under section 33(1) as applied by paragraph (f) above;
- (i) section 35(2) and (3) in so far as it relates to offences under section 33(2) as applied by paragraph (g) above;
- (j) section 36 (offences by bodies corporate); and
- (k) section 44 (protection of officers acting in good faith)."

10. After Schedule 7 (the mineral elements in cows' milk) there shall be inserted as Schedules 7A and 7B the contents of the Schedule to these Regulations.

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

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

10 Chwefror 2004

10th February 2004

D. Elis-Thomas

Llywydd y Cynulliad Cenedlaethol

The Presiding Officer of the National Assembly

YR ATODLEN

Rheoliad 10

ATODLENNI 7A A 7B NEWYDD I'W MEWNOSOD YN RHEOLIADAU FFORMWLA
FABANOD A FFORMWLA DDILYNOL1995

"SCHEDULE 7A

Regulation 12A

PESTICIDES WHOSE RESIDUES MUST NOT BE PRESENT IN INFANT FORMULAE OR
FOLLOW-ON FORMULAE AT A LEVEL EXCEEDING 0.003 MG/KG

Chemical name

Aldrin and dieldrin, expressed as dieldrin

Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)

Endrin

Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)

Fentin, expressed as triphenyltin cation

Haloxypop (sum of haloxypop, its salts and esters including conjugates, expressed as haloxypop)

Heptachlor and *trans*-heptachlor epoxide, expressed as heptachlor

Hexachlorobenzene

Nitrofen

Omethoate

Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

SCHEDULE 7B

Regulation 12A

SPECIFIC MAXIMUM RESIDUE LEVELS OF CERTAIN PESTICIDES IN INFANT
FORMULAE OR FOLLOW-ON FORMULAE

| <i>Column 1</i> <i>Chemical name of the substance</i> | <i>Column 2</i> <i>Maximum residue level(mg/kg)</i> |
|--|--|
| Cadusafos | 0.006 |
| Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl) | 0.006 |
| Ethoprophos | 0.008 |
| Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil) | 0.004 |
| Propineb/propylenethiourea (sum of propineb and propylenethiourea) | 0.006 |

"

SCHEDULE

Regulation 10

NEW SCHEDULES 7A AND 7B TO BE INSERTED IN THE INFANT FORMULA AND FOLLOW-ON FORMULA REGULATIONS 1995

"SCHEDULE 7A

Regulation 12A

PESTICIDES WHOSE RESIDUES MUST NOT BE PRESENT IN INFANT FORMULAE OR FOLLOW-ON FORMULAE AT A LEVEL EXCEEDING 0.003 MG/KG

Chemical name

Aldrin and dieldrin, expressed as dieldrin

Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)

Endrin

Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)

Fentin, expressed as triphenyltin cation

Haloxifop (sum of haloxifop, its salts and esters including conjugates, expressed as haloxifop)

Heptachlor and *trans*-heptachlor epoxide, expressed as heptachlor

Hexachlorobenzene

Nitrofen

Omethoate

Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

SCHEDULE 7B

Regulation 12A

SPECIFIC MAXIMUM RESIDUE LEVELS OF CERTAIN PESTICIDES IN INFANT
FORMULAE OR FOLLOW-ON FORMULAE

| <i>Column 1</i> <i>Chemical name of the substance</i> | <i>Column 2</i> <i>Maximum residue level(mg/kg)</i> |
|--|--|
| Cadusafos | 0.006 |
| Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl) | 0.006 |
| Ethoprophos | 0.008 |
| Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil) | 0.004 |
| Propineb/propylenethiourea (sum of propineb and propylenethiourea) | 0.006 |

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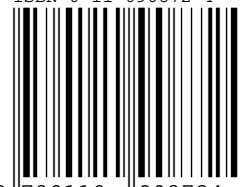
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ISBN 0-11-090872-4



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