OFFERYNNAU STATUDOL CYMRU

WELSH STATUTORY INSTRUMENTS

2014 Rhif 123 (Cy. 13)

2014 No. 123 (W. 13)

BWYD, CYMRU

FOOD, WALES

Rheoliadau Fformiwla Fabanod a Fformiwla Ddilynol (Cymru) (Diwygio) 2014

The Infant Formula and Follow-on Formula (Wales) (Amendment) Regulations 2014

NODYN ESBONIADOL

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

Mae'r Rheoliadau hyn yn diwygio Rheoliadau Fformiwla Fabanod a Fformiwla Ddilynol (Cymru) 2007 (O.S. 2007/3573 (Cy.316)) er mwyn gweithredu Cyfarwyddeb y Comisiwn 2013/46/EU yng Nghymru.

Mae rheoliad 2(3), (5) a (6) yn ei gwneud yn bosibl defnyddio proteinau llaeth geifr wrth weithgynhyrchu fformiwla fabanod a fformiwla ddilynol.

Mae rheoliad 2(4) yn gostwng lleiafswm y lefelau protein a ganiateir mewn fformiwla ddilynol sydd wedi ei gweithgynhyrchu o hydrolysatau protein i sicrhau ei bod yn cyd-fynd â fformiwla fabanod.

Ystyriwyd Cod Ymarfer Gweinidogion Cymru ar gynnal Asesiadau Effaith Rheoleiddiol mewn perthynas â'r Rheoliadau hyn. O ganlyniad, ystyriwyd nad oedd yn angenrheidiol cynnal asesiad effaith rheoleiddiol o'r costau a'r manteision sy'n debygol o ddeillio o gydymffurfio â'r Rheoliadau hyn.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Infant Formula and Follow-on Formula (Wales) Regulations 2007 (S.I. 2007/3573 (W.316)) in order to implement Commission Directive 2013/46/EU in Wales.

Regulation 2(3), (5) and (6) enables the use of goats' milk proteins in the manufacture of infant formula and follow-on formula.

Regulation 2(4) lowers the minimum protein levels permitted in follow-on formula manufactured from protein hydrolysates to bring it in line with infant formula.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.

O F F E R Y N N A U S T A T U D O L
C Y M R U

2014 Rhif 123 (Cy. 13)

BWYD, CYMRU

Rheoliadau Fformiwla Fabanod a Fformiwla Ddilynol (Cymru) (Diwygio) 2014

Gwnaed	*22 Ionawr 2014*
Gosodwyd gerbron Cynulliad Cenedlaethol Cymru	*24 Ionawr 2014*
Yn dod i rym	*28 Chwefror 2014*

Mae Gweinidogion Cymru yn gwneud y Rheoliadau a ganlyn drwy arfer y pwerau a roddwyd gan adran 2(2) o Ddeddf y Cymunedau Ewropeaidd 1972(**1**) ac adrannau 16(1)(e), 17(1) ac 48(1) o Ddeddf Diogelwch Bwyd 1990(**2**)(**3**).

Mae Gweinidogion Cymru wedi eu dynodi at ddibenion adran 2(2) o Ddeddf y Cymunedau Ewropeaidd 1972 mewn perthynas â mesurau sy'n ymwneud â bwyd (gan gynnwys diod) gan gynnwys cynhyrchu sylfaenol o ran bwyd(**4**).

Yn unol ag adran 48(4A) o Ddeddf Diogelwch Bwyd 1990, mae Gweinidogion Cymru wedi rhoi sylw i

(**1**) 1972 p.68. Diwygiwyd adran 2(2) gan adran 27(1)(a) o Ddeddf Diwygio Deddfwriaethol a Rheoleiddiol 2006 (p.51) ac adran 3(3) o Ddeddf yr Undeb Ewropeaidd (Diwygio) 2008 (p.7) a Rhan 1 o'r Atodlen iddi.

(**2**) 1990 p.16. Amnewidiwyd adran 1(1) a (2) (diffiniad o "food") gan O.S. 2004/2990. Diwygiwyd adrannau 17(1) ac 48(1) gan baragraffau 7 ac 8 o Atodlen 5 i Ddeddf Safonau Bwyd 1999 (p.28) ("Deddf 1999"). Diwygiwyd adran 17(1) hefyd gan baragraff 12 o Atodlen 5 i Ddeddf 1999.

(**3**) Trosglwyddwyd swyddogaethau "the Ministers", i'r graddau y maent yn arferadwy o ran Cymru, i Gynulliad Cenedlaethol Cymru gan Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 1999 (O.S. 1999/672) fel y'i darllenir gydag adran 40(3) o Ddeddf 1999, ac yna i Weinidogion Cymru gan baragraff 30 o Atodlen 11 i Ddeddf Llywodraeth Cymru 2006 (2006 p.32).

(**4**) O.S. 2005/1971. Trosglwyddwyd swyddogaethau a roddwyd i Gynulliad Cenedlaethol Cymru wedi hynny i Weinidogion Cymru gan baragraff 30 o Atodlen 11 i Ddeddf Llywodraeth Cymru 2006 (2006 p.32).

W E L S H S T A T U T O R Y
I N S T R U M E N T S

2014 No. 123 (W. 13)

FOOD, WALES

The Infant Formula and Follow-on Formula (Wales) (Amendment) Regulations 2014

Made	*22 January 2014*
Laid before the National Assembly for Wales	*24 January 2014*
Coming into force	*28 February 2014*

The Welsh Ministers make the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**1**) and sections 16(1)(e), 17(1) and 48(1) of the Food Safety Act 1990(**2**)(**3**)**.**

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(**4**).

In accordance with section 48(4A) of the Food Safety Act 1990, the Welsh Ministers have had regard to any

(**1**) 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and section 3(3) of and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c.7).

(**2**) 1990 c.16. Section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Sections 17(1) and 48(1) were amended by paragraphs 7 and 8 of Schedule 5 to the Food Standards Act 1999 (c.28) ("the 1999 Act"). Section 17(1) was also amended by paragraph 12 of Schedule 5 to the 1999 Act.

(**3**) Functions of "the Ministers", so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act, and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32).

(**4**) S.I. 2005/1971. Functions conferred on the National Assembly for Wales were subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32).

unrhyw gyngor perthnasol a roddwyd gan yr Asiantaeth Safonau Bwyd(**1**).

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

Enwi, cychwyn a chymhwyso

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau Fformiwla Fabanod a Fformiwla Ddilynol (Cymru) (Diwygio) 2014.

(2) Daw'r Rheoliadau hyn i rym ar 28 Chwefror 2014 ac maent yn gymwys o ran Cymru.

Diwygio Rheoliadau Fformiwla Fabanod a Fformiwla Ddilynol (Cymru) 2007

2.—(1) Mae Rheoliadau Fformiwla Fabanod a Fformiwla Ddilynol (Cymru) 2007(**3**) wedi eu diwygio fel a ganlyn.

(2) Yn rheoliad 2(1) (dehongli), yn lle'r diffiniad o "y Gyfarwyddeb" rhodder y diffiniad a ganlyn—

> "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(**4**) fel y'i diwygiwyd gan Gyfarwyddeb 2013/46/EU;".

(3) Yn rheoliad 8(2) (meini prawf cyfansoddiadol ar gyfer fformiwla fabanod), ar ôl y geiriau "proteinau llaeth gwartheg" mewnosoder "neu'r proteinau llaeth geifr".

(4) Yn lle rheoliad 9 (meini prawf cyfansoddiadol ar gyfer fformiwla ddilynol) rhodder y rheoliad a ganlyn—

(**1**) Sefydlwyd yr Asiantaeth Safonau Bwyd gan adran 1(1) o Ddeddf 1999.
(**2**) OJ Rhif L 31, 1.2.2002, t.1, fel y'i diwygiwyd ddiwethaf gan Reoliad (EC) Rhif 596/2009 (OJ Rhif L 188, 18.7.2009, t.14).
(**3**) O.S. 2007/3573 (Cy.316), a ddiwygiwyd gan O.S. 2008/2602 (Cy.228). Mae offerynnau diwygio eraill ond nid oes yr un ohonynt yn berthnasol.
(**4**) OJ Rhif L 401, 30.12.2006, t.1. Diwygiwyd y Gyfarwyddeb ddiwethaf gan Gyfarwyddeb y Comisiwn 2013/46/EU (OJ Rhif L 230, 29.08.2013, t.16).

relevant advice given by the Food Standards Agency(**1**).

As required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**2**) there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Title, commencement and application

1.—(1) The title of these Regulations is the Infant Formula and Follow-on Formula (Wales) (Amendment) Regulations 2014.

(2) These Regulations come into force on 28 February 2014 and apply in relation to Wales.

Amendment of the Infant Formula and Follow-on Formula (Wales) Regulations 2007

2.—(1) The Infant Formula and Follow-on Formula (Wales) Regulations 2007(**3**) are amended as follows.

(2) In regulation 2(1) (interpretation) for the definition of "the Directive" substitute the following definition—

> ""the Directive" ("*y Gyfarwyddeb*") means Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC(**4**) as amended by Directive 2013/46/EU;".

(3) In regulation 8(2) (compositional criteria for infant formula) after the words "cows' milk proteins" insert "or goats' milk proteins".

(4) For regulation 9 (compositional criteria for follow-on formula) substitute the following regulation—

(**1**) The Food Standards Agency was established by section 1(1) of the 1999 Act.
(**2**) OJ No L 31, 1.2.2002, p.1, as last amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p.14).
(**3**) S.I. 2007/3573 (W.316), amended by S.I. 2008/2602 (W.228). There are other amending instruments but none is relevant.
(**4**) OJ No L 401, 30.12.2006, p.1. The Directive was last amended by Commission Directive 2013/46/EU (OJ No L 230, 29.08.2013, p.16).

"**Meini prawf cyfansoddiadol ar gyfer fformiwla ddilynol**

9.—(1) Yn ddarostyngedig i baragraff (2), rhaid i fformiwla ddilynol gydymffurfio â'r meini prawf cyfansoddiadol a osodir yn Atodiad II gan gymryd ystyriaeth o'r manylebau yn Atodiad V.

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

(a) rhaid i addasrwydd y fformiwla ddilynol i fodloni gofynion maethol babanod normal iach ar y cyd â bwydo ategol 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 ddilynol fod yn unol â'r manylebau priodol a osodir yn Atodiad VI."

(5) Yn rheoliad 15 (enwi fformiwla fabanod) yn y ddau baragraff, ar ôl "broteinau llaeth gwartheg" mewnosoder "neu broteinau llaeth geifr".

(6) Yn rheoliad 16 (enwi fformiwla ddilynol) yn y ddau baragraff, ar ôl "broteinau llaeth gwartheg" mewnosoder "neu broteinau llaeth geifr".

"**Compositional criteria for follow-on formula**

9.—(1) Subject to paragraph (2), follow-on formula must comply with the compositional criteria set out in Annex II taking into account the specifications in Annex V.

(2) In the case of follow-on formula manufactured from those protein hydrolysates specified in point 2.2 of Annex II with a protein content between the minimum and 0.56g/100kJ (2.25g/100kcal)—

(a) the suitability of the follow-on formula for satisfying the nutritional requirements of normal healthy infants in conjunction with 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 follow-on formula must be in accordance with the appropriate specifications set out in Annex VI."

(5) In regulation 15 (naming of infant formula) in both paragraphs, after "cows' milk proteins" insert "or goats' milk proteins".

(6) In regulation 16 (naming of follow-on formula) in both paragraphs, after "cows' milk proteins" insert "or goats' milk proteins".

Mark Drakeford

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol, un o Weinidogion Cymru.

22 Ionawr 2014

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

22 January 2014

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