



OFFERYNNAU STATUDOL  
CYMRU

WELSH STATUTORY  
INSTRUMENTS

**2021 Rhif 955 (Cy. 219)**

**2021 No. 955 (W. 219)**

**BWYD, CYMRU**

**FOOD, WALES**

**DIOGELWCH BWYD**

**FOOD SAFETY**

**Rheoliadau Fformiwla Fabanod a  
Fformiwla Ddilynol (Cymru)  
(Diwygio) 2021**

**The Infant Formula and Follow-on  
Formula (Wales) (Amendment)  
Regulations 2021**

**NODYN ESBONIADOL**

**EXPLANATORY NOTE**

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

*(This note is not part of the Regulations)*

Mae'r Rheoliadau hyn yn diwygio Rheoliadau Fformiwla Fabanod a Fformiwla Ddilynol (Cymru) 2020 (O.S. 2020/89 (Cy. 13)) ("Rheoliadau 2020") i gymhwyso'r gyfraith a oedd yn bodoli cyn 21 Chwefror 2021 mewn perthynas â fformiwla fabanod a fformiwla ddilynol sydd wedi eu gweithgynhyrchu o hydrolysadau protein o 16 Medi 2021 tan 22 Chwefror 2022.

These Regulations amend the Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89 (W. 13)) ("the 2020 Regulations") to apply the law that existed before 21 February 2021 in relation to infant formula and follow-on formula manufactured from protein hydrolysates from 16 September 2021 until 22 February 2022.

Mae rheoliad 2 yn diwygio rheoliad 5 o Reoliadau 2020 i ddatgymhwyso rheoliadau 2 i 4 o Reoliadau 2020 o fformiwla fabanod a fformiwla ddilynol sydd wedi eu gweithgynhyrchu o hydrolysadau protein.

Regulation 2 amends regulation 5 of the 2020 Regulations to disapply regulations 2 to 4 of the 2020 Regulations from infant formula and follow-on formula manufactured from protein hydrolysates.

Mae rheoliad 2 hefyd yn mewnosod Atodlen newydd 4 yn Rheoliadau 2020. Mae Atodlen newydd 4 yn cynnwys y gyfundrefn reoleiddiol a oedd yn gymwys i fformiwla fabanod a fformiwla ddilynol sydd wedi eu gweithgynhyrchu o hydrolysadau protein cyn 21 Chwefror 2021.

Regulation 2 also inserts a new Schedule 4 into the 2020 Regulations. New Schedule 4 contains the regulatory regime that applied to infant formula and follow-on formula manufactured from protein hydrolysates prior to 21 February 2021.

Ystyriwyd Cod Ymarfer Gweinidogion Cymru ar gynnal Aseidiadau Effaith Rheoleiddiol mewn perthynas â'r Rheoliadau hyn. O ganlyniad, ni luniwyd asesiad effaith rheoleiddiol o'r costau a'r manteision sy'n debygol o ddeillio o gydymffurfio â'r Rheoliadau hyn.

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

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*Gwnaed* 25 Awst 2021  
*Gosodwyd* gerbron *Senedd*  
*Cymru* 26 Awst 2021  
*Yn dod i rym* 16 Medi 2021

*Made* 25 August 2021  
*Laid before Senedd Cymru* 26 August 2021  
*Coming into force* 16 September 2021

Mae Gweinidogion Cymru yn gwneud y Rheoliadau a ganlyn drwy arfer y pwerau a roddir gan adrannau 6(4), 16(1)(a) ac (e) a (2)(b), 17(1) a (2), 26(1) a (3) ac 48(1) o Ddeddf Diogelwch Bwyd 1990(1) ac a freiniwyd bellach ynddynt hwy(2).

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 6(4), 16(1)(a) and (e) and (2)(b), 17(1) and (2), 26(1) and (3) and 48(1) of the Food Safety Act 1990(1) and now vested in them(2).

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- (1) 1990 p. 16. Diwygiwyd adran 6(4) o Ddeddf Diogelwch Bwyd 1990 (“Deddf 1990”) gan baragraff 6 o Atodlen 9 i Ddeddf Dadreoleiddio a Chontractio Allan 1994 (p. 40), paragraff 10(1) a (3)(a) a (b) o Atodlen 5, ac Atodlen 6, i Ddeddf Safonau Bwyd 1999 (p. 28) (“Deddf 1999”) ac O.S. 2002/794. Diwygiwyd adran 16(1) o Ddeddf 1990 gan baragraffau 7 ac 8 o Atodlen 5 i Ddeddf 1999. Diwygiwyd adran 17 o Ddeddf 1990 gan baragraffau 7, 8 a 12 o Atodlen 5 i Ddeddf 1999 ac O.S. 2011/1043. Diwygiwyd adran 26(3) gan Atodlen 6 i Ddeddf 1999. Diwygiwyd adran 48(1) gan baragraffau 7 ac 8 o Atodlen 5 i Ddeddf 1999.
- (2) Mae'r swyddogaethau hynny a oedd gynt yn arferadwy gan “the Ministers” (sef, o ran Cymru a Lloegr ac yn gweithredu ar y cyd, y Gweinidog Amaethyddiaeth, Pysgodfeydd a Bwyd a'r Ysgrifenyddion Gwladol a oedd yn eu trefn yn ymwneud ag iechyd yn Lloegr a bwyd ac iechyd yng Nghymru) bellach yn arferadwy o ran Lloegr gan yr Ysgrifennydd Gwladol yn unol â pharagraff 8 o Atodlen 5 i Ddeddf 1999. Trosglwyddwyd y swyddogaethau hynny, i'r graddau y maent yn arferadwy o ran Cymru, i Gynulliad Cenedlaethol Cymru gan O.S. 1999/672 fel y'i darllenir gydag adran 40(3) o Ddeddf 1999, a'u trosglwyddo wedi hynny i Weinidogion Cymru gan baragraff 30 o Atodlen 11 i Ddeddf Llywodraeth Cymru 2006 (p. 32).

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- (1) 1990 c. 16. Section 6(4) of the Food Safety Act 1990 (“the 1990 Act”) was amended by paragraph 6 of Schedule 9 to the Deregulation and Contracting Out Act 1994 (c. 40), paragraph 10(1) and (3)(a) and (b) of Schedule 5, and Schedule 6 to the Food Standards Act 1999 (c. 28) (“the 1999 Act”) and S.I. 2002/794. Section 16(1) of the 1990 Act was amended by paragraphs 7 and 8 of Schedule 5 to the 1999 Act. Section 17 of the 1990 Act was amended by paragraphs 7, 8 and 12 of Schedule 5 to the 1999 Act and S.I. 2011/1043. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 48(1) was amended by paragraphs 7 and 8 of Schedule 5 to the 1999 Act.
- (2) Those functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting 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) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Those functions, so far as exercisable in relation to Wales, 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 paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32).

Mae Gweinidogion Cymru wedi rhoi sylw i gyngor perthnasol a roddwyd gan yr Asiantaeth Safonau Bwyd yn unol ag adran 48(4A) o Ddeddf Diogelwch Bwyd 1990(1).

Ymgynghorwyd yn agored ac yn dryloyw â'r cyhoedd 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), wrth lunio a gwerthuso'r Rheoliadau hyn.

### Enwi a chychwyn

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau Fformiwla Fabanod a Fformiwla Ddilynol (Cymru) (Diwygio) 2021.

(2) Daw'r Rheoliadau hyn i rym 16 Medi 2021.

### Diwygio Rheoliadau Fformiwla Fabanod a Fformiwla Ddilynol (Cymru) 2020

2.—(1) Mae Rheoliadau Fformiwla Fabanod a Fformiwla Ddilynol (Cymru) 2020(3) wedi eu diwygio fel a ganlyn.

(2) Ar ôl rheoliad 5(3) (dirymiadau, arbedion a darpariaethau trosiannol) mewnosoder—

“(4) Nid yw rheoliadau 2 i 4 yn gymwys mewn cysylltiad â fformiwla fabanod a fformiwla ddilynol sydd wedi eu gweithgynhyrchu o hydrolysadau protein tan 22 Chwefror 2022.

(5) Mae Atodlen 4 yn gwneud darpariaeth mewn perthynas â fformiwla fabanod a fformiwla ddilynol sydd wedi eu gweithgynhyrchu o hydrolysadau protein tan 22 Chwefror 2022.”

(3) Ar ôl Atodlen 3 (Dirymiadau sy'n gysylltiedig â Fformiwla Fabanod a Fformiwla Ddilynol) mewnosoder yr Atodlen newydd 4 a nodir yn yr Atodlen i'r Rheoliadau hyn.

The Welsh Ministers have had regard to relevant advice given by the Food Standards Agency in accordance with section 48(4A) of the Food Safety Act 1990(1).

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

### Title and commencement

1.—(1) The title of these Regulations is the Infant Formula and Follow-on Formula (Wales) (Amendment) Regulations 2021.

(2) These Regulations come into force on 16 September 2021.

### Amendment of the Infant Formula and Follow-on Formula (Wales) Regulations 2020

2.—(1) The Infant Formula and Follow-on Formula (Wales) Regulations 2020(3) are amended as follows.

(2) After regulation 5(3) (revocations, savings and transitional provisions) insert—

“(4) Regulations 2 to 4 do not apply in respect of infant formula and follow-on formula manufactured from protein hydrolysates until 22 February 2022.

(5) Schedule 4 makes provision in relation to infant formula and follow-on formula manufactured from protein hydrolysates until 22 February 2022.”

(3) After Schedule 3 (Revocations relating to Infant Formula and Follow-on Formula) insert the new Schedule 4 set out in the Schedule to these Regulations.

(1) Mewnosodwyd adran 48(4A) gan adran 40(1) o Ddeddf 1999 a pharagraff 21 o Atodlen 5 iddi.

(2) OJ Rhif L 31, 1.2.2002, t. 1, fel y'i diwygiwyd ddiwethaf gan Reoliad (EU) 2019/1243 Senedd Ewrop a'r Cyngor (OJ Rhif L 198, 25.7.2019, t. 241).

(3) O.S. 2020/89 (Cy. 13).

(1) Section 48(4A) was inserted by section 40(1) of, and paragraph 21 of Schedule 5 to, the 1999 Act.

(2) OJ No. L 31, 1.2.2002, p. 1, as last amended by Regulation (EU) 2019/1243 of the European Parliament and of the Council (OJ No. L 198, 25.7.2019, p. 241).

(3) S.I. 2020/89 (W. 13).

Y Dirprwy Weinidog Iechyd Meddwl a Llesiant o dan awdurdod y Gweinidog Iechyd a Gwasanaethau Cymdeithasol, un o Weinidogion Cymru  
25 Awst 2021

Deputy Minister for Mental Health and Wellbeing under authority of the Minister for Health and Social Services, one of the Welsh Ministers  
25 August 2021

YR ATODLEN Rheoliad 2(3)

SCHEDULE Regulation 2(3)

“ATODLEN 4 Rheoliad 5(5)

“SCHEDULE 4 Regulation 5(5)

Rheoleiddio fformiwla fabanod a fformiwla ddilynol sydd wedi eu gweithgynhyrchu o hydrolysadau protein tan 22 Chwefror 2022

Regulation of infant formula and follow-on formula manufactured from protein hydrolysates until 22 February 2022

**Dehongli**

**Interpretation**

1.—(1) Yn yr Atodlen hon—

mae i “awdurdod bwyd” yr ystyr a roddir i “food authority” yn rhinwedd adran 5(1A) o’r Ddeddf(1);

ystyr “babanod” (“*infants*”) yw plant o dan 12 mis oed;

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

ystyr “fformiwla ddilynol” (“*follow-on formula*”) yw bwydydd a fwriedir at ddefnydd maethol neilltuol gan fabanod pan gyflwynir bwydo ategol priodol ac sy’n ffurfio’r brif elfen hylif yn neiet y babanod hynny sy’n amrywio’n gynyddol;

ystyr “fformiwla fabanod” (“*infant formula*”) yw bwydydd a fwriedir at ddefnydd maethol neilltuol gan fabanod yn ystod misoedd cyntaf eu bywyd ac sydd ar eu pennau eu hunain yn bodloni gofynion maethol y babanod hynny hyd nes y cyflwynir bwydo ategol priodol;

1.—(1) In this Schedule—

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

“the Directive” (“*y Gyfarwydddeb*”) means Commission Directive 2006/141/EC(1) on infant formulae and follow-on formulae and amending Directive 1999/21/EC;

“follow-on formula” (“*fformiwla ddilynol*”) means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants;

“food authority” (“*awdurdod bwyd*”) has the meaning that it bears by virtue of section 5(1A) of the Act(2);

(1) Mewnosodwyd adran 5(1A) gan baragraff 16 o Atodlen 9 i Ddeddf Llywodraeth Leol (Cymru) 1994 (p. 19).

(1) OJ L 401, 30.12.2006, p. 1, as last amended by Article 1 of Commission Delegated Regulation (EU) 2021/572 amending Commission Delegated Regulation (EU) No 2016/127 to continue the application of Directive 2006/141/EC to infant formula and follow-on formula manufactured from protein hydrolysates until 21 February 2022.

(2) Section 5(1A) was inserted by paragraph 16 of Schedule 9 to the Local Government (Wales) Act 1994 (c. 19).

ystyr “y Gyfarwyddeb” (“*the Directive*”) yw Cyfarwyddeb y Comisiwn 2006/141/EC(1) ar fformiwlâu babanod a fformiwlâu ddilynol ac sy’n diwygio Cyfarwyddeb 1999/21/EC;

ystyr “plant ifanc” (“*young children*”) yw plant rhwng un a thair blwydd oed;

ystyr “system gofal iechyd” (“*health care system*”) yw sefydliadau neu gyrff sy’n ymwneud, yn uniongyrchol neu’n anuniongyrchol, â gofal iechyd i famau, babanod a menywod beichiog, gan gynnwys meithrinfeydd neu sefydliadau gofal plant a gweithwyr iechyd mewn practis preifat.

(2) Yn ddarostyngedig i is-baragraff (3), mae i unrhyw ymadrodd a ddefnyddir yn yr Atodlen hon, ac eithrio un a ddiffinnir yn is-baragraff (1), ac y defnyddir yr ymadrodd Saesneg cyfatebol yn y Ddeddf, yr ystyr a roddir i’r ymadrodd Saesneg cyfatebol hwnnw yn y Ddeddf.

(3) Mae i unrhyw ymadrodd a ddefnyddir yn yr Atodlen hon ac yn y Gyfarwyddeb yr ystyr a roddir i’r ymadrodd Saesneg cyfatebol hwnnw yn y Gyfarwyddeb.

(4) Yn yr Atodlen hon, mae unrhyw gyfeiriad at Atodiad â rhif yn gyfeiriad at yr Atodiad sy’n dwyn y rhif hwnnw yn y Gyfarwyddeb.

### **Gwaharddiad ar farchnata fformiwlâ fabanod neu fformiwlâ ddilynol oni bai bod amodau penodol wedi eu bodloni**

2.—(1) Ni chaiff unrhyw berson farchnata fformiwlâ fabanod sy’n mynd yn groes i baragraff 4, 5, 7, 9, 10, 11, 13(1), (2) neu (3), 14, 16, 18 neu 19(1) neu sy’n methu â chydymffurfio ag ef.

(2) Ni chaiff unrhyw berson farchnata fformiwlâ ddilynol sy’n mynd yn groes i baragraff 4, 6, 8, 9, 10, 11, 13(1), (2) neu (3), 15, 17, 18 neu 19(2) neu sy’n methu â chydymffurfio ag ef.

“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;

“infant formula” (“*fformiwlâ fabanod*”) means foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding;

“infants” (“*babanod*”) means children under the age of 12 months;

“young children” (“*plant ifanc*”) means children aged between one and three years.

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

(3) Any expression used both in this Schedule and in the Directive has the meaning that it bears in the Directive.

(4) In this Schedule, any reference to a numbered Annex is a reference to the Annex bearing that number in the Directive.

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

2.—(1) No person may market infant formula which contravenes or fails to comply with paragraph 4, 5, 7, 9, 10, 11, 13(1), (2) or (3), 14, 16, 18 or 19(1).

(2) No person may market follow-on formula which contravenes or fails to comply with paragraph 4, 6, 8, 9, 10, 11, 13(1), (2) or (3), 15, 17, 18 or 19(2).

(1) OJ L 401, 30.12.2006, t. 1, fel y’i diwygiwyd ddiwethaf gan Erthygl 1 o Reoliad Dirprwyedig y Comisiwn (EU) 2021/572 sy’n diwygio Rheoliad Dirprwyedig y Comisiwn (EU) Rhif 2016/127 i barhau i gymhwyso Cyfarwyddeb 2006/141/EC i fformiwlâ fabanod a fformiwlâ ddilynol sydd wedi eu gweithgynhyrchu o hydrolisadau protein tan 21 Chwefror 2022.

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

3. Ni chaiff unrhyw berson farchnata neu honni 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.

### **Meintiau o sylweddau sy'n peryglu iechyd babanod a phlant ifanc**

4. Ni chaiff fformiwla fabanod a fformiwla ddilynol gynnwys unrhyw feintiau o unrhyw sylwedd sy'n peryglu iechyd babanod a phlant ifanc.

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

5.—(1) Rhaid i fformiwla fabanod fod wedi ei gweithgynhyrchu—

- (a) o hydrolysadau protein; a
- (b) o gynhwysion bwyd eraill y cafodd eu haddasrwydd at ddefnydd maethol neilltuol gan fabanod o'u genedigaeth ei sefydlu drwy ddata gwyddonol a dderbynnir yn gyffredinol ac a gafodd ei ddangos yn unol ag is-baragraff (2).

(2) Mae addasrwydd i'w ddangos drwy adolygiad systematig o'r data sydd ar gael sy'n ymwneud â'r manteision a ddisgwyllir ac ag ystyriaethau diogelwch yn ogystal â thrwy astudiaethau priodol, pan fo angen hynny, a wnaed gan ddilyn canllawiau arbenigol a dderbynnir yn gyffredinol ar ddylunio a chynnal astudiaethau o'r fath.

### **Hydrolysadau protein a chynhwysion bwyd eraill sy'n addas i fabanod dros 6 mis oed (fformiwla ddilynol)**

6. Rhaid i fformiwla ddilynol fod wedi ei gweithgynhyrchu—

- (a) o hydrolysadau protein; a
- (b) o gynhwysion bwyd eraill y cafodd eu haddasrwydd at ddefnydd maethol neilltuol gan fabanod dros 6 mis oed ei sefydlu drwy ddata gwyddonol a dderbynnir yn gyffredinol ac a gafodd ei ddangos yn unol â pharagraff 5(2).

### **Prohibition on the marketing of products other than infant formula for normal healthy infants**

3. 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**

4. 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 hydrolysates and other food ingredients suitable for infants from birth (infant formula)**

5.—(1) Infant formula must be manufactured from—

- (a) protein hydrolysates; 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 sub-paragraph (2).

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

### **Protein hydrolysates and other food ingredients suitable for infants aged over 6 months (follow-on formula)**

6. Follow-on formula must be manufactured from—

- (a) protein hydrolysates; and
- (b) other food ingredients the suitability of which for particular nutritional use by infants aged over 6 months has been established by generally accepted scientific data and demonstrated in accordance with paragraph 5(2).

### **Meini prawf cyfansoddiadol ar gyfer fformiwla fabanod**

7.—(1) Yn ddarostyngedig i is-baragraff (2), rhaid i fformiwla fabanod gydymffurfio â'r meini prawf cyfansoddiadol a nodir yn Atodiad I gan ystyried y manylebau yn Atodiad V.

(2) Yn achos fformiwla fabanod sydd wedi ei gweithgynhyrchu o hydrolysadau protein a bennir ym mhwynt 2.2 o Atodiad I sydd â'u cynnwys protein rhwng yr isafswm a 0.56g/100kJ (2.25g/100kcal)—

- (a) rhaid i addasrwydd y fformiwla fabanod at y defnydd maethol neilltuol gan fabanod gael ei ddangos drwy astudiaethau priodol, a wnaed gan ddilyn canllawiau arbenigol a dderbynnir yn gyffredinol ar ddylunio a chynnal astudiaethau o'r fath; a
- (b) rhaid i'r fformiwla fabanod fod yn unol â'r manylebau priodol a nodir yn Atodiad VI.

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

8.—(1) Yn ddarostyngedig i is-baragraff (2), rhaid i fformiwla ddilynol gydymffurfio â'r meini prawf cyfansoddiadol a nodir yn Atodiad II gan ystyried y manylebau a nodir yn Atodiad V.

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

- (a) rhaid i addasrwydd y fformiwla ddilynol ar gyfer bodloni gofynion maethol babanod normal iach ar y cyd â bwydo ategol gael ei ddangos drwy astudiaethau priodol, a wnaed gan ddilyn canllawiau arbenigol a dderbynnir yn gyffredinol ar ddylunio a chynnal astudiaethau o'r fath; a
- (b) rhaid i'r fformiwla ddilynol fod yn unol â'r manylebau priodol a nodir yn Atodiad VI.

### **Ychwanegu dŵr (fformiwla fabanod a fformiwla ddilynol)**

9. Er mwyn gwneud fformiwla fabanod neu fformiwla ddilynol yn barod i'w defnyddio rhaid nad oes angen gwneud dim byd mwy nag ychwanegu dŵr.

### **Compositional criteria for infant formula**

7.—(1) Subject to sub-paragraph (2), 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 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 the particular nutritional use by infants 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**

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

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

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

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

10. Rhaid cadw at y gwaharddiadau a'r therfynau ar y defnydd o gynhwysion bwyd mewn fformiwla fabanod a fformiwla ddilynol, a nodir yn y drefn honno yn Atodiadau I a II.

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

11.—(1) Dim ond y sylweddau a restrir yn Atodiad III y caniateir eu defnyddio wrth weithgynhyrchu fformiwla fabanod a fformiwla ddilynol er mwyn bodloni gofynion Atodiadau I a II yn y drefn honno—

- (a) ar sylweddau mwynol;
- (b) ar fitaminau;
- (c) ar asidau amino a chyfansoddion nitrogen eraill; a
- (d) ar sylweddau eraill sydd â diben maethol neilltuol.

(2) Rhaid i sylweddau a ddefnyddir wrth weithgynhyrchu fformiwla fabanod a fformiwla ddilynol yn unol ag is-baragraff (1) fodloni'r meini prawf purdeb perthnasol.

(3) Y meini prawf purdeb perthnasol at ddibenion is-baragraff (2) yw—

- (a) y meini prawf purdeb ar gyfer sylweddau, fel y darperir ar eu cyfer yng nghyfraith yr UE a ddargedwir 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 a dderbynnir yn gyffredinol a argymhellir gan gyrrff rhyngwladol.

### **Hysbysiad o fformiwla fabanod**

12. Ni chaiff unrhyw weithredwr busnes bwyd roi fformiwla fabanod ar y farchnad yng Nghymru nad yw eto wedi ei rhoi ar y farchnad yn y Deyrnas Unedig oni bai bod y gweithredwr busnes bwyd wedi rhoi hysbysiad ymlaen llaw i Weinidogion Cymru drwy anfon atynt fodel o'r label a ddefnyddir ar gyfer y cynnyrch.

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

10. 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.

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

11.—(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 sub-paragraph (1) must meet the relevant purity criteria.

(3) The relevant purity criteria for the purposes of sub-paragraph (2) are—

- (a) the purity criteria for substances, as provided for in retained EU law 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**

12. No food business operator may place an infant formula on the market in Wales that has not yet been placed on the market in the United Kingdom unless the food business operator has given prior notice to the Welsh Ministers by forwarding to them a model of the label used for the product.



### **Gweddillion plaladdwyr (fformiwla fabanod a fformiwla ddilynol)**

**13.**—(1) Yn ddarostyngedig i is-baragraffau (2) a (3), ni chaiff fformiwla fabanod na fformiwla ddilynol gynnwys lefelau uwch na 0.01 mg/kg o weddillion plaladdwyr unigol.

(2) Ni chaiff fformiwla fabanod na fformiwla ddilynol gynnwys lefel uwch na 0.003 mg/kg o unrhyw weddill plaladdwr o blaladdwr a restrir yn Nhabl 1 neu Dabl 2 o Atodiad VIII.

(3) Ni chaiff fformiwla fabanod na fformiwla ddilynol gynnwys lefel uwch o unrhyw weddill plaladdwr o blaladdwr a restrir yn Atodiad IX nag uchafswm lefel y gweddill a bennir yn yr Atodiad hwnnw.

(4) Mae'r lefelau y cyfeirir atynt yn is-baragraffau (1) i (3) yn gymwys i'r fformiwla fabanod neu'r fformiwla ddilynol—

- (a) sydd wedi ei gweithgynhyrchu ar ffurf sy'n barod i'w defnyddio; neu
- (b) os nad yw wedi ei gweithgynhyrchu felly, fel y mae wedi ei hailgyfansoddi yn ôl cyfarwyddiadau'r gweithgynhyrchwr.

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

### **Enwi fformiwla fabanod**

**14.** Ni chaniateir gwerthu fformiwla fabanod onis gwerthir o dan yr enw "infant formula".

### **Enwi fformiwla ddilynol**

**15.** Ni chaniateir gwerthu fformiwla ddilynol onis gwerthir o dan yr enw "follow-on formula".

### **Labelu fformiwla fabanod**

**16.**—(1) Ni chaniateir gwerthu fformiwla fabanod oni bai bod y labelu yn dwyn—

- (a) datganiad i'r perwyl bod y cynnyrch yn addas i'w ddefnyddio at ddiben maethol neilltuol gan fabanod o'u genedigaeth pan nad ydynt yn cael eu bwydo o'r fron;
- (b) y gwerth egni sydd ar gael, wedi ei fynegi mewn kJ a kcal, a chynnwys proteinau, carbohydradau a lipidau, wedi ei fynegi ar ffurf rifyddegol, sydd ym mhob 100ml o'r cynnyrch sy'n barod i'w ddefnyddio;

### **Pesticide residues (infant formula and follow-on formula)**

**13.**—(1) Subject to sub-paragraphs (2) and (3), infant formula and follow-on formula must not contain residues of individual pesticides at levels exceeding 0.01 mg/kg.

(2) Infant formula and follow-on formula must not contain any pesticide 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 must not contain any pesticide 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 sub-paragraphs (1) to (3) apply to the infant formula or follow-on formula—

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

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

### **Naming of infant formula**

**14.** Infant formula must not be sold unless it is sold under the name "infant formula".

### **Naming of follow-on formula**

**15.** Follow-on formula must not be sold unless it is sold under the name "follow-on formula".

### **Labelling of infant formula**

**16.**—(1) Infant formula must not be sold unless the labelling bears—

- (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) pa faint ar gyfartaledd o bob sylwedd mwynol ac o bob fitamin a grybwyllir yn Atodiad I a, phan fo'n gymwys, o gôlin, inositol a charnitîn, wedi ei fynegi ar ffurf rifyddegol, sydd ym mhob 100ml o'r cynnyrch sy'n barod i'w ddefnyddio;
- (d) cyfarwyddiadau ar gyfer paratoi, storio a gwaredu'r cynnyrch yn briodol a rhybudd rhag y peryglon i iechyd o'i baratoi a'i storio yn amhriodol; ac
- (e) 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 sy'n argymhell mai dim ond wedi cael cyngor gan bersonau annibynnol sydd â chymwysterau mewn meddygaeth, maethiad neu fferylliaeth, neu broffesiynolion eraill sy'n gyfrifol am ofal mamau a gofal plant y dylid defnyddio'r cynnyrch.
- (2) Rhaid i labelu'r fformiwla fabanod—
- (a) bod wedi ei ddylunio i ddarparu'r wybodaeth angenrheidiol am y defnydd priodol o'r cynnyrch mewn modd nad yw'n annog peidio â bwydo ar y fron; a
- (b) peidio â chynnwys y termau "humanised", "maternalised", "adapted" neu unrhyw derm tebyg.
- (3) Ni chaniateir i labelu fformiwla fabanod gynnwys—
- (a) unrhyw lun o faban; neu
- (b) unrhyw lun arall neu destun a all ddefnyddio'r cynnyrch,
- ond caiff gynnwys delweddau graffig er mwyn adnabod y cynnyrch yn hawdd neu er mwyn dangos dulliau paratoi.
- (4) Ni chaiff labelu fformiwla fabanod ddwyn honiadau o ran maethiad ac iechyd ond—
- (a) pan yw'r honiad wedi ei restru yng ngholofn gyntaf Atodiad IV ac wedi ei fynegi yn y termau a nodir yno; a
- (b) pan yw'r amod a bennir yn ail golofn Atodiad IV mewn perthynas â'r honiad perthnasol a wneir yn y golofn gyntaf wedi ei fodloni.
- (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
- (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 must 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) Caiff labelu fformiwla fabanod ddwyn manylion ynghylch pa faint ar gyfartaledd o'r maetholion a grybwyllir yn Atodiad III, pan nad yw is-baragraff (1)(c) yn cwmpasu gwybodaeth o'r fath, wedi ei fynegi ar ffurf rifyddegol, sydd ym mhob 100 ml o'r cynnyrch sy'n barod i'w ddefnyddio.

### Labelu fformiwla ddilynol

17.—(1) Ni chaniateir gwerthu fformiwla ddilynol oni bai bod y labelu yn dwyn—

- (a) datganiad i'r perwyl—
  - (i) mai dim ond i'w ddefnyddio at ddiben maethol neilltuol gan fabanod dros 6 mis oed y mae'r cynnyrch yn addas;
  - (ii) na ddylai fod ond yn rhan o ddeiet amrywiol;
  - (iii) nad yw i gael ei ddefnyddio gan fabanod yn lle llaeth y fron yn ystod 6 mis cyntaf eu bywyd; a
  - (iv) mai dim ond wedi cael cyngor gan bersonau annibynnol sydd â chymwysterau mewn meddygaeth, maethiad neu fferylliaeth, neu broffesiynolion eraill sy'n gyfrifol am ofal mamau neu ofal plant 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 6 mis oed, a hynny ar sail anghenion twf a datblygiad penodol y baban unigol;
- (b) y gwerth egni sydd ar gael, wedi ei fynegi mewn kJ a kcal, a chynnwys proteinau, carbohydradau a lipidau, wedi ei fynegi ar ffurf rifyddegol, sydd 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 a, phan fo'n gymwys, o golîn, inositol a charnitîn, wedi ei fynegi ar ffurf rifyddegol, sydd ym mhob 100ml o'r cynnyrch sy'n barod i'w ddefnyddio;
- (d) cyfarwyddiadau ar gyfer paratoi, storio a gwaredu'r cynnyrch yn briodol a rhybudd rhag y peryglon i iechyd o'i baratoi a'i storio yn amhriodol.

(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 covered by sub-paragraph (1)(c) expressed in numerical form, per 100 ml of the product ready for use.

### Labelling of follow-on formula

17.—(1) Follow-on formula must not be sold unless the labelling bears—

- (a) a statement to the effect that—
  - (i) the product is suitable only for particular nutritional use by infants over the age of 6 months;
  - (ii) it should form only part of a diversified diet;
  - (iii) it is not to be used by infants as a substitute for breast milk during the first 6 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 6 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) Rhaid i labelu fformiwla ddilynol—
- (a) bod wedi ei ddylunio i ddarparu'r wybodaeth angenrheidiol am y defnydd priodol o'r cynnyrch mewn modd nad yw'n annog peidio â bwydo ar y fron; a
  - (b) peidio â chynnwys y termau "humanised", "maternalised", "adapted" neu unrhyw derm tebyg.
- (3) Caiff labelu fformiwla ddilynol ddwyn manylion ynghylch—
- (a) pa faint ar gyfartaledd o'r maetholion a grybwyllir yn Atodiad III, pan nad yw is-baragraff (1)(c) yn cwmpasu gwybodaeth o'r fath, wedi ei fynegi ar ffurf rifyddegol, sydd ym mhob 100 ml o'r cynnyrch sy'n barod i'w ddefnyddio; a
  - (b) yn ychwanegol at wybodaeth rifyddegol, gwybodaeth ar fitaminau a mwynau sydd wedi eu cynnwys yn Atodiad VII, wedi ei mynegi fel canran o'r gwerthoedd cyfeiriadol a roddir yn yr Atodiad hwnnw, sydd ym mhob 100ml o'r cynnyrch sy'n barod i'w ddefnyddio.

#### **Osgoi'r risg o ddryswch rhwng fformiwla fabanod a fformiwla ddilynol**

**18.** Rhaid labelu fformiwla fabanod a fformiwla ddilynol mewn ffordd sy'n galluogi defnyddwyr i wahaniaethu'n glir rhwng y cynhyrchion hynny er mwyn osgoi unrhyw risg o ddryswch rhwng fformiwla fabanod a fformiwla ddilynol.

#### **Cyflwyniad (fformiwla fabanod a fformiwla ddilynol)**

**19.**—(1) Rhaid i gyflwyniad fformiwla fabanod gydymffurfio â darpariaethau paragraffau 16(1)(e), (2), (3) a (4) a 18.

(2) Rhaid i gyflwyniad fformiwla ddilynol gydymffurfio â darpariaethau paragraffau 17(2) a 18.

(3) At ddibenion y paragraff hwn, mae "cyflwyniad" yn cynnwys siâp, gwedd neu ddull pacio'r cynhyrchion o dan sylw, y deunyddiau pacio a ddefnyddir, y ffordd y maent wedi eu trefnu a'r man lle y maent yn cael eu harddangos.

- (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 covered by subparagraph (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 100ml of the product ready for use.

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

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

**19.**—(1) The presentation of infant formula must comply with the provisions of paragraphs 16(1)(e), (2), (3) and (4) and 18.

(2) The presentation of follow-on formula must comply with the provisions of paragraphs 17(2) and 18.

(3) For the purposes of this paragraph, "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.

### **Cyfyngiadau ar hysbysebu fformiwla fabanod**

**20.**—(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 ar wahân i'r cyhoedd yn gyffredinol; na
- (b) oni bai bod yr hysbyseb yn cydymffurfio â darpariaethau paragraff 16(1)(e), (2), (3) a (4), paragraff 18 ac is-baragraffau (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 bod bwydo â photel yn cyfateb i fwydo ar y fron neu'n rhagori arno.

### **Cyfyngiadau ar hysbysebu fformiwla ddilynol**

**21.** Ni chaiff unrhyw berson hysbysebu fformiwla ddilynol pan fo'r hysbyseb yn mynd yn groes i'r darpariaethau a nodir ym mharagraffau 17(2) a 18 neu'n methu â chydymffurfio â hwy.

### **Cyfyngiadau ar hyrwyddo fformiwla fabanod**

**22.**—(1) Mewn unrhyw fan lle y 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 ei ddylunio i hyrwyddo gwerthiannau;
- (c) rhoi i ffwrdd—
  - (i) unrhyw fformiwla fabanod fel sampl am ddim; na
  - (ii) unrhyw gwpon y gellir ei ddefnyddio i brynu fformiwla fabanod ar ddisgownt;
- (d) hyrwyddo gwerthiant fformiwla fabanod drwy breimymau, gwerthiannau arbennig, gwerthiannau islaw cost neu werthiannau rhwym; nac

### **Restrictions on advertising infant formula**

**20.**—(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 paragraphs 16(1)(e), (2), (3) and (4), paragraph 18 and subparagraphs (2) and (3).

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

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

### **Restrictions on advertising follow-on formula**

**21.** No person may advertise follow-on formula where the advertisement contravenes or fails to comply with the provisions set out in paragraphs 17(2) and 18.

### **Restrictions on promotion of infant formula**

**22.**—(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) 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) ymgymryd ag unrhyw weithgaredd hyrwyddo arall i gymell gwerthiant o fformiwla fabanod.

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

- (a) i'r cyhoedd yn gyffredinol;
- (b) i fenywod beichiog;
- (c) i famau; na
- (d) i aelodau o deuluoedd personau a grybwyllir ym mharagraffau (b) ac (c),

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

### **Darparu deunydd gwybodaethol ac addysgol sy'n ymdrin â bwydo babanod**

**23.**—(1) Ni chaiff unrhyw berson gynhyrchu na chyhoeddi unrhyw ddeunydd gwybodaethol neu addysgol, pa un ai ar ffurf ysgrifenedig neu glyweledol, sy'n ymdrin â bwydo babanod ac y bwriedir iddo gyrraedd menywod beichiog a mamau babanod a mamau plant ifanc, onid yw'r deunydd hwnnw yn 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 bwydo ar y fron a'i gynnal;
- (d) effaith negyddol bosibl cyflwyno bwydo rhannol â photel ar fwydo ar y fron;
- (e) anhawster newid y penderfyniad i beidio â bwydo ar y fron; ac
- (f) pan fo angen, y defnydd priodol o fformiwla fabanod.

(2) Pan yw'r deunydd y cyfeirir ato yn isbaragraff (1) yn cynnwys gwybodaeth am y defnydd o fformiwla fabanod, rhaid iddo gynnwys gwybodaeth—

- (a) am y goblygiadau cymdeithasol ac ariannol o'i ddefnyddio;
- (b) am beryglon bwydydd neu ddulliau bwydo amhriodol i iechyd; ac
- (c) am beryglon camddefnyddio fformiwla fabanod i iechyd.

- (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, samples 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 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**

**23.**—(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 subparagraph (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 formula.

(3) Pan yw'r deunydd y cyfeirir ato yn is-baragraff (1) yn cynnwys gwybodaeth am y defnydd o fformiwla fabanod, ni chaiff ddefnyddio unrhyw luniau a all ddelfrydu'r defnydd o fformiwla fabanod.

(4) Ni chaiff unrhyw weithgynhyrchwr na dosbarthwr fformiwla fabanod wneud rhodd o unrhyw gyfarpar na deunyddiau gwybodaethol neu addysgol ac eithrio yn unol â'r amodau a ganlyn—

- (a) rhaid bod y rhodd wedi ei gwneud ar ôl cael cais amdani gan y sawl y bwriedir iddo ei derbyn;
- (b) rhaid bod y rhodd wedi ei gwneud gydag awdurdod ysgrifenedig Gweinidogion Cymru neu yn 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; a
- (d) dim ond drwy'r system gofal iechyd y mae rhaid dosbarthu'r cyfarpar neu'r deunyddiau.

#### **Fformiwla fabanod ddi-dâl neu am bris gostyngol**

**24.** Rhaid i sefydliad neu gorff sy'n cael unrhyw fformiwla fabanod yn ddi-dâl neu am bris gostyngol—

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

#### **Troseddau a gorfodi**

**25.**—(1) Mae unrhyw berson sy'n mynd yn groes i unrhyw un neu ragor o'r darpariaethau sydd wedi eu cynnwys ym mharagraffau 2, 3, 12, 20(1), 21, 22, 23 a 24 neu sy'n methu â chydymffurfio ag unrhyw un neu ragor ohonynt yn euog o drosedd ac yn agored, ar euogfarn ddiannod, i ddirwy.

(3) When the material referred to in subparagraph (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 or materials must not be marked or labelled with the name of a proprietary brand of infant formula; and
- (d) the equipment or materials must be distributed only through the health care system.

#### **Free or reduced rate infant formula**

**24.** 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 for infants who have to be fed on infant formula and only for as long as required by those infants.

#### **Offences and enforcement**

**25.**—(1) Any person who contravenes or fails to comply with any of the provisions contained in paragraphs 2, 3, 12, 20(1), 21, 22, 23 and 24, is guilty of an offence and is liable, on summary conviction, to a fine.

(2) Rhaid i bob awdurdod bwyd orfodi a gweithredu'r Atodlen hon yn ei ardal.

### **Cymhwyso darpariaethau hysbysiadau gwella'r Ddeddf**

**26.**—(1) Mae adran 10(1) a (2) o'r Ddeddf (hysbysiadau gwella) yn gymwys, gyda'r addasiad (yn achos adran 10(1)) a bennir yn is-baragraff (2), at ddibenion—

- (a) galluogi i hysbysiad gwella gael ei gyflwyno i berson, sy'n ei gwneud yn ofynnol i'r person sicrhau cydymffurfedd ag unrhyw un neu ragor o'r gofynion a bennir ym mharagraff 2; a
- (b) gwneud methu â chydymffurfio â hysbysiad y cyfeirir ato ym mharagraff (a) yn drosedd.

(2) Yn lle adran 10(1) o'r Ddeddf (hysbysiadau gwella) rhodder—

“(1) If an authorised officer of an enforcement authority has reasonable ground for suspecting that a person is failing to comply with paragraph 2 of Schedule 4 to the Infant Formula and Follow-on Formula (Wales) Regulations 2020, the authorised officer may, by a notice served on that person (in this Act referred to as an “improvement notice”)—

- (a) state the officer's grounds for suspecting that the person is failing to comply or as the case may be, that the food does not comply with the relevant provision;
- (b) specify the matters which constitute the failure to so comply;
- (c) specify the measures which, in the officer's opinion, the person must take in order to secure compliance; and
- (d) require the person to take those measures, or such measures that are at least equivalent to them, within such period as may be specified in the notice.”

(2) Each food authority must enforce and execute this Schedule in its area.

### **Application of the improvement notice provisions of the Act**

**26.**—(1) Section 10(1) and (2) of the Act (improvement notices) applies, with the modification (in the case of section 10(1)) specified in sub-paragraph (2), for the purposes of—

- (a) enabling an improvement notice to be served on a person requiring the person to secure compliance with any of the requirements specified in paragraph 2; and
- (b) making the failure to comply with a notice referred to in paragraph (a) an offence.

(2) For section 10(1) of the Act (improvement notices) substitute—

“(1) If an authorised officer of an enforcement authority has reasonable ground for suspecting that a person is failing to comply with paragraph 2 of Schedule 4 to the Infant Formula and Follow-on Formula (Wales) Regulations 2020, the authorised officer may, by a notice served on that person (in this Act referred to as an “improvement notice”)—

- (a) state the officer's grounds for suspecting that the person is failing to comply or as the case may be, that the food does not comply with the relevant provision;
- (b) specify the matters which constitute the failure to so comply;
- (c) specify the measures which, in the officer's opinion, the person must take in order to secure compliance; and
- (d) require the person to take those measures, or such measures that are at least equivalent to them, within such period as may be specified in the notice.”



(3) Mae adran 32(1) i (8) o'r Ddeddf (pwerau mynediad) yn gymwys, gyda'r addasiad (yn achos adran 32(1)) a bennir yn is-baragraff (4), at ddibenion galluogi swyddog awdurdodedig o awdurdod gofodi—

- (a) i arfer pŵer mynediad i ganfod a yw bwyd nad yw'n cydymffurfio â gofynion paragraff 2 yn cael ei werthu neu wedi ei werthu; a
- (b) i arfer pŵer mynediad i ganfod a oes unrhyw dystiolaeth o unrhyw doriad o baragraff 2.

(4) Yn lle paragraffau (a) i (c) o adran 32(1) (pwerau mynediad) o'r Ddeddf rhodder—

- “(a) to enter any premises within the authority's area for the purposes of ascertaining whether there has been any contravention of paragraph 2 of Schedule 4 to the Infant Formula and Follow-on Formula (Wales) Regulations 2020; and
- (b) to enter any business premises, whether within or outside the authority's area, for the purpose of ascertaining whether there is on the premises any evidence of any contravention of that paragraph.”

(5) Mae adran 35 o'r Ddeddf (cosbi troseddau) yn gymwys, gyda'r addasiad a bennir yn is-baragraff (6), at ddiben pennu'r gosb am drosedd a gyflawnir o dan baragraff 26(1)(b).

(6) Yn adran 35 (cosbi troseddau) o'r Ddeddf, ar ôl is-adran (1) mewnosoder—

“(1A) A person guilty of an offence under section 10(2), as applied and modified by paragraph 26(1) and (2) of Schedule 4 to the Infant Formula and Follow-on Formula (Wales) Regulations 2020, is liable, on summary conviction, to a fine.”

(7) Mae adran 37(1), (3), (5) a (6) o'r Ddeddf (apelau) yn gymwys at ddiben galluogi i benderfyniad i gyflwyno hysbysiad y cyfeirir ato ym mharagraff 26(1)(a) gael ei ddiddymu, gyda'r addasiadau a ganlyn—

- (a) yn lle'r pennawd rhodder “Appeals”;
- (b) yn lle adran 37(1) rhodder—

(3) Section 32(1) to (8) of the Act (powers of entry) applies, with the modification (in the case of section 32(1)) specified in sub-paragraph (4), for the purposes of enabling an authorised officer of an enforcement authority—

- (a) to exercise a power of entry to ascertain whether food that does not comply with the requirements of paragraph 2 is, or has been sold; and
- (b) to exercise a power of entry to ascertain whether there is any evidence of any contravention of paragraph 2.

(4) For paragraphs (a) to (c) of section 32(1) (powers of entry) of the Act substitute—

- “(a) to enter any premises within the authority's area for the purposes of ascertaining whether there has been any contravention of paragraph 2 of Schedule 4 to the Infant Formula and Follow-on Formula (Wales) Regulations 2020; and
- (b) to enter any business premises, whether within or outside the authority's area, for the purpose of ascertaining whether there is on the premises any evidence of any contravention of that paragraph.”

(5) Section 35 of the Act (punishment of offences) applies, with the modification specified in sub-paragraph (6), for the purpose of specifying the punishment of an offence committed under paragraph 26(1)(b).

(6) In section 35 (punishment of offences) of the Act, after subsection (1) insert—

“(1A) A person guilty of an offence under section 10(2), as applied and modified by paragraph 26(1) and (2) of Schedule 4 to the Infant Formula and Follow-on Formula (Wales) Regulations 2020, is liable, on summary conviction, to a fine.”

(7) Section 37(1), (3), (5) and (6) of the Act (appeals) applies for the purpose of enabling a decision to serve a notice referred to in paragraph 26(1)(a) to be repealed, with the following modifications—

- (a) for the heading substitute “Appeals”;
- (b) for section 37(1) substitute—

“(1) Any person who is aggrieved by a decision of an authorised officer of an enforcement authority to serve an improvement notice under section 10(1) as applied and modified by paragraph 26(1) and (2) of Schedule 4 to the Infant Formula and Follow-on Formula (Wales) Regulations 2020, may apply to the magistrates’ court.”;

(c) yn lle adran 37(5) rhodder—

“(5) The period within which such an appeal as is mentioned in sub-section (1) above may be brought must be, whichever ends the earlier—

- (a) one month from the date on which notice of the decision was served on the person desiring to appeal; or
- (b) the period specified in the improvement notice,

and in the case of such an appeal, the making of the complaint shall be deemed for the purposes of this subsection to be the bringing of the appeal.”;

(d) yn adran 37(6)—

- (i) yn lle “subsection (3) or (4)” rhodder “subsection (1)”;
- (ii) ym mharagraff (a), hepgorer “or to the sheriff”.

(8) Mae adran 39 o’r Ddeddf (apelau yn erbyn hysbysiadau gwella) yn gymwys, gyda’r addasiad a bennir yn is-baragraff (9), at ddiben ymdrin ag apelau yn erbyn penderfyniad i gyflwyno hysbysiad y cyfeirir ato ym mharagraff 26(1)(a).

(9) Yn adran 39(3) (apelau yn erbyn hysbysiadau gwella), hepgorer “for want of prosecution”.

### **Cymhwyso adrannau amrywiol o’r Ddeddf**

**27.** Mae’r darpariaethau a ganlyn yn y Ddeddf yn gymwys at ddibenion yr Atodlen hon gyda’r addasiad bod unrhyw gyfeiriad yn y darpariaethau hynny at y Ddeddf neu at Ran ohoni i’w ddehongli fel cyfeiriad at yr Atodlen hon—

- (a) adran 3 (rhagdybiaethau y bwriedir i fwyd gael ei fwyta gan bobl);
- (b) adran 20 (troseddau oherwydd bai person arall);

“(1) Any person who is aggrieved by a decision of an authorised officer of an enforcement authority to serve an improvement notice under section 10(1) as applied and modified by paragraph 26(1) and (2) of Schedule 4 to the Infant Formula and Follow-on Formula (Wales) Regulations 2020, may apply to the magistrates’ court.”;

(c) for section 37(5) substitute—

“(5) The period within which such an appeal as is mentioned in sub-section (1) above may be brought must be, whichever ends the earlier—

- (a) one month from the date on which notice of the decision was served on the person desiring to appeal; or
- (b) the period specified in the improvement notice,

and in the case of such an appeal, the making of the complaint shall be deemed for the purposes of this subsection to be the bringing of the appeal.”;

(d) in section 37(6)—

- (i) for “subsection (3) or (4)” substitute “subsection (1)”;
- (ii) in paragraph (a), omit “or to the sheriff”.

(8) Section 39 of the Act (appeals against improvement notices) applies, with the modification specified in sub-paragraph (9), for the purpose of dealing with appeals against a decision to serve a notice referred to in paragraph 26(1)(a).

(9) In section 39(3) (appeals against improvement notices), omit “for want of prosecution”.

### **Application of various sections of the Act**

**27.** The following provisions of the Act apply for the purposes of this Schedule with the modification that any reference in those provisions to the Act or Part thereof are to be construed as a reference to this Schedule—

- (a) section 3 (presumptions that food intended for human consumption);
- (b) section 20 (offences due to fault of another person);

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|--|---|
| <p>(c) adran 21 (amddiffyniad diwydrwydd dyladwy), fel y mae'n gymwys at ddiben adran 14 neu 15;</p> <p>(d) adran 30(8) (sy'n ymwneud â thystiolaeth ddogfennol);</p> <p>(e) adran 33(1) (rhwystro etc. swyddogion);</p> <p>(f) adran 33(2), gyda'r addasiad bod y cyfeiriad at "any such requirement as is mentioned in subsection (1)(b) above" i'w ddehongli fel cyfeiriad at unrhyw ofyniad o'r fath a grybwyllir yn adran 33(1)(b) fel y'i cymhwysir gan is-baragraff (e);</p> <p>(g) adran 35(1) (cosbi troseddau), i'r graddau y mae'n ymwneud â throseddau o dan adran 33(1) fel y'i cymhwysir gan is-baragraff (e);</p> <p>(h) adran 35(2), i'r graddau y mae'n ymwneud â throseddau o dan adran 33(2) fel y'i cymhwysir gan is-baragraff (f);</p> <p>(i) adran 36 (troseddau gan gyrff corfforedig);</p> <p>(j) adran 36A (troseddau gan bartneriaethau Albanaidd); ac</p> <p>(k) adran 44 (amddiffyn swyddogion sy'n gweithredu'n ddidwyll)."</p> | <p>(c) section 21 (defence of due diligence), as it applies for the purpose of section 14 or 15;</p> <p>(d) section 30(8) (which relates to documentary evidence);</p> <p>(e) section 33(1) (obstruction etc. of officers);</p> <p>(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 construed as a reference to any such requirement as is mentioned in section 33(1)(b) as applied by sub-paragraph (e);</p> <p>(g) section 35(1) (punishment of offences), in so far as it relates to offences under section 33(1) as applied by sub-paragraph (e);</p> <p>(h) section 35(2), in so far as it relates to offences under section 33(2) as applied by sub-paragraph (f);</p> <p>(i) section 36 (offences by bodies corporate);</p> <p>(j) section 36A (offences by Scottish partnerships); and</p> <p>(k) section 44 (protection of officers acting in good faith)."</p> |
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