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WELSH STATUTORY INSTRUMENTS

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**2018 No. 275 (W. 51)**

**FOOD, WALES**

**The Condensed Milk and Dried Milk (Wales) Regulations 2018**

<i>Made</i>	- - - -	<i>27 February 2018</i>
<i>Laid before the National Assembly for Wales</i>	- -	<i>5 March 2018</i>
<i>Coming into force</i>	- -	<i>26 March 2018</i>

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 6(4), 16(1)(e), 17(1) and (2), 26(1) and (3) and 48(1) of the Food Safety Act 1990(1) and paragraph 1A of Schedule 2 to the European Communities Act 1972(2).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Welsh Ministers that it is expedient for references to the European instruments, and the Annex to the European instrument, listed in regulation 2(4) to be construed as references to those instruments and that Annex as amended from time to time.

So far as these Regulations are made in exercise of powers under the Food Safety Act 1990, the Welsh Ministers have had regard to relevant advice given by the Food Standards Agency in accordance with section 48(4A)(3) of that Act.

There has been open and transparent public consultation during the preparation and evaluation of these Regulations 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(4).

**Title, application and commencement**

**1.—(1)** The title of these Regulations is the Condensed Milk and Dried Milk (Wales) Regulations 2018.

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- (1) 1990 c. 16. Section 16(1) was amended by paragraph 8 of Schedule 5 to the Food Standards Act 1999 (c. 28) (“the 1999 Act”). Section 17(1) and (2) was amended by paragraphs 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 paragraph 8 of Schedule 5 to the 1999 Act. Functions formerly exercisable by “the Ministers” 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 subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32).
- (2) 1972 c. 68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c. 51) and was amended by Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c. 7) and S.I. 2007/1388.
- (3) Section 48(4A) was inserted by paragraph 21 of Schedule 5 to the 1999 Act.
- (4) OJ No L 31, 1.2.2002, p 1, last amended by Regulation (EU) No 652/2014 of the European Parliament and of the Council (OJ No L 189, 27.6.2014, p 1).

- (2) These Regulations apply in relation to Wales.
- (3) These Regulations come into force on 26 March 2018.

## Interpretation

### 2.—(1) In these Regulations—

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

“designated product” (“*cynnyrch dynodedig*”) means any product specified in the third column of the table in Schedule 1 (as read with the Notes to that Schedule) ready for delivery to a final consumer or to a mass caterer;

“partly dehydrated milk” (“*llaeth wedi ei ddadhydradu'n rhannol*”) means the liquid product, whether or not sweetened, obtained by the partial removal of water from milk, wholly or partly skimmed milk or a mixture of these products and includes such a product to which cream or totally dehydrated milk (or both) has been added, provided that the addition of totally dehydrated milk does not exceed, in the finished product, 25% of total milk solids;

“reserved description” (“*disgrifiad neilltuedig*”), as respects any designated product, means any description specified in relation to that product in the first column of the table in Schedule 1 or any alternative description permitted by Schedule 2;

“sell” (“*gwerthu*”) includes offer or expose for sale or have in possession for sale;

“totally dehydrated milk” (“*llaeth wedi ei ddadhydradu'n llwyr*”) means the solid product, where the water content does not exceed 5% by weight of the finished product, obtained by removal of water from milk, wholly or partly skimmed milk, cream or a mixture of those products;

“total milk solids” (“*cyfanswm y solidau llaeth*”) means all the constituents of milk other than water, including milk fat, the constituents other than milk fat being present in their natural proportions;

“Welsh equivalent reserved description” (“*disgrifiad neilltuedig cyfatebol Cymraeg*”), as respects any designated product, means the Welsh language description in relation to that product specified in the second column of the table in Schedule 1 or the Welsh language equivalent specified in Schedule 2 of any alternative description permitted by that Schedule.

(2) In this regulation, “final consumer” (“*defnyddiwr olaf*”) means any person who buys otherwise than for—

- (a) resale;
- (b) a mass caterer;
- (c) a manufacturing business.

(3) In this regulation, “mass caterer” (“*arlwywr mawr*”) means a restaurant, canteen, club, public house, school, hospital or similar establishment (including a vehicle or a fixed or mobile stall) where, in the course of a business, food is prepared for delivery to the final consumer and is ready for consumption without further preparation and, for the purposes of this definition, “preparation” (“*paratoi*”) includes manufacture and any form of processing or treatment.

(4) In these Regulations, references to the following European instruments and Annex are references to those instruments and that Annex as amended from time to time—

- (a) Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives<sup>(5)</sup>;

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(5) OJ No L 354, 31.12.08, p 16, last amended by Commission Regulation (EU) 2017/874 (OJ No L 134, 23.5.17, p 18).

- (b) Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods(6);
- (c) First Commission Directive 79/1067/EEC laying down Community methods of analysis for testing certain partly or wholly dehydrated preserved milk for human consumption(7);
- (d) the Annex to First Commission Directive 87/524/EEC laying down Community methods of sampling for chemical analysis for the monitoring of preserved milk products(8).

### Reserved descriptions

3. No person may sell any food with a label, whether or not attached to or printed on the wrapper or container, which bears, comprises or includes any reserved description or Welsh equivalent reserved description, or an equivalent description in any other language, a derivative of such description, or a substantially similar word or description unless—

- (a) such food is the designated product to which the reserved description, Welsh equivalent reserved description or equivalent description in any other language, relates;
- (b) such description, derivative or word is used in such a context as to indicate explicitly or by clear implication that the substance to which it relates is only an ingredient of that food; or
- (c) such description, derivative or word is used in such a context as to indicate explicitly or by clear implication that such food is not and does not contain a designated product.

### Labelling and description

4.—(1) No person may sell any designated product unless it is marked or labelled with the following particulars—

- (a) its reserved description,
- (b) except in the case of the products specified in paragraphs 1(d) and (g) and 2(d) in the table in Schedule 1, the percentage of milk fat, expressed by weight in relation to the finished product,
- (c) in the case of the products specified in paragraph 1 in the table in Schedule 1, the percentage of fat-free dried milk extract, and
- (d) in the case of the products specified in paragraph 2 in the table in Schedule 1—
  - (i) the recommendations as to the method of dilution or reconstitution and the details of the fat content of the product when diluted or reconstituted, and
  - (ii) a statement containing the words “not intended as a food for infants under 12 months”.

(2) Nothing in paragraph (1)(a) prevents the use of the Welsh equivalent reserved description or equivalent description in any other language in addition to the reserved description.

(3) Nothing in paragraph (1)(d)(ii) prevents the use of the words “nid yw wedi ei fwrriadu yn fwyd i fabanod o dan 12 mis oed”, or equivalent words in any other language, in addition to “not intended as a food for infants under 12 months”.

### Manner of marking or labelling

5.—(1) The particulars with which a designated product is required to be marked or labelled by virtue of regulation 4(1)(b) or (c) (or both) must appear near the trade name of the product.

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(6) OJ No L 404, 30.12.06, p 26, last amended by Commission Regulation (EU) 2017/1203 (OJ No L 173, 6.7.17, p 9).

(7) OJ No L 327, 24.12.79, p 29.

(8) OJ No L 306, 28.10.87, p 24.

(2) Where designated products weighing less than 20 grams per unit are packed in an outer packaging, the particulars required by regulation 4(1)(b) to (d) may appear on the label or the outer packaging.

### **Application and modification of provisions of the Act**

6.—(1) Section 10(1) and (2) of the Act (improvement notices) applies for the purposes of these Regulations with the modification (in the case of section 10(1)) set out in Part 1 of Schedule 3 for the purposes of—

- (a) enabling an improvement notice to be served on a person requiring that person to comply with any of the provisions of regulations 3, 4 or 5; and
- (b) making the failure to comply with a notice referred to in sub-paragraph (a) an offence.

(2) The provisions of the Act specified in the first column of the table in Part 2 of Schedule 3 apply, with the modifications specified in column 2 of that table, for the purposes of these Regulations.

(3) Paragraphs (1) and (2) are without prejudice to the application of the Act to these Regulations for purposes other than those specified in paragraph (1).

### **Enforcement**

7. It is the duty of each food authority to enforce these Regulations in its area.

### **Revocations**

8. The following Regulations are revoked to the extent specified—

<i>Regulations revoked</i>	<i>Extent of revocation</i>
The Condensed Milk and Dried Milk (Wales) Regulations 2003 <sup>(9)</sup>	The whole Regulations
The Food Hygiene (Wales) Regulations 2006 <sup>(10)</sup>	Regulation 33(2)
The Condensed Milk and Dried Milk (Wales) (Amendment) Regulations 2008 <sup>(11)</sup>	The whole Regulations

27 February 2018

*Vaughan Gething*  
Cabinet Secretary for Health and Social  
Services, one of the Welsh Ministers

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<sup>(9)</sup> S.I. 2003/3053 (W. 291).

<sup>(10)</sup> S.I. 2006/31 (W. 5).

<sup>(11)</sup> S.I. 2008/137 (W. 19).

## SCHEDULE 1

Regulation 2(1)

## Partly or totally dehydrated preserved milk products and their reserved description

<i>Reserved description</i>	<i>Welsh equivalent reserved description</i>	<i>Designated product</i>
<b>1. Partly dehydrated milk</b>		
<i>Types of unsweetened condensed milk</i>		
(a) Condensed high-fat milk	Llaeth cyddwys sydd â braster uchel	Partly dehydrated milk containing, by weight, not less than 15% fat and not less than 26.5% total milk solids
(b) Condensed milk	Llaeth cyddwys	Partly dehydrated milk containing, by weight, not less than 7.5% fat and not less than 25% total milk solids
(c) Condensed partly skimmed milk	Llaeth rhannol sgim cyddwys	Partly dehydrated milk containing, by weight, not less than 1% and less than 7.5% fat and not less than 20% total milk solids
(d) Condensed skimmed milk	Llaeth sgim cyddwys	Partly dehydrated milk containing, by weight, not more than 1% fat and not less than 20% total milk solids
<i>Types of sweetened condensed milk</i>		
(e) Sweetened condensed milk	Llaeth cyddwys sydd wedi ei felysu	Partly dehydrated milk with an admixture of sucrose (semi-white sugar, white sugar or extra-white sugar) and containing, by weight, not less than 8% fat and not less than 28% total milk solids
(f) Sweetened condensed partly skimmed milk	Llaeth rhannol sgim cyddwys sydd wedi ei felysu	Partly dehydrated milk with an admixture of sucrose (semi-white sugar, white sugar or extra-white sugar) and containing, by weight, not less than 1% and less than 8% fat and not less than 24% total milk solids
(g) Sweetened condensed skimmed milk	Llaeth sgim cyddwys sydd wedi ei felysu	Partly dehydrated milk with an admixture of sucrose (semi-white sugar, white sugar or extra-white sugar) and containing, by weight, not more

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<i>Reserved description</i>	<i>Welsh equivalent reserved description</i>	<i>Designated product</i>
		than 1% fat and not less than 24% total milk solids
<b>2. Totally dehydrated milk</b>		
(a) Dried high-fat milk or high-fat milk powder	Llaeth sych sydd â braster uchel neu laeth powdr sydd â braster uchel	Totally dehydrated milk containing, by weight, not less than 42% fat
(b) Dried whole milk or whole milk powder	Llaeth cyflawn sych neu laeth powdr cyflawn	Totally dehydrated milk containing, by weight, not less than 26% and less than 42% fat
(c) Dried partly skimmed milk or partly skimmed milk powder	Llaeth rhannol sgim sych neu laeth powdr rhannol sgim	Totally dehydrated milk containing, by weight, more than 1.5% and less than 26% fat
(d) Dried skimmed milk or skimmed milk powder	Llaeth sgim sych neu laeth powdr sgim	Totally dehydrated milk containing, by weight, not more than 1.5% fat

## Notes

1. Any designated product may contain—

- (a) any substance permitted pursuant to Regulation (EC) No 1333/2008 of the European Parliament and of the Council(12); and
- (b) vitamins and minerals in accordance with the requirements of Regulation (EC) No 1925/2006(13).

2. An additional quantity of lactose, not greater than 0.03% by weight of the finished product, may be added in the manufacture of any designated product referred to in paragraph 1(e), (f) or (g) in the table in this Schedule.

3. Without prejudice to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin(14), the preservation of the designated products must be achieved—

- (a) by heat treatment for the products referred to in paragraph 1(a) to (d) in the table in this Schedule;
- (b) by the addition of sucrose for the products referred to in paragraph 1(e) to (g) in the table in this Schedule; and
- (c) by dehydration for the products referred to in paragraph 2(a) to (d) in the table in this Schedule.

4.—(1) Without prejudice to the compositional requirements set out in the table in this Schedule, the protein content of milk may be adjusted to a minimum content of 34% by weight (expressed on fat-free dry matter) by the addition or withdrawal (or both) of milk constituents in such a way as not to alter the ratio of whey protein to casein in the milk being adjusted.

(2) Authorised raw materials for protein adjustment purposes referred to in paragraph (1) are as follows—

(12) OJ No L 354, 31.12.08, p 16, last amended by Commission Regulation (EU) 2017/874 (OJ No L 134, 23.5.17, p 18).

(13) OJ No L 404, 30.12.06, p 26, last amended by Commission Regulation (EU) 2017/1203 (OJ No L 173, 6.7.17, p 9).

(14) OJ No L 139, 30.4.04, p 55, last amended by Commission Regulation (EU) 2016/355 (OJ No L 67, 12.3.16, p 22).

- (a) milk retentate, which is the product obtained by concentrating milk protein by ultrafiltration of milk, partly skimmed milk or skimmed milk;
- (b) milk permeate, which is the product obtained by removing milk proteins and milk fat from milk, partly skimmed milk or skimmed milk by ultrafiltration; and
- (c) lactose, which is a natural constituent of milk normally obtained from whey with an anhydrous lactose content of not less than 99.0% m/m (mass over mass) on a dry basis, and which may be anhydrous or contain one molecule of water of crystallisation or be a mixture of both forms.

5. The levels of dry matter, moisture content, fat, sucrose, lactic acid and lactates and phosphatase activity in the designated products must be determined in accordance with the methods set out in First Commission [Directive 79/1067/EEC\(15\)](#).

## SCHEDULE 2

Regulation 2(1)

Permitted alternative descriptions to the reserved descriptions specified in Schedule 1

1.—(1) The term “evaporated milk” may be used instead of the term “condensed milk” in the case of partly dehydrated milk containing, by weight, at least 9% fat and 31% total milk solids.

(2) The Welsh equivalent of “evaporated milk” is “llaeth anwedd”.

2.—(1) The term “evaporated semi-skimmed milk” may be used instead of the term “condensed partly skimmed milk” in the case of partly dehydrated milk containing, by weight, between 4% and 4.5% fat and not less than 24% total milk solids.

(2) The Welsh equivalent of “evaporated semi-skimmed milk” is “llaeth anwedd hanner sgim”.

3.—(1) The term “semi-skimmed milk powder” or “dried semi-skimmed milk” may be used instead of the term “dried partly skimmed milk” or “partly skimmed milk powder” in the case of totally dehydrated milk with a fat content of between 14% and 16%.

(2) The Welsh equivalent of—

- (a) “semi-skimmed milk powder” is “llaeth powdr hanner sgim”, and
- (b) “dried semi-skimmed milk” is “llaeth sych hanner sgim”.

## SCHEDULE 3

Regulation 6

Application and modification of provisions of the Act

### PART 1

#### Modification of section 10(1)

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

“If an authorised officer has reasonable grounds for believing that a person is failing to comply with any of regulations 3, 4 or 5 of the Condensed Milk and Dried Milk (Wales)

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(15) OJ No L 327, 24.12.79, p 29.

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Regulations 2018, 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 believing that the person is failing to comply with the relevant provisions;
- (b) specify the matters which constitute the person’s failure so to 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 measures, or measures that are at least equivalent to them, within such period (not being less than 14 days) as may be specified in the notice.”

## PART 2

### Application and modification of other provisions of the Act

<i>Column 1</i>	<i>Column 2</i>
<i>Provision of the Act</i>	<i>Modifications</i>
Section 2 (extended meaning of “sale” etc.)	<p>In subsection (1), for “this Act” substitute “the Condensed Milk and Dried Milk (Wales) Regulations 2018”.</p> <p>In subsection (2), for “This Act” substitute “The Condensed Milk and Dried Milk (Wales) Regulations 2018”.</p>
Section 3 (presumptions that food intended for human consumption)	In subsection (1), for “this Act” substitute “the Condensed Milk and Dried Milk (Wales) Regulations 2018”.
Section 20 (offences due to fault of another person)	For “any of the preceding provisions of this Part” substitute “section 10(2), as applied by regulation 6(1) of the Condensed Milk and Dried Milk (Wales) Regulations 2018”.
Section 21(1) and (5) (defence of due diligence)	In subsection (1), for “any of the preceding provisions of this Part” substitute “section 10(2), as applied by regulation 6(1) of the Condensed Milk and Dried Milk (Wales) Regulations 2018”.
Section 29 (procurement of samples)	After the words “enforcement authority”, insert “, when carrying out duties under this section in relation to the Condensed Milk and Dried Milk (Wales) Regulations 2018, must exercise and perform those duties in accordance with the methods described



<i>Column 1</i>	<i>Column 2</i>
<i>Provision of the Act</i>	<i>Modifications</i>
Section 30(8) (analysis etc. of samples)	<p>in the Annex to First Commission Directive 87/524/EEC laying down Community methods of sampling for chemical analysis for the monitoring of preserved milk products<sup>(16)</sup> and”.</p> <p>For “this Act” substitute “the Condensed Milk and Dried Milk (Wales) Regulations 2018”.</p> <p>In sub-paragraph (a) omit “under subsection (6) above”.</p>
Section 33 (obstruction etc. of officers)	<p>In subsection (1), for “this Act” (in each place where it occurs) substitute “the Condensed Milk and Dried Milk (Wales) Regulations 2018”.</p>
Section 35(1) <sup>(17)</sup> and (2) <sup>(18)</sup> (punishment of offences)	<p>In subsection (1), after “section 33(1) above”, insert “, as applied and modified by regulation 6(2) of, and Part 2 of Schedule 3 to, the Condensed Milk and Dried Milk (Wales) Regulations 2018”.</p> <p>After subsection (1), insert—</p> <p>“(1A) A person guilty of an offence under section 10(2), as applied by regulation 6(1) of the Condensed Milk and Dried Milk (Wales) Regulations 2018, is liable, on summary conviction, to a fine.”</p> <p>In subsection (2), for “any other offence under this Act” substitute “an offence under section 33(2), as applied by regulation 6(2) of, and Part 2 of Schedule 3 to, the Condensed Milk and Dried Milk (Wales) Regulations 2018,”.</p>
Section 36 (offences by bodies corporate)	<p>In subsection (1), for “this Act” substitute “section 10(2), as applied by regulation 6(1) of the Condensed Milk and Dried Milk (Wales) Regulations 2018,”.</p>

<sup>(16)</sup> OJ No L 306, 28.10.87, p 24.

<sup>(17)</sup> Section 35(1) is amended by paragraph 42 of Schedule 26 to the Criminal Justice Act 2003 (c. 44) from a date to be appointed. There are other amendments to section 35(1) not relevant to these Regulations.

<sup>(18)</sup> Section 35(2) was amended by S.I. 2015/664. There are other amendments to section 35(2) not relevant to these Regulations.

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<i>Column 1</i>	<i>Column 2</i>
<i>Provision of the Act</i>	<i>Modifications</i>
Section 36A(19) (offences by Scottish partnerships)	For “this Act” substitute “section 10(2), as applied by regulation 6(1) of the Condensed Milk and Dried Milk (Wales) Regulations 2018,”.
Section 37(1), (3), (5) and (6) (appeals to magistrates’ court)	<p>For subsection (1) substitute—</p> <p>“(1) Any person who is aggrieved by a decision of an authorised officer of a food authority to serve an improvement notice under section 10(1), as applied and modified by regulation 6(1) of, and Part 1 of Schedule 3 to, the Condensed Milk and Dried Milk (Wales) Regulations 2018, may appeal to a magistrates’ court.”</p> <p>For subsection (5) substitute—</p> <p>“(5) The period within which such an appeal as is mentioned in subsection (1) above may be brought shall be—</p> <p style="padding-left: 40px;">one month from the date on which notice of the decision was served on the person desiring to appeal; or the period specified in the improvement notice, whichever ends the earlier; 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.”</p> <p>In subsection (6)—</p> <p>for “(3) or (4)” substitute “(1)”, and</p> <p>in paragraph (a), omit “or to the sheriff”.</p>
Section 39 (appeals against improvement notices)	<p>For subsection (1) substitute—</p> <p>“(1) On an appeal against an improvement notice served under section 10(1), as applied and modified by regulation 6(1) of, and Part 1 of Schedule 3 to, the Condensed Milk</p>

(19) Section 36A was inserted by section 40(1) of, and paragraphs 7 and 16 of Schedule 5 to, the Food Standards Act 1999 (c. 28).

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<i>Column 1</i>	<i>Column 2</i>
<i>Provision of the Act</i>	<i>Modifications</i>
	and Dried Milk (Wales) Regulations 2018, the magistrates' court may either cancel or affirm the notice and, if it affirms it, may do so either in its original form or with such modifications as the court may in the circumstances think fit."
	In subsection (3), omit "for want of prosecution".
Section 44 (protection of officers acting in good faith)	For "this Act" (in each place where it occurs) substitute "the Condensed Milk and Dried Milk (Wales) Regulations 2018".

## EXPLANATORY NOTE

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

These Regulations, which apply in relation to Wales, revoke and replace the Condensed Milk and Dried Milk (Wales) Regulations 2003 (S.I. 2003/3053 (W. 291)) and revoke the Condensed Milk and Dried Milk (Wales) (Amendment) Regulations 2008 (S.I. 2008/137 (W. 19)). They transpose Council Directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption (OJ No L 15, 17.1.02, p 19).

Regulation 2 and Schedules 1 and 2 define condensed milk and dried milk products and the reserved descriptions that apply to them.

Regulation 3 prohibits the labelling with reserved descriptions of food other than the designated condensed and dried milk products to which they relate.

Regulation 4 sets out the labelling requirements for designated condensed and dried milk products.

Regulation 5 sets out the manner of marking or labelling the designated condensed and dried milk products with the particulars required by regulation 4. The marking and labelling requirements are in accordance with Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (OJ No L 304, 22.11.11, p 18).

Regulation 6 and Schedule 3 apply certain provisions of the Food Safety Act 1990 (1990 c. 16) with modifications. This includes the application of section 10(1) (with modifications) and (2), enabling an improvement notice to be served to require compliance with regulations 3, 4 and 5. The provisions, as applied, make the failure to comply with an improvement notice an offence under section 10(2).

Regulation 7 imposes an obligation on food authorities to enforce these Regulations.

Regulation 8 revokes previous Regulations, as set out above.

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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.