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WELSH STATUTORY INSTRUMENTS

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**2016 No. 1130 (W. 270)**

**FOOD, WALES**

**The Caseins and Caseinates (Wales) Regulations 2016**

<i>Made</i>	- - - -	<i>20 November 2016</i>
<i>Laid before the National Assembly for Wales</i>	- -	<i>25 November 2016</i>
<i>Coming into force</i>	- -	<i>22 December 2016</i>

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 6(4), 16(1)(a), (e), (f), 17(1), 26(1), (2)(e) and (3), 31(1) and 48 of the Food Safety Act 1990<sup>(1)</sup>.

In accordance with section 48(4A)(2) of that Act, the Welsh Ministers have had regard to relevant advice given by the Food Standards Agency before making these Regulations.

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<sup>(3)</sup>.

**Title, application and commencement**

- 1.—(1) The title of these Regulations is the Caseins and Caseinates (Wales) Regulations 2016.
- (2) These Regulations apply in relation to Wales.
- (3) These Regulations come into force on 22 December 2016.

**Interpretation**

2. In these Regulations—

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- (1) 1990 c. 16. Section 6(4) was amended by paragraph 6 of Schedule 9 to the Deregulation and Contracting Out Act 1994 (c. 40), paragraph 10(1) and (3) 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) was amended by paragraph 8 of Schedule 5 to the 1999 Act. Section 17(1) was amended by paragraphs 8 and 12(a) 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 was amended by paragraph 8 of Schedule 5 to the 1999 Act. Functions formerly exercisable by the “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) Section 48(4A) was inserted by paragraph 21 of Schedule 5 to the 1999 Act.
- (3) 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).

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

“casein product” (“*cynnyrch casein*”) means edible acid casein, edible caseinate or edible rennet casein;

“edible acid casein” (“*casein asid bwyttadwy*”) means a milk product obtained by separating, washing and drying the acid-precipitated coagulum of skimmed milk and/or of other products obtained from milk and complying with the standards set out in Schedule 1;

“edible caseinate” (“*caseinad bwyttadwy*”) means a milk product obtained by action of edible casein or edible casein curd coagulum with neutralizing agents, followed by drying and complying with the standards set out in Schedule 2;

“edible rennet casein” (“*casein cywair llaeth bwyttadwy*”) means a milk product obtained by separating, washing and drying the coagulum of skimmed milk and/or of other products obtained from milk; the coagulum is obtained through the reaction of rennet or other coagulating enzymes and complying with the standards set out in Schedule 3;

“FIC” (“*FIC*”) means Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004<sup>(4)</sup>;

“food business operator” (“*gweithredydd busnes bwyd*”) has the meaning given in Article 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council;

“Regulation (EC) No 1332/2008” (“*Rheoliad (EC) Rhif 1332/2008*”) means Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97<sup>(5)</sup>;

“sell” (“*gwerthu*”) includes possess for sale and offer, expose or advertise for sale, and “sale” (“*gwerthu*”) is to be construed accordingly.

## Scope

3. These Regulations apply to caseins and caseinates intended for sale for human consumption.

## Restriction on the use of caseins and caseinates in the preparation of food

4.—(1) No person may use any casein or caseinate in the preparation of food if it does not comply with the standards set out in Schedule 4.

(2) A person marketing caseins or caseinates which do not comply with paragraph (1), for a purpose other than the caseins or caseinates being used in the preparation of food, must indicate explicitly or by clear implication the nature, quality or intended use of the product.

## General restriction on marketing of casein products

5.—(1) No person may sell any food with a label, whether or not attached to or printed on the package or container, which includes the name of any casein product unless the requirements set out in paragraph (4) are complied with.

(4) OJ No L 304, 22.11.2011, p 18, last amended by Commission Delegated Regulation (EU) No 78/2014 (OJ No L 27, 30.1.2014, p 7).

(5) OJ No L 354, 3.12.2008, p 7, last amended by Commission Regulation (EU) No 1056/2012 (OJ No L 313, 13.11.2012, p 9).

(2) No person may display with any food offered or exposed for sale by that person any ticket or notice which includes the name of any casein product unless the requirements set out in paragraph (4) are complied with.

(3) No person may publish, or be a party to the publication of, any advertisement for food which includes the name of a casein product unless the requirements set out in paragraph (4) are complied with.

(4) The requirements are that—

- (a) the food is or contains a casein product; or
- (b) the name is used in such a context as to indicate explicitly or by clear implication that the food is not a casein product and does not contain one.

### **Labelling of casein products**

**6.—**(1) Without prejudice to the provisions of FIC, no person may sell any casein product unless it is marked or labelled with—

- (a) the name of that casein product as defined in regulation 2 and in the case of edible caseinates with an indication of the cation or cations listed in paragraph 4 of Schedule 2;
- (b) in the case of casein products sold as mixtures—
  - (i) the words “mixture of” followed by the names of the casein products which make up the mixture, in descending order of weight;
  - (ii) an indication of the cation or cations listed in paragraph 4 of Schedule 2 in the case of edible caseinates;
  - (iii) in the case of mixtures containing edible caseinates, the protein content;
- (c) the net quantity of the casein product, expressed in kilograms or grams;
- (d) the name or business name and the address of the food business operator under whose name or business name the product is marketed or, if that food business operator is not established in the European Union, the importer into the European Union market;
- (e) in the case of a casein product imported from countries outside the European Union, the name of the country of origin; and
- (f) the lot identification of the casein product or the date of production.

(2) The particulars required by paragraph (1) must be easily visible, clearly legible, indelible and given in English, either exclusively or in addition to any other language.

(3) The particulars referred to in paragraph (1)(b)(iii), (c), (d) and (e) may be given in a document accompanying the product.

(4) Without prejudice to the provisions of FIC, where any casein product exceeds the minimum milk protein content set out for that product in—

- (a) entry 2 of the table in paragraph 1 of Schedule 1 in relation to edible acid caseins;
- (b) entry 2 of the table in paragraph 1 of Schedule 2 in relation to edible caseinates; or
- (c) entry 2 of the table in paragraph 1 of Schedule 3 in relation to edible rennet casein,

a person may mark that fact on the package, label or container of that product.

(5) Where a casein product that is marked or labelled with “edible acid casein” in accordance with paragraph (1)(a) is marked or labelled in Welsh in addition to English, the words “casein asid bwyttadwy” must be used.

(6) Where a casein product that is marked or labelled with “edible caseinate” in accordance with paragraph (1)(a) is marked or labelled in Welsh in addition to English, the words “caseinad bwyttadwy” must be used.

(7) Where a casein product that is marked or labelled with “edible rennet casein” in accordance with paragraph (1)(a) is marked or labelled in Welsh in addition to English, the words “casein cywair llaeth bwytdwy” must be used.

(8) Where a casein product that is marked or labelled with “mixture of” in accordance with (1)(b)(i) is marked or labelled in Welsh in addition to English, the words “cymysgedd o” must be used followed by the names of the casein products which make up the mixture, in descending order of weight.

## **Enforcement**

7. It is the duty of a food authority within its area and a port health authority within its district to enforce these Regulations.

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

8.—(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 5 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 4, 5 or 6; 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 column 1 of the table in Part 2 of Schedule 5 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).

## **Revocations**

9. The following Regulations are revoked—

- (a) The Caseins and Caseinates Regulations 1985<sup>(6)</sup>;
- (b) The Caseins and Caseinates (Amendment) Regulations 1989<sup>(7)</sup>.

*Rebecca Evans*  
Minister for Social Services and Public Health  
under authority of the Cabinet Secretary for  
Health, Well-being and Sport, one of the Welsh  
Ministers

20 November 2016

<sup>(6)</sup> S.I. 1985/2026.

<sup>(7)</sup> S.I. 1989/2321.

## SCHEDULE 1

Regulation 2

Standards applicable to edible acid caseins

**1. Essential factors of composition**

1	Maximum moisture content	12% by weight
2	Minimum milk protein content calculated on the dried extract	90% by weight
	of which minimum casein content	95% by weight
3	Maximum milk fat content	2% by weight
4	Maximum titratable acidity, expressed in ml of decinormal sodium hydroxide solution per g	0,27
5	Maximum ash content (P <sub>2</sub> O <sub>5</sub> included)	2,5% by weight
6	Maximum anhydrous lactose content	1% by weight
7	Maximum sediment content (burnt particles)	22,5 mg in 25 g

**2. Contaminants**

Maximum lead content	0,75 mg/kg
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**3. Impurities**

Extraneous matter (such as wood or metal particles, hairs or insect fragments)	nil in 25 g
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**4. Processing aids, bacterial cultures and authorised ingredients**

1. acids:
  - lactic acid
  - hydrochloric acid
  - sulphuric acid
  - citric acid
  - acetic acid
  - orthophosphoric acid
2. bacterial cultures producing lactic acid
3. Whey

**5. Organoleptic characteristics**

1.	Odour	No foreign odours
2.	Appearance	Colour ranging from white to creamy white; the product must not contain any lumps that would not break up under slight pressure.

## SCHEDULE 2

Regulation 2

Standards applicable to edible caseinates

### 1. Essential factors of composition

1	Maximum moisture content	8% by weight
2	Minimum milk protein content calculated on the dried extract	88% by weight
	of which minimum casein content	95% by weight
3	Maximum milk fat content	2% by weight
4	Maximum anhydrous lactose content	1% by weight
5	pH value	6,0 to 8,0
6	Maximum sediment content (burnt particles)	22,5 mg in 25 g

### 2. Contaminants

Maximum lead content	0,75 mg/kg
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### 3. Impurities

Extraneous matter (such as wood or metal particles, hairs or insect fragments)	nil in 25 g
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### 4. Food additives

(optional neutralising and buffering agents)

hydroxydes carbonates phosphates citrates	of	sodium potassium calcium ammonium magnesium
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### 5. Characteristics

1.	Odour	Very slight foreign flavours and odours
2.	Appearance	Colour ranging from white to creamy white; the product must not contain any lumps that would not break up under slight pressure.
3.	Solubility	Almost entirely soluble in distilled water, except for calcium caseinate.

## SCHEDULE 3

Regulation 2

Standards applicable to edible rennet caseins

**1. Essential factors of composition**

1	Maximum moisture content	12% by weight
2	Minimum milk protein content calculated on the dried extract	84% by weight
	of which minimum casein content	95% by weight
3	Maximum milk fat content	2% by weight
4	Maximum ash content (P <sub>2</sub> O <sub>5</sub> included)	7,5% by weight
5	Maximum anhydrous lactose content	1% by weight
6	Maximum sediment content (burnt particles)	15 mg in 25 g

**2. Contaminants**

Maximum lead content	0,75 mg/kg
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**3. Impurities**

Extraneous matter (such as wood or metal particles, hairs or insect fragments)	nil in 25 g
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**4. Processing aids**

- rennet meeting the requirements of Regulation (EC) No 1332/2008(8);
- other milk-coagulating enzymes meeting the requirements of Regulation (EC) No 1332/2008.

**5. Organoleptic characteristics**

1.	Odour	No foreign odours
2.	Appearance	Colour ranging from white to creamy white; the product must not contain any lumps that would not break up under slight pressure.

## SCHEDULE 4

Regulation 4

Standards applicable to caseins and caseinates in food

**1. Contaminants**

Maximum lead content	0,75 mg/kg
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(8) OJ No L 354, 3.12.2008, p 7, last amended by Commission Regulation (EU) No 1056/2012 of 12 November 2012.

2. Impurities

Extraneous matter (such as wood or metal particles, hairs or insect fragments)	nil in 25 g
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SCHEDULE 5

Regulation 8

Application and modification of provisions of the Act

PART 1

Modification of section 10(1)

1. For section 10(1) substitute—
- “If an authorised officer has reasonable grounds for believing that a person is failing to comply with any of regulations 4, 5 or 6 of the Caseins and Caseinates (Wales) Regulations 2016, 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

Column 1	Column 2
Provision of the Act	Modifications
Section 2 (extended meaning of “sale” etc.)	In subsection (1), for “this Act” substitute “the Caseins and Caseinates (Wales) Regulations 2016”. In subsection (2), for “this Act” substitute “the Caseins and Caseinates (Wales) Regulations 2016”.
Section 3 (presumptions that food intended for human consumption)	In subsection (1), for “this Act” substitute “the Caseins and Caseinates (Wales) Regulations 2016”
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 8 of the Caseins



<i>Column 1</i>	<i>Column 2</i>
<i>Provision of the Act</i>	<i>Modifications</i>
	and Caseinates (Wales) Regulations 2016”
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 8 of the Caseins and Caseinates (Wales) Regulations 2016”
Section 30(8) (evidence of certificates given by a food analyst or examiner)	For “this Act” substitute “the Caseins and Caseinates (Wales) Regulations 2016”
Section 33 (obstruction etc. of officers)	In subsection (1), for “this Act” (in each place occurring) substitute “the Caseins and Caseinates (Wales) Regulations 2016”
Section 35(1)(9) and (2)(10) (punishment of offences)	In subsection (1), after “section 33(1) above”, insert “, as applied and modified by regulation 8 of, and Schedule 5 to, the Caseins and Caseinates (Wales) Regulations 2016”
	After subsection (1), insert— “(1A) A person guilty of an offence under section 10(2), as applied by regulation 8 of the Caseins and Caseinates (Wales) Regulations 2016, is liable, on summary conviction, to a fine.”
	In subsection (2) for “any other offence under this Act” substitute “an offence under section 33(2), as applied by regulation 8 of, and Schedule 5 to, the Caseins and Caseinates (Wales) Regulations 2016”
Section 36 (offences by body corporate)	In subsection (1), for “this Act” substitute “section 10(2), as applied by regulation 8 of the Caseins and Caseinates (Wales) Regulations 2016”
Section 36A(11) (offences by Scottish partnerships)	For “this Act” substitute “section 10(2), as applied by regulation 8 of the Caseins and Caseinates (Wales) Regulations 2016”

(9) 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.

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

(11) 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).

**Status:** This is the original version (as it was originally made).

<i>Column 1</i>	<i>Column 2</i>
<i>Provision of the Act</i>	<i>Modifications</i>
Section 37(1), (3), (5) and (6) (appeals)	<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 8 of the Caseins and Caseinates (Wales) Regulations 2016, 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</p> <p style="padding-left: 40px;">the period specified in the improvement notice, whichever ends the earlier; and</p> <p style="padding-left: 40px;">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 8 of the Caseins and Caseinates (Wales) Regulations 2016, 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.”</p>

<i>Column 1</i>	<i>Column 2</i>
<i>Provision of the Act</i>	<i>Modifications</i>
Section 44 (protection of officers acting in good faith)	<p>In subsection (3), omit “for want of prosecution”.</p> <p>For “this Act” (in each place occurring) substitute “the Caseins and Caseinates (Wales) Regulations 2016”</p>

## EXPLANATORY NOTE

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

These Regulations implement Directive (EU) 2015/2203 of the European Parliament and of the Council on the approximation of the laws of the Member States relating to caseins and caseinates intended for human consumption and repealing Council [Directive 83/417/EEC](#) (OJ No L 314, 1.12.2015, p 1).

These Regulations revoke and replace the Caseins and Caseinates Regulations 1985 ([S.I. 1985/2026](#)) and the Caseins and Caseinates (Amendment) Regulations 1989 ([S.I. 1989/2321](#)) in relation to Wales.

These Regulations only apply to casein products intended for human consumption (regulation 3).

These Regulations—

- (a) prescribe definitions and standards for certain casein products (regulation 2 and Schedules 1 to 3);
- (b) prohibit the use of any casein or caseinate in the preparation of food if it does not comply with particular standards (regulation 4 and Schedule 4);
- (c) subject to specified exceptions, prohibit the labelling or advertisement of food with the names of casein products unless the food is or contains a casein product (regulation 5);
- (d) impose additional requirements as to the labelling of casein products (regulation 6);
- (e) impose an obligation on each county council or county borough council to enforce the Regulations in its area (regulation 7);
- (f) apply certain provisions of the Food Safety Act 1990 ([1990 c. 16](#)), with modifications. This includes the application (with modifications) of section 10(1), enabling an improvement notice to be served to require compliance with regulations 4, 5 or 6 of these Regulations. The provisions, as applied, make the failure to comply with an improvement notice an offence (regulation 8).

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.