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SCOTTISH STATUTORY INSTRUMENTS

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**2016 No. 383**

**FOOD**

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

	<i>22nd November</i>
<i>Made</i> - - - -	<i>2016</i>
<i>Laid before the Scottish</i>	
<i>Parliament</i> - - - -	<i>23rd November 2016</i>
	<i>22nd December</i>
<i>Coming into force</i> - -	<i>2016</i>

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 6(4), 16(1), 17(1), 26(1) and (3), 31(1) and 48(1) of the Food Safety Act 1990<sup>(1)</sup>, section 2(2) and paragraph 1A of schedule 2 of the European Communities Act 1972<sup>(2)</sup> and all other powers enabling them to do so.

In accordance with section 48(4A)<sup>(3)</sup> of the Food Safety Act 1990, the Scottish Ministers have had regard to relevant advice given by Food Standards Scotland.

There has been consultation, as required by Article 9 of Regulation (EC) 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>(4)</sup>.

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- (1) 1990 c.16. Section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Section 6(4) was amended by the Deregulation and Contracting Out Act 1994 (c.40), schedule 9, paragraph 6, the Food Standards Act 1999 (c.28) (“the 1999 Act”), schedule 5, paragraph 10(1) and (3) and schedule 6, and S.I. 2002/794. Under section 6(4A) (which was inserted by the Food (Scotland) Act 2015 (asp 1) (“the 2015 Act”), paragraph 3(2) of the schedule) the reference to the Food Standards Agency in section 6(4) is to be read as a reference to Food Standards Scotland. Sections 16(1) and 48(1) were amended by paragraph 8 of schedule 5 of the 1999 Act and section 34(1) of the 2015 Act. Section 17(1) was amended by the 1999 Act, schedule 5, paragraphs 8 and 12(a) and S.I. 2011/1043. Section 26(3) was amended by the 1999 Act, schedule 6, paragraph 1. Section 31(1) was amended by the 1999 Act, schedule 5, paragraph 8. Section 48(6) was inserted by paragraph 3 (11) of the schedule of the 2015 Act. Section 48(4) is disapplied in respect of these Regulations by virtue of section 48(4C) which was inserted by S.I. 2004/2990. Amendments made by schedule 5 of the 1999 Act shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) (“the 1998 Act”) by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State, so far as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. Insofar as not transferred, and insofar as relating to food (including drink) including the primary production of food, those functions were transferred to the Scottish Ministers by S.I. 2005/849.
- (2) 1972 c.68. Section 2(2) was amended by the 1998 Act, schedule 8, paragraph 15(3) (which was amended by section 27(4) of the Legislative and Regulatory Reform Act 2006 (c.51) (“the 2006 Act”). Section 2(2) was also amended by section 27(1)(a) of the 2006 Act and by the European Union (Amendment) Act 2008 (c.7) (“the 2008 Act”), schedule, Part 1. Paragraph 1A of schedule 2 was inserted by the 2006 Act, section 28 and was amended by the 2008 Act, schedule, Part 1 and S.I. 2007/1388. The functions conferred upon the Minister of the Crown under section 2(2), insofar as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act.
- (3) Section 48(4A) was inserted by paragraphs 7 and 21 of Schedule 5 to the 1999 Act.
- (4) OJ L 31, 1.2.2002, p.1, last amended by Regulation (EU) 652/2014 of the European Parliament and of the Council (OJ L 189, 15.05.2014, p.1).

### Citation, commencement and extent

1.—(1) These Regulations may be cited as the Caseins and Caseinates (Scotland) Regulations 2016 and come into force on 22nd December 2016.

(2) These Regulations extend to Scotland only.

### Interpretation

2. In these Regulations—

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

“edible rennet casein” means a milk product obtained by separating, washing and drying the coagulum of skimmed milk and/or other products from milk; the coagulum is obtained through the reaction of rennet or other coagulating enzymes and complying with the standards set out in schedule 2;

“edible caseinate” means a milk product obtained by the action of edible casein or edible casein curd coagulum with neutralizing agents, followed by drying and complying with the standards set out in schedule 3;

“the Directive” means 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](#)(5);

“food authority” means a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994(6);

“food business operator” has the meaning given in Article 3(3) of Regulation (EC) 178/2002;

“place on the market” has the meaning given in Article 3(8) of Regulation (EC) 178/2002;

Reference to a “schedule” means reference to a schedule of these Regulations;

“Regulation (EU) 1169/2011” means Regulation (EU) 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, amending Regulations (EC) 1924/2006 and (EC) 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) 608/2004(7).

“the Act” means the Food Safety Act 1990(8).

### Scope

3. These Regulations apply to caseins and caseinates intended for human consumption and mixtures of these.

### Restriction on the marketing and use of edible acid caseins, edible rennet caseins and edible caseinates

4. A person must not—

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(5) OJ L 314, 1.12.2015, p.1.

(6) [1994 c.39](#). Section 2 was amended by the Environment Act 1995 (c.25), schedule 22, paragraph 232(1).

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

(8) [1990 c.16](#).

- (a) place on the market edible acid caseins, edible rennet caseins or edible caseinates under those names unless they comply with the rules laid down in the Directive and with the standards set out in schedules 1, 2 or 3;
- (b) place on the market edible acid caseins, edible rennet caseins and edible caseinates for purposes other than the preparation of food unless they are named and labelled clearly as to their nature, quality or intended use; or
- (c) use for the preparation of food, caseins and caseinates which do not comply with the standards set out in points (b) and (c) of schedules 1, 2 or 3.

### **Labelling of edible acid caseins, edible rennet caseins and edible caseinates**

5.—(1) The following particulars must be marked clearly and indelibly on the packages, containers or labels of edible acid caseins, edible rennet caseins or edible caseinates—

- (a) the name of the edible acid casein, edible rennet casein or, edible caseinate, and in the case of an edible caseinate, an indication of the cation or cations as listed in point (d) of schedule 3;
- (b) in the case of edible acid caseins, edible rennet caseins or edible caseinates marketed as mixtures:
  - (i) the words ‘mixture of ...’ followed by the names of the different products of which the mixture is composed, in decreasing order of weight,
  - (ii) an indication of the cation or cations, as listed in point (d) of schedule 3, in the case of edible caseinates,
  - (iii) the protein content in the case of mixtures containing edible caseinates;
- (c) the net quantity of the edible acid caseins, edible rennet caseins and edible caseinates expressed in kilograms or grams;
- (d) the name or business name and 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 edible acid caseins, edible rennet caseins or edible caseinates imported from third countries, the name of the country of origin;
- (f) the lot identification of the casein or caseinate products or the date of production.

(2) A person must not place on the market any edible acid caseins, edible rennet caseins or edible caseinates unless the particulars referred to in regulation 5(1) are given in English either exclusively or in addition to any other language.

(3) Where the minimum milk protein content set out at item 2 in table 1 of schedule 1, item 2 in table 1 of schedule 2, or item 2 in table 1 of schedule 3 is exceeded in the milk products defined in regulation 2, this fact may, without prejudice to the provisions of Regulation (EU) 1169/2011, be marked on the packages, containers or labels of the products.

### **Enforcement**

- 6. Each food authority must execute and enforce these Regulations within its area.

### **Offences and penalties**

7. A person is guilty of an offence if they fail to comply with any of the foregoing provisions of these regulations and shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

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**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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### **Application of provisions of the Act**

**8.** The provisions of the Act specified in column 1 of the table in schedule 4 apply, with the modifications specified in column 2 of that table, for the purposes of these Regulations.

### **Revocations**

- 9.**—(1) The Caseins and Caseinates (Scotland) Regulations 1986<sup>(9)</sup> are revoked.  
(2) The Caseins and Caseinates (Scotland) Amendment Regulations 1990<sup>(10)</sup> are revoked.

St Andrew's House, Edinburgh  
22nd November 2016

*AILEEN CAMPBELL*  
Authorised to sign by the Scottish Ministers

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<sup>(9)</sup> S.I. 1986/836.  
<sup>(10)</sup> S.I. 1990/1.

## SCHEDULE 1

Regulations 4 and 5

## 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
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2.	Appearance	Colour ranging from white to creamy white; the product must not contain any lumps that would not break up under slight pressure.
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## SCHEDULE 2

Regulations 4 and 5

### 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, bacterial cultures and authorised ingredients

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— rennet meeting the requirements of Regulation (EC) No 1332/2008(11);

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

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#### 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.

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(11) OJ No L 354, 31.12.2008, p.7, last amended by Commission Regulation (EU) No 1056/2012 of 12th November 2012.

## SCHEDULE 3

Regulations 4 and 5

## 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 neutralizing and buffering agents)

hydroxydes carbonates phosphates citrates	of	sodium potassium calcium ammonium magnesium
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## 5. Organoleptic 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 4

Regulation 8

## Modification of provisions of the Act

<i>Provision of the Act</i>	<i>Modifications</i>
Section 3 (presumptions that food intended for human consumption)	In subsection (1), for “this Act” substitute “the Caseins and Caseinates (Scotland) Regulations 2016”.
Section 20 (offences due to fault of another person)	For “any of the preceding provisions of this Part” substitute “the Caseins and Caseinates (Scotland) Regulations 2016”.
Section 21(12) (defence of due diligence)	In subsection (1), for “any of the preceding provisions of this Part” substitute “the Caseins and Caseinates (Scotland) Regulations 2016”.
Section 22 (defence of publication in the course of business)	In subsection (1), for “any of the preceding provisions of this Part” substitute “any provision of the Caseins and Caseinates (Scotland) Regulations 2016”.
Section 29 (procurement of samples)	In paragraph (b)(ii), after “under section 32 below” insert “including under section 32 as applied and modified by regulation 9 and the schedule of the Caseins and Caseinates Groups (Scotland) Regulations 2016”.
Section 30(8) (evidence of certificates given by a food analyst or examiner)	For “this Act” substitute “the Caseins and Caseinates (Scotland) Regulations 2016”.
Section 32 (powers of entry)	In subsection (1), for paragraphs (a) to (c) substitute “(a) to enter any premises within the authority’s area for the purpose of ascertaining whether there has been any contravention of a specified EU requirement (as defined in regulation 9 of the Caseins and Caseinates (Scotland) Regulations 2016); (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 such a requirement; and (c) when exercising a power of entry under this section, to exercise the associated powers in sub-sections (5) and (6) relating to records.”.
Section 33 (obstruction etc. of officers)	In subsection (1), for “this Act” (in each place where it occurs) substitute “the Caseins and Caseinates (Scotland) Regulations 2016”.
Section 35(1) (punishment of offences)	After “section 33(1) above” insert “as applied and modified by regulation 9 and the schedule of the Caseins and Caseinates (Scotland) Regulations 2016,”.
Section 36 (offences by bodies corporate)	In subsection (1), for “this Act” substitute “the Caseins and Caseinates (Scotland) Regulations 2016”.
Section 36A(13) (offences by Scottish partnerships)	For “this Act” substitute “the Caseins and Caseinates (Scotland) Regulations 2016”.

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(12) Section 21(2) was amended by S.I. 2004/3279.

(13) Section 36A was inserted by the Food Standards Act 1999, schedule 5, paragraph 16.



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<i>Provision of the Act</i>	<i>Modifications</i>
Section 44 (protection of officers acting in good faith)	For “this Act”—  (a) where it first appears substitute “the Caseins and Caseinates (Scotland) Regulations 2016 (“the 2016 Regulations”)”; and  (b) on each other occasion it appears substitute “the 2016 Regulations”.

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## EXPLANATORY NOTE

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

These Regulations make provision to implement in Scotland certain provisions of 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](#).

Regulation 4 provides for the restrictions in use and marketing of edible caseins and caseinates and Regulation 5 provides for labelling requirements.

Regulation 6 provides for the execution and enforcement of these Regulations by local authorities and Regulation 7 provides for offences and penalties.

Regulation 9 provides for the revocation of subordinate legislation.

These Regulations revoke the Caseins and Caseinates (Scotland) Regulations 1986 ([S.I. 1986/836](#)) and the Caseins and Caseinates (Scotland) Amendment Regulations 1990 ([S.I. 1990/1](#)).