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## SCOTTISH STATUTORY INSTRUMENTS

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# 2016 No. 422

## FOOD

### The Caseins and Caseinates (Scotland) (No. 2) Regulations 2016

*Made - - - - 15th December 2016*  
*Laid before the Scottish*  
*Parliament - - - - 15th December 2016*  
*Coming into force in accordance with regulation 1*

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> and section 2(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) 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>(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. Under section 48(6) (which was inserted by paragraph 3(11) of the schedule of the 2015 Act) references to the Food Standards Agency in section 48 are to be read as references to Food Standards Scotland. 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), schedule, Part 1. 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 of the 1999 Act.
- (4) OJ L 31, 1.2.2002, p.1, last amended by Regulation (EU) No 652/2014 of the European Parliament and of the Council (OJ L 189, 15.05.2014, p.1).

### Modifications etc. (not altering text)

- C1** Regulations applied in part (with modifications) (N.I.) (1.10.2023) by [The Windsor Framework \(Retail Movement Scheme: Public Health, Marketing and Organic Product Standards and Miscellaneous Provisions\) Regulations 2023](#) (S.I. 2023/959), regs. 1(2), 4(b), **Sch. 2** (with regs. 7, 8)

### Citation, commencement and extent

- 1.—(1) These Regulations may be cited as the Caseins and Caseinates (Scotland) (No. 2) Regulations 2016.
- (2) This regulation and regulation 9(c) come into force on 21st December 2016.
- (3) The remaining provisions of these Regulations come into force on 22nd December 2016.
- (4) These Regulations extend to Scotland only.

### Commencement Information

- II** Reg. 1 in force at 21.12.2016, see [reg. 1\(2\)](#)

### Interpretation

#### 2. In these Regulations—

“the Act” means the Food Safety Act 1990<sup>(5)</sup>;

“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<sup>(6)</sup>;

“edible acid casein” 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;

“edible caseinate” means a milk product obtained by action of edible casein or edible casein curd coagulum with neutralizing agents, followed by drying;

“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;

“food authority” means a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994<sup>(7)</sup>;

“food business operator” has the meaning given in Article 3(3) of Regulation (EC) No 178/2002;

“place on the market” has the meaning given in Article 3(8) of Regulation (EC) No 178/2002;

“Regulation (EC) No 178/2002” means 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; and

“Regulation (EU) No 1169/2011” means Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, amending

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(5) 1990 c.16.

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

(7) 1994 c.39. Section 2 was amended by the Environment Act 1995 (c.25), schedule 22, paragraph 232(1).

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(8).

#### Commencement Information

**I2** Reg. 2 in force at 22.12.2016, see [reg. 1\(3\)](#)

### Scope

**3.** These Regulations apply to caseins and caseinates intended for human consumption and mixtures thereof.

#### Commencement Information

**I3** Reg. 3 in force at 22.12.2016, see [reg. 1\(3\)](#)

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

- 4.** A person must not—
- (a) place on the market—
    - (i) edible acid caseins under that name unless they comply with the rules laid down in the Directive and the standards set out in schedule 1;
    - (ii) edible rennet caseins under that name unless they comply with the rules laid down in the Directive and the standards set out in schedule 2; or
    - (iii) edible caseinates under that name unless they comply with the rules laid down in the Directive and the standards set out in schedule 3;
  - (b) place on the market caseins or 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 or caseinates which do not comply with the standards set out in tables 2 and 3 of schedule 1, 2 or 3.

#### Commencement Information

**I4** Reg. 4 in force at 22.12.2016, see [reg. 1\(3\)](#)

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

**5.—(1)** The following particulars must be marked on the packages, containers or labels of edible acid caseins, edible rennet caseins and edible caseinates in easily visible, clearly legible and indelible characters:—

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

- (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 table 4 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 edible acid casins, edible rennet caseins or edible caseinates of which the mixture is composed, in decreasing order of weight;
  - (ii) an indication of the cation or cations, as listed in table 4 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 [F1United Kingdom], the importer into the [F1United Kingdom] 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 edible acid caseins, edible rennet caseins or edible caseinates 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 paragraph (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, 2 or 3 is exceeded in edible acid caseins, edible rennet caseins or edible caseinates, this fact may, without prejudice to the provisions of Regulation (EU) No 1169/2011, be marked on the packages, containers or labels of the products.

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#### Textual Amendments

- F1** Words in [reg. 5\(1\)\(d\)](#) substituted (31.12.2020) by [The Food Information, Labelling and Standards \(EU Exit\) \(Scotland\) \(Amendment\) Regulations 2019 \(S.S.I. 2019/285\)](#), regs. 1(1), **6(2)**; 2020 c. 1, Sch. 5 para. 1(1)

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#### Commencement Information

- I5** Reg. 5 in force at 22.12.2016, see [reg. 1\(3\)](#)

#### Offences and penalties

**6.** A person is guilty of an offence if that person fails to comply with regulation 4 or 5 and is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

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#### Commencement Information

- I6** Reg. 6 in force at 22.12.2016, see [reg. 1\(3\)](#)

## [<sup>F2</sup>Transitional provisions: withdrawal from the EU

**6A.**—(1) A person is to be considered to have complied with regulation 5(1)(d) in the following circumstances—

- (a) edible acid caseins, edible rennet caseins or edible caseinates are marked with 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,
- (b) this would have complied with regulation 5(1)(d) as it applied immediately before IP completion day, and
- (c) the edible acid caseins, edible rennet caseins or edible caseinates are placed on the market no later than [<sup>F3</sup>31 December 2023].

(2) A person is to be considered to have complied with regulation 5(1)(e) in the following circumstances—

- (a) edible acid caseins, edible rennet caseins or edible caseinates imported from a third country are marked with the name of the country of origin,
- (b) this would have complied with regulation 5(1)(e) as it applied immediately before IP completion day, and
- (c) the edible acid caseins, edible rennet caseins or edible caseinates are placed on the market no later than [<sup>F4</sup>31 December 2023].

(3) In this regulation, “third country” means any country other than the United Kingdom.]

### Textual Amendments

- F2** Reg. 6A inserted (31.12.2020) by [The Food Information, Labelling and Standards \(EU Exit\) \(Scotland\) \(Amendment\) Regulations 2019](#) (S.S.I. 2019/285), regs. 1(1), **6(3)** (as amended by S.S.I. 2020/372, regs. 1(2)(a), **9(6)**); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F3** Words in [reg. 6A\(1\)\(c\)](#) substituted (30.9.2022) by [The Food Information \(Transitional Provisions\) \(Miscellaneous Amendments\) \(Scotland\) Regulations 2022](#) (S.S.I. 2022/265), regs. 1(1), **13(a)**
- F4** Words in [reg. 6A\(2\)\(c\)](#) substituted (30.9.2022) by [The Food Information \(Transitional Provisions\) \(Miscellaneous Amendments\) \(Scotland\) Regulations 2022](#) (S.S.I. 2022/265), regs. 1(1), **13(b)**

### Enforcement

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

### Commencement Information

**I7** Reg. 7 in force at 22.12.2016, see [reg. 1\(3\)](#)

### 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.

### Commencement Information

**I8** Reg. 8 in force at 22.12.2016, see [reg. 1\(3\)](#)

## Revocations

9. The following instruments are revoked:—

- (a) the Caseins and Caseinates (Scotland) Regulations 1986<sup>(9)</sup>;
- (b) the Caseins and Caseinates (Scotland) Amendment Regulations 1990<sup>(10)</sup>; and
- (c) the Caseins and Caseinates (Scotland) Regulations 2016<sup>(11)</sup> are revoked.

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### Commencement Information

**I9** Reg. 9(a)(b) in force at 22.12.2016, see [reg. 1\(3\)](#)

**I10** Reg. 9(c) in force at 21.12.2016, see [reg. 1\(2\)](#)

St Andrew's House,  
Edinburgh

*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.  
<sup>(11)</sup> S.S.I. 2016/383.

## SCHEDULE 1

Regulations 4 and 5

## Standards applicable to edible acid caseins

**Commencement Information****III** Sch. 1 in force at 22.12.2016, see **reg. 1(3)***Table 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

*Table 2**Contaminants*

Maximum lead content	0.75 mg/kg
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*Table 3**Impurities*

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

1.	Acids: — lactic acid — hydrochloric acid — sulphuric acid
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**Changes to legislation:** There are currently no known outstanding effects for the The Caseins and Caseinates (Scotland) (No. 2) Regulations 2016. (See end of Document for details)

	— citric acid — acetic acid — orthophosphoric acid
2.	Bacterial cultures producing lactic acid
3.	Whey

*Table 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

Regulations 4 and 5

Standards applicable to edible rennet caseins

**Commencement Information**

**I12** Sch. 2 in force at 22.12.2016, see **reg. 1(3)**

*Table 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

*Table 2*  
*Contaminants*

Maximum lead content	0.75 mg/kg
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**Changes to legislation:** There are currently no known outstanding effects for the The Caseins and Caseinates (Scotland) (No. 2) Regulations 2016. (See end of Document for details)

*Table 3*  
*Impurities*

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

<p>— rennet meeting the requirements of 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(12);</p> <p>— other milk-coagulating enzymes meeting the requirements of Regulation (EC) No 1332/2008.</p>
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*Table 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 3

Regulations 4 and 5

#### Standards applicable to edible caseinates

#### Commencement Information

**I13** Sch. 3 in force at 22.12.2016, see **reg. 1(3)**

*Table 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

(12) OJ No L 354, 31.12.2008, p.7, last amended by Commission Regulation (EU) No 1056/2012 (OJ L 313, 13.11.2012, p.9).

**Changes to legislation:** There are currently no known outstanding effects for the The Caseins and Caseinates (Scotland) (No. 2) Regulations 2016. (See end of Document for details)

6.	Maximum sediment content (burnt particles)	22.5 mg in 25 g
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*Table 2  
Contaminants*

Maximum lead content	0.75 mg/kg
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*Table 3  
Impurities*

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

(optional neutralizing and buffering agents)

<i>hydroxydes</i> carbonates phosphates citrates	<i>of</i>	<i>sodium</i> potassium calcium ammonium magnesium
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*Table 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

<p><b>Commencement Information</b>  <b>I14</b> Sch. 4 in force at 22.12.2016, see <a href="#">reg. 1(3)</a></p>
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<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) (No. 2) 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) (No. 2) Regulations 2016”.
Section 21(13) (defence of due diligence)	In subsection (1), for “any of the preceding provisions of this Part” substitute “the Caseins and Caseinates (Scotland) (No. 2) Regulations 2016”.
Section 22 (defence of the publication in the course of business)	For “any of the preceding provisions of this Part” substitute “the Caseins and Caseinates (Scotland) (No. 2) 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 8 and schedule 4 of the Caseins and Caseinates (Scotland) (No. 2) Regulations 2016”.
Section 30 (evidence of certificates given by a food analyst or examiner)	In subsection (8), for “this Act” substitute “the Caseins and Caseinates (Scotland) (No. 2) Regulations 2016”.
Section 32 (powers of entry)	In subsection (1), for paragraphs (a) to (c) substitute— <ul style="list-style-type: none"> <li>“(a) to enter any premises within the authority’s area for the purpose of ascertaining whether there has been any contravention of the Caseins and Caseinates (Scotland) (No. 2) Regulations 2016;</li> <li>(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</li> <li>(c) when exercising a power of entry under this section, to exercise the associated powers in subsections (5) and (6) relating to records.”.</li> </ul>
Section 33 (obstruction etc. of officers)	In subsection (1), for “this Act” (in each place where it occurs) substitute “the Caseins and Caseinates (Scotland) (No. 2) Regulations 2016”.
Section 35(1) (punishment of offences)	After “section 33(1) above” insert “as applied and modified by regulation 8 and schedule 4 of the Caseins and Caseinates (Scotland) (No. 2) Regulations 2016”.
Section 36 (offences by bodies corporate)	In subsection (1), for “this Act” substitute “the Caseins and Caseinates (Scotland) (No. 2) Regulations 2016”.
Section 36A(14) (offences by Scottish partnerships)	For “this Act” substitute “the Caseins and Caseinates (Scotland) (No. 2) Regulations 2016”.

(13) Section 21(2) was amended by [S.I. 2004/3279](#).

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

**Changes to legislation:** There are currently no known outstanding effects for the The Caseins and Caseinates (Scotland) (No. 2) Regulations 2016. (See end of Document for details)

<i>Provision of the Act</i>	<i>Modifications</i>
Section 44 (protection of officers acting in good faith)	For “this Act”— <ul style="list-style-type: none"> <li>(a) where it first appears substitute “the Caseins and Caseinates (Scotland) (No. 2) Regulations 2016 (“the 2016 Regulations”); and</li> <li>(b) on each other occasion it appears substitute “the 2016 Regulations”.</li> </ul>

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

Regulation 8 modifies provisions of the Food Safety Act 1990.

Regulation 9 revokes the Caseins and Caseinates (Scotland) Regulations 1986, the Caseins and Caseinates (Scotland) Amendment Regulations 1990 and the Caseins and Caseinates (Scotland) Regulations 2016.

**Changes to legislation:**

There are currently no known outstanding effects for the The Caseins and Caseinates (Scotland) (No. 2) Regulations 2016.