

**2013 No. 000**

**FOOD, ENGLAND**

**The Caseins and Caseinates (England) Regulations 2013**

*Made* - - - - \*\*\*

*Laid before Parliament* \*\*\*

*Coming into force* - - *1st October 2013*

These Regulations are made 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(a) and now vested in the Secretary of State(b), and, in relation to regulation 2(2), paragraph 1A of Schedule 2 to the European Communities Act 1972(c).

It appears to the Secretary of State that it is expedient for the references to the European instruments listed in regulation 2(3) to be construed as references to those instruments as amended from time to time.

The Secretary of State, in relation to England, has had regard to relevant advice given by the Food Standards Agency in accordance with section 48(4A) of the Food Safety Act 1990.

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(d).

**Citation, commencement and application**

1.—(1) These Regulations may be cited as the Caseins and Caseinates (England) Regulations 2013.

(2) They come into force on 1st October 2013.

(3) They apply in relation to England only.

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- (a) 1990 c.16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Section 17 was amended by the Food Standards Act 1999 (c.28), Schedule 5, paragraph 12. Section 26 was amended by the Food Standards Act 1999, Schedule 6. Section 48 was amended by the Food Standards Act 1999, Schedule 5, paragraph 21 and by S.I. 2004/2990.
- (b) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999.
- (c) 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c.51).
- (d) OJ No L 31, 1.2.2002, p1 as last amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p14)

## Interpretation

2.—(1) In these Regulations—

“the Act” means the Food Safety Act 1990;

“casein” means the principal protein constituent of milk, washed and dried, insoluble in water and obtained from skimmed milk by precipitation:

- (a) by the addition of acid, or
- (b) by microbial acidification, or
- (c) by using rennet, or
- (d) by using other milk-coagulating enzymes

without prejudice to the possibility of prior use of ion exchange processes and concentration processes;

“caseinate” means a product obtained by drying casein treated with neutralising agents;

“casein product” means edible acid casein, edible rennet casein or any edible caseinate;

“edible acid casein” has the meaning given to it in column 2 of Part 1 of Schedule 1;

“edible caseinates” has the meaning given to it in column 2 of Part 1 of Schedule 1;

“edible rennet casein” has the meaning given to it in column 2 of Part 1 of Schedule 1;

“reserved description”, as respects any casein product, means a description specified in relation to that product in column 1 of Part 1 of Schedule 1, and the use of any such description in these Regulations is to be construed as meaning any casein product specified in relation to that description in column 2 of that Part of that Schedule;

“sell” includes offer or expose for sale or have in possession for sale, and “sale” and “seller” are to be construed accordingly;

“skimmed milk” means the milk of one or more cows to which nothing has been added and of which only the fat content has been reduced.

(2) Any reference in Part III of Schedule 1 to a “method” identified by a number is to be construed as a reference to the method of analysis for casein products described under that number in, and as read with the General Provisions of, Annex II to First Commission Directive on methods of analysis for edible caseins and caseinates (85/503/EEC)(a).

(3) In these Regulations, references to the following European instruments are references to the instruments as amended from time to time:

- (a) First Commission Directive on methods of analysis for edible caseins and caseinates (85/503/EEC);
- (b) First Commission Directive laying down methods of sampling for chemical analysis of edible caseins and caseinates (86/424/EEC)(b).

## Exemption

3. These Regulations do not apply to any casein or caseinate not intended for sale for human consumption.

## General restrictions on use of reserved descriptions

4.—(1) A person must not sell any food with a label, whether or not attached to or printed on the wrapper or container, or display with any food offered or exposed by that person for sale any ticket or notice which includes any reserved description or any derivative of such a description or any word or description substantially similar to such a description unless it complies with the requirements in paragraph (3).

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(a) OJ No L 308, 20.11.1985, p12.

(b) OJ No L 243, 28.8.1986, p29.

(2) A person must not publish, or be a party to the publication of, any advertisement for food which includes any reserved description or any derivative of such a description or any word or description substantially similar to such a description unless it complies with the requirements in paragraph (3).

(3) The requirements referred to in paragraphs (1) and (2) are that—

- (a) such food is a casein product to which the reserved description relates, or
- (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 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 a casein product and does not contain one.

### **Labelling of casein products**

**5.**—(1) Without prejudice to the legislation referred to in paragraph (5), a person must not sell any casein product unless it is marked or labelled with—

- (a) the reserved description for that product with, in the case of caseinates, an indication of the cation;
- (b) in the case of casein products sold as mixtures—
  - (i) the words “mixture of” followed by the reserved descriptions of the casein products which make up the mixture, in decreasing order of weight;
  - (ii) an indication of the cation in the case of a caseinate;
  - (iii) in the case of mixtures containing caseinates, the protein content, calculated on the dried extract, expressed as a percentage of the total weight of the product as sold;
- (c) the name or business name and the address of the manufacturer or packer or of a seller established within the European Union;
- (d) in the case of products imported from countries outside the European Union, the name of the country of origin; and
- (e) the date of manufacture or some marking by which the batch can be identified.

(2) The particulars required by subparagraphs (a), (b), (d) and (e) of paragraph (1) must be given in English, either exclusively or in addition to any other language.

(3) The particulars required by subparagraphs (b)(iii), (c) and (d) of paragraph (1) may be given only in a document accompanying the product.

(4) In the case of a product transported in bulk, the indication of the cation in any caseinate and the particulars required by subparagraphs (b)(ii) and (e) of paragraph (1) may also be given only in an accompanying document.

(5) The legislation is—

- (a) until and including 12th December 2014, Part II of the Food Labelling Regulations 1996(a); and
- (b) after 12th December 2014, Article 17 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers(b).

### **Heat treatment**

**6.** A person must not use as an ingredient in the preparation of any casein product any casein or caseinate which has not been subjected to heat treatment at least equivalent to pasteurisation unless that casein product is itself subjected to such heat treatment during its preparation.

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(a) S.I. 1996/1499, the relevant amending instrument is S.I. 1998/1398; there are other amending instruments but none is relevant.

(b) O.J. No L 304, 22.11.2011, p18.

## **Enforcement**

7.—(1) It is the duty of each food authority within its area and each port health authority within its district to enforce these Regulations.

(2) In paragraph (1), “food authority” means for each non-metropolitan county, metropolitan district and London borough, the council of that county, district or borough, and for the City of London and the Inner Temple and the Middle Temple, the Common Council of the City of London.

## **Offence**

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

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

9.—(1) Section 10(1) and (2) of the Act (improvement notices) apply with the modification (in the case of section 10(1)) specified in Part 1 of Schedule 2 for the purposes of—

- (a) enabling an improvement notice to be served on a person requiring the person to comply with regulation 4, 5 or 6; and
- (b) making the failure to comply with a notice referred to in sub-paragraph (a) an offence.

(2) Section 37(1) and (6) (appeals) of the Act apply with the modifications specified in Part 2 of Schedule 2 for the purposes of enabling a decision to serve a notice referred to in paragraph (1)(a) to be appealed.

(3) The provisions of the Act specified in column 1 of Part 3 of Schedule 2 apply, with the modifications specified in column 2 of that Part for the purposes of these Regulations.

(4) Paragraphs (1) and (3) apply without prejudice to the application of sections 10 and 37 of the Act to these Regulations for purposes other than those specified in those paragraphs.

## **Revocations**

10. The Caseins and Caseinates Regulations 1985(a) and the Caseins and Caseinates (Amendment) Regulations 1989(b) are revoked.

## **Review**

11.—(1) The Secretary of State must from time to time—

- (a) carry out a review of these Regulations;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how Council Directive 83/417/EEC on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption(c) (which is implemented by means of these Regulations) is implemented in other member States.

(3) The report must in particular—

- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
- (b) assess the extent to which those objectives are achieved; and
- (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

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(a) S.I. 1985/2026.

(b) S.I. 1989/2321.

(c) OJ No L 237, 26.8.1983, p25.

(4) The first report under this regulation must be published before 1st October 2018.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

Date \_\_\_\_\_ Name \_\_\_\_\_  
Department for Environment, Food and Rural Affairs  
Minister of State

## SCHEDULE 1

Regulation 2

### PART 1

#### CASEIN PRODUCTS AND THEIR RESERVED DESCRIPTIONS

<b>Column 1</b> <b>Reserved descriptions</b>	<b>Column 2</b> <b>Casein products</b>
Edible acid casein	Edible casein obtained by precipitation using the technological adjuvants and bacterial cultures specified in relation to edible acid casein in Part 2 of this Schedule and complying with the standards laid down for edible acid casein in Part 3
Edible rennet casein	Edible casein obtained by precipitation using the technological adjuvants specified in relation to edible rennet casein in Part 2 of this Schedule and complying with the standards laid down for edible rennet casein in Part 3
Edible caseinates	Caseinates obtained from edible caseins using neutralising agents of edible quality specified in relation to edible caseinates in Part 2 of this Schedule and complying with the standards laid down for edible caseinates in Part 3

### PART 2

#### TECHNOLOGICAL ADJUVANTS AND BACTERIAL CULTURES

Edible acid casein	<i>Technological adjuvants and bacterial cultures</i> lactic acid (E270) hydrochloric acid (507) sulphuric acid (513) citric acid (E330) acetic acid (E260) orthophosphoric acid (E338) whey bacterial cultures producing lactic acid
Edible rennet casein	<i>Technological adjuvants</i>  rennet meeting the requirements of Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes(a)

(a) OJ No L 354, 31.12.2007, p7.

	other milk-coagulating enzymes meeting the requirements of Regulation (EC) No 1332/2008 of the European Parliament and of the Council		
Edible caseinates	<i>Technological adjuvants</i> <i>(optional neutralising and buffering agents)</i> hydroxides carbonates phosphates citrates		
	of		sodium potassium calcium ammonium magnesium

### PART 3 STANDARDS

*(All percentages are by weight)*

Edible acid casein

*(a) Essential factors of composition*

1. Moisture content of not more than 10% determined by method 1.
2. Milk protein content, calculated on the dried extract, of not less than 90% determined by method 2.
3. Milk fat content, calculated on the dried extract, of not more than 2.25%.
4. Titratable acidity, expressed in ml of decinormal sodium hydroxide solution per g, of not more than 0.27 determined by method 3.
5. Ash content (including P<sub>2</sub>O<sub>5</sub>) of not more than 2.5% determined by method 4.
6. Anhydrous lactose content of not more than 1%.
7. Sediment content (burnt particles) of not more than 22.5 mg in 25g.

*(b) Contaminants*

Lead content of not more than 1 mg per kg.

*(c) Impurities*

No extraneous matter (such as wood or metal particles, hairs or insect fragments) in 25 g.

*(d) 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.

Edible rennet casein

*(a) Essential factors of composition*

1. Moisture content of not more than 10% determined by method 1.
2. Milk protein content, calculated on the dried extract, of not less than 84% determined by method 2.
3. Milk fat content, calculated on the dried extract, of not more than 2%.
4. Ash content (including P<sub>2</sub>O<sub>5</sub>) of not less than 7.5% determined by method 5.
5. Anhydrous lactose content of not more than 1%.
6. Sediment content (burnt particles) of not more than 22.5 mg in 25g.

*(b) Contaminants*

Lead content of not more than 1 mg per kg.

*(c) Impurities*

Edible caseinates

No extraneous matter (such as wood or metal particles, hairs or insect fragments) in 25 g.

*(d) 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.

*(a) Essential factors of composition*

1. Moisture content of not more than 8% determined by method 1.
2. Milk protein content, calculated on the dried extract, of not less than 88% determined by method 2.
3. Milk fat content, calculated on the dried extract, of not more than 2%.
4. Anhydrous lactose content of not more than 1%.
5. pH value of 6.0 to 8.0 determined by method 6.
6. Sediment content (burnt particles) of not more than 22.5 mg in 25g.

*(b) Contaminants*

Lead content of not more than 1 mg per kg.

*(c) Impurities*

No extraneous matter (such as wood or metal particles, hairs or insect fragments) in 25 g.

*(d) Characteristics*

1. *Odour*: No more than 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 the calcium caseinate.

## SCHEDULE 2

Regulation 9

### Application and modification of provisions of the Act

#### PART 1

##### Modification of section 10(1)

For subsection (1) of section 10 of the Act, substitute—

“(1) If an authorised officer of an enforcement authority has reasonable grounds for believing that a person is failing to comply with regulation 4, 5 or 6 of the Caseins and Caseinates (England) Regulations 2013, 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 provision;
- (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 those measures, or measures that are at least equivalent to them, within such period as may be specified in the notice.”.

## PART 2

### Modification of section 37(1) and (6)

1. For subsection (1) of section 37 of the Act, substitute—

“(1) Any person who is aggrieved by a decision of an authorised officer of an enforcement authority to serve an improvement notice under section 10(1), as applied and modified by regulation 9(1) of, and Part 1 of Schedule 2 to, the Caseins and Caseinates (England) Regulations 2013, may appeal to the First-tier Tribunal.”.

2. In subsection (6) of section 37 of the Act—

- (a) for “(3) or (4)”, substitute “(1)”; and
- (b) in paragraph (a), for “a magistrates’ court or to the sheriff”, substitute “the First-tier Tribunal”.

## PART 3

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

<i>Column 1</i> <i>Provision of the Act</i>	<i>Column 2</i> <i>Modifications</i>
Section 2 (extended meaning of “sale” etc.)	For “this Act” substitute “the Caseins and Caseinates (England) Regulations 2013”.
Section 3 (presumptions that food intended for human consumption)	In subsection (1), for “this Act” substitute “the Caseins and Caseinates (England) Regulations 2013”.
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 9(1) of the Caseins and Caseinates (England) Regulations 2013, or regulation 8 of those Regulations”.
Section 21(a) (defence of due diligence)	In subsection (1), for “any of the preceding provisions of this Part” substitute “section 10(2), as applied by regulation 9(1) of the Caseins and Caseinates (England) Regulations 2013, or regulation 8 of those Regulations”. In subsection (2), for “section 14 or 15” substitute “regulation 8 of the Caseins and Caseinates (England) Regulations 2013”.
Section 22 (defence of publication in the course of business)	For “any of the preceding provisions of this Part” substitute “regulation 8 of the Caseins and Caseinates (England) Regulations 2013”.
Section 29 (samples)	After the words “enforcement authority” insert the following— “when carrying out duties under this section in relation to the Caseins and Caseinates (England) Regulations 2013, must exercise and perform those duties in accordance with the methods described in the Annex to First Commission Directive 86/424/EEC and”.
Section 30(8) (which relates to evidence of certificates given by a food analyst or examiner)	For “this Act” substitute “the Caseins and Caseinates (England) Regulations 2013”.
Section 33 (obstruction etc.)	In subsection (1), for “this Act” (in each place occurring)

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



of officers)	substitute “the Caseins and Caseinates (England) Regulations 2013”.
Section 35(1)(a) and (2) (punishment of offences)	<p>In subsection (1), after “section 33(1) above”, insert “, as applied and modified by regulation 9(3) of, and Part 3 of Schedule 2 to, the Caseins and Caseinates (England) Regulations 2013,”.</p> <p>After subsection (1), insert the following subsection—</p> <p>“(1A) A person guilty of an offence under section 10(2), as applied by regulation 9(1) of the Caseins and Caseinates (England) Regulations 2013, shall be liable, on summary conviction, to a fine not exceeding level 5 on the standard scale.”.</p> <p>In subsection (2)—</p> <p>(c) for “any other offence under this Act”, substitute “an offence under section 33(2), as applied by regulation 9(3) of, and Part 3 of Schedule 2 to, the Caseins and Caseinates (England) Regulations 2013,”; and</p> <p>(d) in paragraph (b), for “the relevant amount”, substitute “the statutory maximum”.</p>
Section 36 (offences by body corporate)	In subsection (1), for “this Act” substitute “section 10(2), as applied by regulation 9(1) of the Caseins and Caseinates (England) Regulations 2013, or regulation 8 of those Regulations,”.
Section 36A(b) (offences by Scottish partnerships)	In subsection (1), for “this Act” substitute “section 10(2), as applied by regulation 9(1) of the Caseins and Caseinates (England) Regulations 2013, or regulation 8 of those Regulations,”.
Section 44 (protection of officers acting in good faith)	For “this Act” (in each place occurring) substitute “the Caseins and Caseinates (England) Regulations 2013”.

### EXPLANATORY NOTE

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

These Regulations, which apply to England only, 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).

These Regulations do not apply to casein products not intended for human consumption (regulation 3).

These Regulations—

- (a) implement Council Directive 83/417/EEC on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption (OJ No L 237, 26.8.83, p.25);
- (b) prescribe reserved descriptions and composition and manufacturing characteristics for the casein products to which they apply (regulation 2 and Schedule 1);
- (c) subject to specified exceptions, prohibit the labelling or advertisement with reserved descriptions of food other than casein products to which those descriptions relate (regulation 4);
- (d) impose requirements as to the labelling of casein products additional to those of the Food Labelling Regulations 1996 (S.I. 1996/1499) (regulation 5);

(a) 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.

(b) Section 36A was inserted by paragraphs 7 and 16 of Schedule 5 to the Food Standards Act 1999.

- (e) require heat treatment for casein products (regulation 6);
- (f) impose an obligation on food authorities and port health authorities to enforce the Regulations (regulation 7);
- (g) make it an offence to fail to comply with regulation 6 (regulation 8);
- (h) apply certain provisions of the Food Safety Act 1990 (c.16) with modifications (regulation 9 and Schedule 2). This includes the application (with modifications) of section 10(1), enabling an improvement notice to be served to require compliance with regulations 4, 5 and 6. The provisions, as applied, make the failure to comply with an improvement notice an offence;
- (i) revoke S.I. 1985/2026 and S.I. 1989/2321 (regulation 10);
- (j) make provision for a review of the Regulations (regulation 11).

A full impact assessment of the effect these Regulations will have on the costs of business, the voluntary sector and the public sector is available from the Food Policy Unit, Department for Environment, Food and Rural Affairs, Nobel House, 17 Smith Square, London SW1P 3JR and is published with the Explanatory Memorandum alongside the Regulations on [www.legislation.gov.uk](http://www.legislation.gov.uk).