

## I

(Legislative acts)

## DIRECTIVES

### **DIRECTIVE (EU) 2015/2203 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of 25 November 2015**

#### **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**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

- (1) Council Directive 83/417/EEC <sup>(3)</sup> provides for the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption. Since the entry into force of that Directive, several changes have taken place, in particular the development of a comprehensive legal framework in the area of food law and the adoption of an international standard for edible casein products by the Codex Alimentarius Commission ('Codex standard for edible casein products'), which need to be taken into account.
- (2) Directive 83/417/EEC confers powers on the Commission in order to implement some of its provisions. As a consequence of the entry into force of the Lisbon Treaty, those powers need to be aligned to Article 290 of the Treaty on the Functioning of the European Union ('TFEU').
- (3) For the sake of clarity, Directive 83/417/EEC should therefore be repealed and replaced with a new Directive.
- (4) Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>(4)</sup> contains general, horizontal and uniform Union rules concerning the adoption of emergency measures for food and feed. The related provisions of Directive 83/417/EEC are therefore no longer necessary.
- (5) Regulation (EC) No 882/2004 of the European Parliament and of the Council <sup>(5)</sup> contains general, horizontal and uniform Union rules concerning the methods of sampling and analysis of foodstuffs. The related provisions of Directive 83/417/EEC are therefore no longer necessary.

<sup>(1)</sup> OJ C 424, 26.11.2014, p. 72.

<sup>(2)</sup> Position of the European Parliament of 7 October 2015 (not yet published in the Official Journal) and decision of the Council of 10 November 2015.

<sup>(3)</sup> Council Directive 83/417/EEC of 25 July 1983 on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption (OJ L 237, 26.8.1983, p. 25).

<sup>(4)</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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 (OJ L 31, 1.2.2002, p. 1).

<sup>(5)</sup> Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

- (6) Under Regulation (EU) No 1169/2011 of the European Parliament and of the Council <sup>(1)</sup>, sufficient information is to be provided in business to business relations in order to ensure the presence and accuracy of food information for the final consumer. Since the products covered by this Directive are meant to be sold from business to business, for the preparation of food products, it is appropriate to maintain and adapt the specific rules already included in Directive 83/417/EEC to the current legal framework and simplify them. Such specific rules should provide for the information to be provided for the products covered by this Directive, in business to business relations, in order, on the one hand, to make available to food business operators the information they need for the labelling of the final products, for example when it comes to allergens, and, on the other hand, to avoid those products being confused with similar products not meant or not suitable for human consumption.
- (7) Regulation (EC) No 1333/2008 of the European Parliament and of the Council <sup>(2)</sup> lays down a definition of food additives and processing aids referred to as technological adjuvants in Directive 83/417/EEC. Consequently, this Directive should use the terms 'food additives' and 'processing aids' instead of 'technological adjuvants'. Such use of terminology would also be in line with the Codex standard for edible casein products.
- (8) Other terms and references used in the Annexes to Directive 83/417/EEC should be adapted to take into account those used in Regulation (EC) No 1332/2008 of the European Parliament and of the Council <sup>(3)</sup> and Regulation (EC) No 1333/2008.
- (9) Annex I to Directive 83/417/EEC fixes the maximum moisture content for edible caseins at 10 % and the maximum milk fat content for edible acid casein at 2,25 %. Taking into consideration that the Codex standard for edible casein products fixes those parameters at 12 % and 2 % respectively, the corresponding parameters should be set in line with that standard so as to avoid trade distortions.
- (10) In order to promptly adapt or update the technical elements contained in the Annexes to this Directive so as to take account of developments in relevant international standards or technical progress, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the standards applicable to edible caseins and edible caseinates laid down in Annexes I and II. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (11) Since the objectives of this Directive, namely to facilitate, through approximation of the laws of the Member States, the free movement of caseins and caseinates intended for human consumption while providing a high level of protection of health, and to bring existing provisions into line with general Union legislation on food and with international standards, cannot be sufficiently achieved by the Member States but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS DIRECTIVE:

#### Article 1

#### Scope

This Directive applies to caseins and caseinates which are intended for human consumption and mixtures thereof.

<sup>(1)</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 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 (OJ L 304, 22.11.2011, p. 18).

<sup>(2)</sup> Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

<sup>(3)</sup> Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 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 (OJ L 354, 31.12.2008, p. 7).

*Article 2***Definitions**

For the purposes of this Directive, the following definitions apply:

- (a) '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;
- (b) 'edible rennet casein' 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;
- (c) 'edible caseinate' means a milk product obtained by action of edible casein or edible casein curd coagulum with neutralizing agents, followed by drying.

*Article 3***Obligations of Member States**

Member States shall take all the necessary steps to ensure that:

- (a) the milk products defined in Article 2 are marketed, under the names specified therein, only if they comply with the rules laid down in this Directive and the standards set out in Annexes I and II; and
- (b) caseins and caseinates which do not comply with the standards set out in points (b) and (c) of Section I of Annex I, points (b) and (c) of Section II of Annex I or points (b) and (c) of Annex II, are not used for the preparation of food, and, where lawfully marketed for other purposes, are named and labelled in such a way that the purchaser is not misled as to their nature, quality or intended use.

*Article 4***Labelling**

1. The following particulars shall be marked on the packages, containers or labels of the milk products defined in Article 2 in easily visible, clearly legible and indelible characters:

- (a) the name of the milk product as laid down in points (a), (b) and (c) of Article 2 with, in the case of edible caseinates, an indication of the cation or cations as listed in point (d) of Annex II;
- (b) in the case of products 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 Annex II, in the case of edible caseinates,
  - (iii) the protein content in the case of mixtures containing edible caseinates;
- (c) the net quantity of the products, 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 Union, the importer into the Union market;
- (e) in the case of products imported from third countries, the name of the country of origin;
- (f) the lot identification of the products or the date of production.

By way of derogation from the first subparagraph, the particulars referred to in point (iii) of point (b) and in points (c), (d) and (e) of the first subparagraph may be marked only in an accompanying document.

2. A Member State shall prohibit the marketing of milk products defined in points (a), (b) and (c) of Article 2 in its territory if the particulars referred to in the first subparagraph of paragraph 1 of this Article are not marked in a language easily understood by the purchasers of that Member State where those products are marketed, unless such information is provided by the food business operator by other means. Those particulars may be marked in several languages.

3. Where the minimum milk protein content set out in point (a)2 of Section I of Annex I, point (a)2 of Section II of Annex I, and point (a)2 of Annex II is exceeded in the milk products defined in Article 2, this fact may, without prejudice to other provisions of Union law, be adequately marked on the packages, containers or labels of the products.

#### Article 5

### Delegation of power

The Commission shall be empowered to adopt delegated acts in accordance with Article 6 to amend the standards set out in Annexes I and II in order to take account of developments in relevant international standards and of technical progress.

#### Article 6

### Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article. It is of particular importance that the Commission follow its usual practice and carry out consultations with experts, including Member States' experts, before adopting the delegated acts referred to in Article 5.

2. The power to adopt delegated acts referred to in Article 5 shall be conferred on the Commission for a period of five years from 21 December 2015. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 5 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of the delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 5 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

#### Article 7

### Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 22 December 2016. They shall immediately inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main measures of national law which they adopt in the field covered by this Directive.

*Article 8***Repeal**

Directive 83/417/EEC is repealed with effect from 22 December 2016.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex III.

*Article 9***Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

*Article 10***Addresses**

This Directive is addressed to the Member States.

Done at Strasbourg, 25 November 2015.

*For the European Parliament*  
*The President*  
M. SCHULZ

*For the Council*  
*The President*  
N. SCHMIT

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## ANNEX I

## EDIBLE CASEINS

## I. STANDARDS APPLICABLE TO EDIBLE ACID CASEINS

## (a) 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

## (b) Contaminants

Maximum lead content	0,75 mg/kg
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## (c) Impurities

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

## (e) 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.

## II. STANDARDS APPLICABLE TO EDIBLE RENNET CASEINS

## (a) 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. Minimum 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

## (b) Contaminants

Maximum lead content	0,75 mg/kg
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## (c) Impurities

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

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

## (e) 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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## ANNEX II

## EDIBLE CASEINATES

## STANDARDS APPLICABLE TO EDIBLE CASEINATES

## (a) 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

## (b) Contaminants

Maximum lead content	0,75 mg/kg
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## (c) Impurities

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

(optional neutralizing and buffering agents)

hydroxydes	} of	sodium
carbonates		potassium
phosphates		calcium
citrates		ammonium
		magnesium

## (e) Characteristics

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

## ANNEX III

## CORRELATION TABLE

Council Directive 83/417/EEC	This Directive
Article 1	Articles 1 and 2
Article 2	Article 3
Article 3	Article 3
Article 4(1)	Article 4(1) first subparagraph
Article 4(2), first subparagraph	Article 4(2)
Article 4(2), second subparagraph	Article 4(1) second subparagraph
Article 5	—
Article 6(1)	—
Article 6(2)	—
Article 7	—
Article 8	—
Article 9	—
Article 10	—
Article 11	—
—	Article 5
—	Article 6
Article 12	Article 7
—	Article 8
—	Article 9
Article 13	Article 10
Annex I, section I	Article 2, points (a) and (b)
Annex I, section II	Annex I, section I
Annex I, section III	Annex I, section II
Annex II, section I	Article 2, point (c)
Annex II, section II	Annex II
—	Annex III