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Delegations will find attached document COM(2014) 174 final.

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2014/0096 (COD)

Proposal for a

DIRECTIVE 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**

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Grounds for and objectives of the proposal

Council Directive 83/417/EEC provides for the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption. It is proposed to repeal this Directive and replace it with a new text for the following reasons: (1) align the powers conferred on the Commission with the new distinction introduced by the Treaty on the Functioning of the European Union (TFEU) (2) take account of other legislation adopted in the meantime, notably with regard to food law (3) align the compositional requirements of the products concerned to the relevant international standard issued by the Codex Alimentarius.

- (1) The Treaty on the Functioning of the European Union (TFEU) distinguishes between, on the one hand, the power delegated to the Commission to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of a legislative act, as set out in Article 290 (delegated acts), and, on the other hand, the power conferred on the Commission to adopt implementing acts where uniform conditions are needed, as referred to in Article 291 (implementing acts). The scrutiny exercise of the provisions of Directive 83/417/EEC in relation to the new distinction between delegated and implementing acts has shown the need for the Commission to be empowered to adopt delegated acts to amend, where appropriate, the technical definitions and standards established in the annexes for edible caseins and caseinates to take account of developments in relevant international standards and of technical progress. A corresponding empowerment is included in the present proposal.
- (2) The present proposal takes account of the further development of parallel legislation, notably with regard to food law. This notably concerns updates to Directive 2000/13/EC¹, Regulation (EC) No 178/2002², Regulation (EC) No 882/2004³, Regulation (EC) No 1332/2008⁴ and Regulation (EC) No 1333/2008⁵.
- (3) An international standard has been adopted by the Codex Alimentarius for edible casein products⁶. That standard defines, among others, the essential

¹ Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

² 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

³ 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

⁴ 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

⁵ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives

⁶ Codex Stan 290-1995

composition and quality factors of casein products. To allow food business operators to benefit from a level-playing field on the world market, the present proposal adjusts the compositional requirements laid down in the annexes for edible casein and caseinates to those applicable in the above mentioned Codex standard. This adjustment results in two changes: the maximum moisture content of edible casein is increased from 10 to 12% and the maximum milk fat content of edible acid casein is decreased from 2.25 to 2%. With this change, the compositional requirements laid down in the proposal are fully in line with the international standard.

The proposal has no financial implications for the EU budget.

General context

Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU) distinguish two different types of Commission acts:

Article 290 of the TFEU allows the legislator to "delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of a legislative act". Legal acts adopted by the Commission in this way are referred to in the terminology used by the Treaty as "delegated acts" (Article 290(3)).

Article 291 of the TFEU allows Member States to "adopt all measures of national law necessary to implement legally binding Union acts". Those acts shall confer implementing powers on the Commission where uniform conditions for implementing them are needed. Legal acts adopted by the Commission in this way are referred to in the terminology used by the Treaty as "implementing acts" (Article 291(4)).

Since the adoption of the original Directive in 1983, a number of legal acts have been adopted in the field of food law. They must be taken account of.

The production of casein and caseinates from milk was subject to an internal subsidy scheme operated by the Union until 2006. This subsidy scheme has ceased to be applied since then and has been definitively repealed by the political agreement reached on the reformed single Common Market Organisation for Agricultural Products in 2013. Specific provisions, differing from international standards, are therefore no longer justified. As a consequence, the proposal adjusts the compositional requirements of casein products to the relevant Codex standard.

Existing provisions in the area of the proposal

Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU).

Directive 2000/13/EC, Regulation (EC) No 178/2002, Regulation (EC) No 882/2004, Regulation (EC) No 1332/2008 and Regulation (EC) No 1333/2008.

Codex Stan 290-1995.

Consistency with the other policies and objectives of the Union

The proposal is consistent with the new classification of powers conferred to the Commission by the TFEU, with the relevant legal acts in the field of food law and with the international standard issued for casein products by the Codex Alimentarius.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

Consultation of interested parties

There is no need for consultation of interested parties since the proposal deals mainly with inter-institutional issues and does not alter the substance of Directive 83/417/EEC which has worked well for decades. The proposal also allows for a better integration of the rules on caseins and caseinates into the wider legal framework related to food law which brings advantages in terms of clarity and simplification. Also the rules on the provision of information from business to business have been streamlined.

The further alignment to the international standard has been discussed with the industry and they warmly welcome the proposed change.

Collection and use of expertise

There is equally no need for external expertise for the same reasons.

Impact assessment

There is equally no need for an impact assessment for the same reasons.

3. LEGAL ELEMENTS OF THE PROPOSAL

Summary of the proposed action

The proposal (1) identifies the need for delegated power to be conferred on the Commission for the purpose of adopting amendments to Annexes I and II and establishes the corresponding procedure for adoption of these acts in the new legal context determined by the entry into force of Articles 290 and 291 of the TFEU (2) adapts existing provisions to the further development of legislation notably in the field of food law (3) adjust, where appropriate, the composition requirements of edible caseins to the corresponding Codex standard.

Legal basis

Article 114 of the Treaty on the Functioning of the European Union.

Subsidiarity principle

The proposal falls under shared competence between the EU and the Member States and complies with the subsidiarity principle.

Proportionality principle

The proposal complies with the proportionality principle.

Choice of instruments

The form of the original act (a Directive) is not changed. The proposal is aimed at designing the Commission's empowerment in the new legal context created by the Lisbon Treaty. It also takes account of the further development of legislation in the past years and of existing, updated international standards.

Moreover the proposal takes into consideration the need for the Member States to have some margin to adapt the implementation to the national legal and administrative environment, in particular with reference to the possible adoption of national measures in matters not specifically harmonised by the proposal.

Proposal for a

DIRECTIVE 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

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 Committee¹,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Council Directive 83/417/EEC² 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, notably the development of a comprehensive legal framework in the area of food law and the adoption of an international standard by the Codex Alimentarius³ 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 (the Treaty).
- (3) For the sake of clarity, Directive 83/417/EEC should therefore be repealed and replaced with a new Directive.
- (4) Taking into account that Regulation (EC) No 882/2004 of the European Parliament and of the Council⁴, contains general, horizontal and uniform Union rules concerning

¹ OJ C , , p. .

² 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).

³ Standard 290-1995 <http://www.codexalimentarius.org/standards/en/>

⁴ 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).

the methods of sampling and analysis of foodstuffs, the related provisions of Directive 83/417/EEC are therefore no longer necessary.

- (5) Taking into account that Regulation (EC) No 178/2002 of the European Parliament and of the Council⁵ 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.
- (6) Directive 2000/13/EC of the European Parliament and of the Council⁶ does not apply to business to business relations. Since the products covered by this Directive are not meant to be sold to the final consumer but only from business to business for the preparation of food products, it is appropriate to maintain, adapt to the current legal framework and simplify the specific rules already included in Directive 83/417/EEC. Those rules provide for the information to be provided for those products in order to allow the food business operators, on the one hand, to avail of 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 that those products can be confused with similar products not meant for human consumption.
- (7) Regulation (EC) No 1333/2008 of the European Parliament and of the Council⁷ provides for the definition of processing aids referred to as technological adjuvants in Directive 83/417/EEC. Consequently, this Directive should use the term ‘processing aids’ instead of ‘technological adjuvants’.
- (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 1333/2008 and Regulation (EC) No 1332/2008 of the European Parliament and of the Council⁸.
- (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 international standard 290–1995 set by the Codex Alimentarius fixes those parameters at respectively 12% and 2%, the corresponding parameters should be set in line with the international standard so as to avoid trade distortions.
- (10) In order to promptly adapt or update the technical elements contained in the Annexes to take account of developments in relevant international standards or technical progress, the power to adopt acts in accordance with Article 290 of the Treaty 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.

⁵ 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).

⁶ Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29).

⁷ 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).

⁸ 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).

- (11) It is of particular importance that the Commission carries 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.
- (12) Member States should have some margin to adopt national measures in matters not specifically harmonised by this Directive to adapt to the national legal and administrative environment. In such cases, Member States should notify their national measures to the Commission in accordance with the procedure laid down in Directive 98/34/EC of the European Parliament and of the Council⁹,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

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

Article 2

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

- (a) ‘caseins’ means the principal protein constituent of milk, washed and dried, insoluble in water and obtained from skimmed milk by precipitation:
- (i) by the addition of acid, or
 - (ii) by microbial acidification, or
 - (iii) by using rennet, or
 - (iv) by using other milk-coagulating enzymes,
- and subjected to heat treatment rendering the phosphatase negative, without prejudice to the possibility of prior use of ion exchange processes and concentration processes;
- (b) ‘caseinates’ means products obtained by drying caseins treated with neutralizing agents and subjected to heat treatment rendering the phosphatase negative;
- (c) ‘skimmed milk’ means milk to which nothing has been added and of which only the fat content has been reduced.
- (d) ‘edible acid casein’ means casein intended for human consumption obtained by precipitation using the processing aids and bacterial cultures listed in Section I(d) of Annex I which comply with the standards laid down in Section I of that Annex;

⁹ Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 204, 21.7.1998, p. 37)

- (e) 'edible rennet casein' means casein intended for human consumption obtained by precipitation using the processing aids listed in Section II(d) of Annex I which comply with the standards laid down in Section II of that Annex;
- (f) 'edible caseinates' means caseinates obtained from edible caseins using neutralizing agents of edible quality listed under point (d) of Annex II and complying with the standards set out in that Annex.

Article 3

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

- (a) the products defined in Article 2 are marketed only if they conform to the rules and standards laid down in this Directive and Annexes I and II thereto, and
- (b) products which do not satisfy the standards laid down in Annexes I and II are not used for the preparation of foodstuffs and are named and labelled in such a way that the buyer is not misled as to their nature, quality or use.

Article 4

The names laid down in Article 2(d), (e) and (f) shall be reserved for the products defined and shall be used commercially to designate those products.

Article 5

1. The mandatory particulars to be marked on the packages, containers or labels of the products defined in Article 2 shall be easily visible, clearly legible and in indelible characters, and shall be the following:
 - (a) the name reserved for those products in accordance with Article 4 with, in the case of caseinates, an indication of the cation or cations;
 - (b) in the case of products marketed as mixtures:
 - (i) the words 'mixture of ...' followed by the names of the different products which make up the mixture, in decreasing order of weight,
 - (ii) an indication of the cation or cations in the case of caseinate or caseinates,
 - (iii) the protein content in the case of mixtures containing caseinates;
 - (c) the net quantity expressed in kilograms or grams;
 - (d) the name or business name and the address of the operator under whose name or business name the food is marketed or, if that 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 or the date of production.
2. Member States shall prohibit the marketing of products defined in Article 2(d), (e) and (f) in their territory if the particulars referred to in paragraph 1 do not appear in a language easily understood by the purchasers of the Member States where those products are marketed, unless such information is given by other means; this shall not preclude the appearance of those particulars in several languages.
 3. The particulars referred to in paragraph 1(b)(iii) and in paragraph 1(c), (d) and (e), need appear only in an accompanying document.

Article 6

1. Member States may adopt national measures concerning matters not specifically harmonised by this Directive provided that they do not prohibit, impede or restrict the free movement of goods that are in conformity with this Directive.
2. Member States shall immediately communicate to the Commission any such national measure in accordance with the procedure laid down in Directive [98/34/EC](#).

Article 7

The Commission shall be empowered to adopt delegated acts in accordance with Article 8, concerning amendments to Annexes I and II to take account of the developments in relevant international standards and of technical progress.

Article 8

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 7 shall be conferred on the Commission for an indeterminate period of time from (...). (**Publications Office is to fill in the date of entry into force of this Act**).
3. The delegation of power referred to in Article 7 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 7 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 from the date of notification of that act to the European Parliament and 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 9

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 March 2015 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

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

Article 10

Directive 83/417/EEC is repealed.

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

Article 11

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

Article 12

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

EDIBLE CASEINS

I. STANDARDS APPLICABLE TO EDIBLE ACID CASEIN'

(g) Essential factors of composition

1.	Maximum moisture content	12,0 % 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 calculated on the dried extract	2,0 % by weight
4.	Maximum titratable acidity, expressed in ml of decinormal sodium hydroxide solution per g	0,27
5.	Maximum ash content (P ₂ O ₅ 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

(h) Contaminants

Maximum lead content	1 mg/kg
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(i) Impurities

Extraneous matter (such as wood or metal particles, hairs or insect fragments)	nil in 25 g
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(j) Processing aids and bacterial cultures

- (i) —lactic acid
 - hydrochloric acid
 - sulphuric acid
 - citric acid
 - acetic acid
 - orthophosphoric acid
- (ii) — whey
 - bacterial cultures producing lactic acid

(k) 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 CASEIN

(l) Essential factors of composition

1.	Maximum moisture content	12 % m/m
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 calculated on the dried extract	2 % by weight
4.	Minimum ash content (P ₂ O ₅ included)	7,50 % by weight
5.	Maximum anhydrous lactose content	1 % by weight
6.	Maximum sediment content (burnt particles)	22,5 mg in 25 g

(m) Contaminants

Maximum lead content	1 mg /kg
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(n) Impurities

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

(o) 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.

(p) Organoleptic characteristics

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

ANNEX II

EDIBLE CASEINATES

STANDARDS APPLICABLE TO EDIBLE CASEINATES

(q) Essential factors of composition

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

(r) Contaminants

Maximum lead content	1 mg /kg
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(s) Impurities

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

(optional neutralizing and buffering agents)

hydroxydes	sodium
carbonates	potassium
	of calcium
phosphates	ammonium
citrates	magnesium

(u) Characteristics

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

ANNEX III

Correlation table

Council Directive No 83/417/EEC	This Directive
Article 1	Articles 1 and 2
Article 2	Article 3
Article 3	Article 4
Article 4(1)	Article 5(1)
Article 4(2), first subparagraph	Article 5(2)
-Article 4(2), second subparagraph	Article 5(3)
Article 5	Article 2(a) and (b)
-	Article 6(1)
Article 6(1)	Article 6(2)
Article 6(2)	Article 6(3)
Article 7	-
Article 8	-
Article 9	-
Article 10	-
Article 11	-
-	Article 7
-	Article 8
Article 12	Article 9
-	Article 10
-	Article 11
Article 13	Article 12
Annex I, section I	Article 2, points (d) and (e)
Annex I, section II	Annex I, section I
Annex I, section III	Annex I, section II
Annex II, section I	Article 2, point (f)
Annex II, section II	Annex II
-	Annex III