Council of the
European Union

Brussels, 26 November 2014
(OR. en)

15875/14

Interinstitutional File:
2014/0096 (COD)

DENLEG 180
AGRI 729
CODEC 2325

"A" ITEM NOTE

From:	General Secretariat of the Council
To:	Council
No. prev. doc.:	15367/14 DENLEG 171 AGRI 698 CODEC 2216
No. Cion doc.:	8099/1/14 DENLEG 72 AGRI 245 CODEC 886 REV1 + ADD1
Subject:	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 (First reading) (Legislative deliberation) - *General approach*

On 20 March 2014, the Commission submitted the above proposal for a Directive of the European Parliament and of the Council[1] on the basis of Article 114 of the Treaty on the Functioning of the European Union (TFEU). The ordinary legislative procedure is applicable to the adoption of the proposed act.

The proposal aims at replacing Council Directive 83/417/EEC, with the objective to:

– align the provisions conferring implementing powers on the Commission to the provisions introduced by the TFEU;

[1] COM(2014) 174 final + Annexes 1 to 3.

– align the compositional requirements of caseins and caseinates to the relevant Codex Alimentarius standard (Codex Stan 290-1995);

– update the provisions applicable to caseins and caseinates taking into account EU legislation adopted in the meantime, in particular where applicable to food.

In accordance with Article 114(1) of the TFEU, the Economic and Social Committee adopted its opinion on 4 June 2014[2], endorsing the proposed text.

In the European Parliament, the file should be examined by the Environment, Public Health and Food Safety (ENVI) Committee. At this stage, the ENVI Committee has appointed Mr. Giovanni La Via (EPP) as rapporteur and Ms Susanne Melior (S&D) and Mr. Jan Huitema (ALDE) as shadow rapporteurs. The ENVI Committee has not yet started the examination of this file.

The United Kingdom delegation entered a parliamentary scrutiny reservation.

On 21 November 2014, the Coreper decided to invite the Council to reach a general approach on the above text as set out in the Annex to this document, as an "A" item of the agenda of one of its next meetings.

---

[2] NAT/645 – EESC-2014-02896-00-00-AC.

ANNEX

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of […]

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[3],

Acting in accordance with the ordinary legislative procedure,

[3] OJ C , , p. .

Whereas:

(1) Council Directive 83/417/EEC[4] 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 Alimentarius[5] 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) Regulation (EC) No 882/2004 of the European Parliament and of the Council[6], 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.

---

4 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).

5 Standard 290-1995 http://www.codexalimentarius.org/standards/en/

6 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).

(5) Regulation (EC) No 178/2002 of the European Parliament and of the Council[7] 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) According to Regulation (EU) No 1169/2011 of the European Parliament and of the Council[8], sufficient information should be provided in business to business relations in order to ensure the presence and accuracy of food information to 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 allow food business operators 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 Council[9] provides for the 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’.

---

7 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).

8 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 (OJ L 304, 22.11.2011, p. 18).

9 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) 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 Council[10].

(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 12% and 2% respectively, the corresponding parameters should be set in line with that 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.

(11) 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.

HAVE ADOPTED THIS DIRECTIVE:

10 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 1

Scope

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

Article 2

Definitions

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

(a) ‘edible acid casein’ means the milk product obtained by separating, washing and drying the acid precipitated coagulum of skimmed milk and/or of products obtained from milk;

(b) ‘edible rennet casein’ means the milk product obtained by separating, washing and drying the coagulum of skimmed milk and/or of products obtained from milk; the coagulum is obtained through the reaction of rennet or other coagulating enzymes;

(c) ‘edible caseinates’ means the 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 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 laid down in Annexes I and II thereto, and

(b) caseins and caseinates which do not comply with the standards laid down 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, are named and labelled in such a way that the purchaser is not misled as to their nature, quality or use.

Article 4

Labelling

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

(a) the name laid down for those products in accordance with 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 which the mixture is composed of, 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 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. A Member State shall prohibit the marketing of products defined in points (a), (b) and (c) of Article 2 in its territory if the particulars referred to in paragraph 1 are not marked in a language easily understood by the purchasers of the Member State where those products are marketed, unless such information is given by other means; those particulars may be marked in several languages.

3. The particulars referred to in sub-point (iii) of point (b) and in points (c), (d) and (e) of paragraph 1 need to be marked only in an accompanying document.

Article 5

Delegation of power

In order to take account of developments in relevant international standards and technical progress, the Commission shall be empowered to amend the standards laid down in Annexes I and II by means of delegated acts adopted in accordance with Article 6.

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 those delegated acts.

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 […+]. 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.

+ OJ: please insert the date of entry into force of this Directive.

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 by the Council within a period of two months from the date 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 […[+]]. They shall immediately inform the Commission thereof.

   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. 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 provisions of national law which they adopt in the field covered by this Directive.

Article 8

Repeal

Directive 83/417/EEC is repealed from the date referred to in the first sub-paragraph of Article 7(1) of this Directive.

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

[+] OJ: please insert the date of 12 months after the entry into force of this Directive.

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

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I

EDIBLE CASEINS

I. STANDARDS APPLICABLE TO EDIBLE ACID CASEIN

(a) Essential factors of composition

1.	Maximum moisture content	12,0 % by weight
2.	Minimum milk protein content calculated on the dried extract of which minimum casein content	90 % by weight 95 % by weight
3.	Maximum milk fat content	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_2O_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

(b) Contaminants

Maximum lead content 0,75 mg/kg

(c) Impurities

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

(d) Processing aids, bacterial cultures and authorised ingredients

(i) acids:

—lactic acid

—hydrochloric acid

—sulphuric acid

—citric acid

—acetic acid

—orthophosphoric acid

(ii) bacterial cultures producing lactic acid

(iii) 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 CASEIN

(a) Essential factors of composition

1.	Maximum moisture content	12 % by weight
2.	Minimum milk protein content calculated on the dried extract of which minimum casein content	84 % by weight 95 % by weight
3.	Maximum milk fat content	2,0 % by weight
4.	Minimum ash content (P_2O_5 included)	7,50 % by weight
5.	Maximum anhydrous lactose content	1,0 % by weight
6.	Maximum sediment content (burnt particles)	15 mg in 25 g

(b) Contaminants

Maximum lead content	0,75 mg /kg

(c) Impurities

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

(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.

ANNEX II

EDIBLE CASEINATES

STANDARDS APPLICABLE TO EDIBLE CASEINATES

(a) Essential factors of composition

1.	Maximum moisture content	8 % by weight
2.	Minimum content of milk protein casein calculated on the dried extract of which minimum casein content	88 % by weight 95 % by weight
3.	Maximum content of milk fat	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

(b) Contaminants

Maximum lead content	0,75 mg/kg

(c) Impurities

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

(d) Food additives

(optional neutralizing and buffering agents)

hydroxydes		sodium
carbonates		potassium
	of	calcium
phosphates		ammonium
citrates		magnesium

(e) 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 under slight pressure.
3.	*Solubility:*	Almost entirely soluble in distilled water, except for the calcium caseinate.

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(1)	Article 4(1)
Article 4(2), first subparagraph	Article 4(2)
- Article 4(2), second subparagraph	Article 4(3)
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