COUNCIL DIRECTIVE

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

(83/417/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas the laws, regulations and administrative provisions in force in some Member States define the composition and manufacturing characteristics of caseins and caseinates intended for human consumption, together with the conditions with which these products must comply in order that certain designations may be used in their regard or that their use in the preparation of other foodstuffs may be authorized; whereas such provisions do not exist at present in other Member States;

Whereas this situation is such as to hinder the free movement of caseins and caseinates intended for human consumption and to create conditions of unfair competition between users; whereas it therefore has a direct effect on the establishment and functioning of the common market;

Whereas it is therefore necessary to determine, at Community level, the rules which must be observed as regards the composition and labelling of these products;

Whereas at present edible caseins and caseinates are not generally sold to the ultimate consumer; whereas, however, should such a sale occur, Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate customer (4) will also apply;

Whereas, on the other hand, with a view to facilitating trade it is advisable to adopt, at Community level, rules for labelling applicable to edible caseins and caseinates *intended for use within the trade*;

Whereas the preliminary programme of the European Economic Community for a consumer protection and information policy (5) provides for Community action in fields which are of special importance for the protection of the consumer's health and safety, notably in that of foodstuffs;

Whereas the process of defining the sampling procedures and methods of analysis necessary for testing the composition and other properties of the products in question constitutes a technical implementing measure the adoption of which should be entrusted to the Commission in order to simplify and speed up the procedure;

Whereas, in all the cases for which the Commission is empowered by the Council to implement the rules applicable to foodstuffs for human consumption, a procedure should be provided for instituting close cooperation between the Member States and the Commission within the Standing Committee for Foodstuffs set up pursuant to Decision 69/414/EEC (6),

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns lactoproteins, as defined in the Annexes, which are intended for human consumption and mixtures thereof.

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(1) OJ No C 50, 24. 2. 1979, p. 5.
(2) OJ No C 140, 5. 6. 1979, p. 174.
(3) OJ No C 247, 1. 10. 1979, p. 54.
(4) OJ No L 33, 8. 2. 1979, p. 1.
(5) OJ No C 92, 25. 4. 1975, p. 1.
(6) OJ No L 291, 29. 11. 1969, p. 9.

2. For the purposes of this Directive:

— 'caseins' means the principal protein constituent of milk, washed and dried, insoluble in water and obtained from skimmed milk by precipitation:

  — by the addition of acid, or

  — by microbial acidification, or

  — by using rennet, or

  — by using other milk-coagulating enzymes,

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

— 'caseinates' means products obtained by drying caseins treated with neutralizing agents,

— '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.

Article 2

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

— the products defined in the Annexes may be marketed only if they conform to the definitions and rules laid down in this Directive and the Annexes thereto, and

— products which do not satisfy the criteria laid down in the Annexes are named and labelled in such a way that the buyer is not misled as to their nature, quality or use.

Article 3

The names referred to in the Annexes shall be reserved for the products defined and must be used commercially to designate those products.

Article 4

1. Without prejudice to Directive 79/112/EEC and without prejudice to the provisions to be adopted by the Community concerning the labelling of foodstuffs not intended for the ultimate consumer, the only mandatory particulars to be marked on the packages, containers or labels of the products defined in the Annexes, particulars which must be clearly visible, easily legible and in indelible characters, shall be as follows:

(a) the name reserved for these products in accordance with Article 3 with, in the case of caseinates, an indication of the cation or cations;

(b) in the case of products marketed as mixtures,

  — the words 'mixture of ...' followed by the names of the different products which make up the mixture, in decreasing order of weight,

  — an indication of the cation or cations in the case of caseinate or caseinates,

  — the protein content in the case of mixtures containing caseinates;

(c) the net quantity expressed in the following units of mass: kilograms or grams. Until the end of the transitional period during which use of the imperial units of measurement contained in Chapter D of the Annex to Council Directive 71/354/EEC of 18 October 1971 on the approximation of the laws of the Member States relating to units of measurement (1), as last amended by Directive 76/770/EEC (2), is authorized in the Community, Ireland and the United Kingdom may permit the quantity to be expressed only in imperial units of measurement calculated on the basis of the following conversion rates:

  — 1 ml = 0,0352 fluid ounces,

  — 1 l = 1,760 pints or 0,220 gallons,

  — 1 g = 0,0353 ounces (avoirdupois),

  — 1 kg = 2,205 pounds;

(d) the name or business name and the address of the manufacturer or packager or of a seller established within the Community;

  however, in the case of their national production, Member States may maintain in force national provisions requiring details of the manufacturing or packaging establishment to be mentioned;

(e) in the case of products imported from third countries, the name of the country of origin;

(f) the date of manufacture or some marking by which the batch can be identified.

2. Member States shall prohibit the marketing of edible caseins and caseinates in their territory if the particulars referred to in paragraphs 1 (a), (b), (e)

(1) OJ No L 243, 29. 10. 1971, p. 29.
(2) OJ No L 262, 27. 9. 1976, p. 204.

and (f) do not appear in a language easily understood by the purchaser, unless the latter is given such information by other means; this provision shall not preclude the appearance of the said particulars in several languages.

The particulars specified in paragraph 1 (b), third indent, (c), (d) and (e), need appear only in an accompanying document. For transport in bulk, this derogation may be extended to (b), second indent, and (f).

Article 5

Without prejudice to Community provisions to be adopted in the field of health and hygiene in connection with the basic materials referred to in Annexes I and II, such products must be subjected to heat treatment which will render the phosphatase negative.

Article 6

1. Member States shall take all the necessary steps to ensure that trade in products referred to in Article 1 which comply with the definitions and rules laid down in this Directive and the Annexes thereto cannot be impeded by the application of non-harmonized national provisions governing the composition, manufacturing specifications, packaging or labelling of these products or of foodstuffs in general.

2. Paragraph 1 shall not apply to non-harmonized provisions which are justified on the grounds of:

— protection of public health,

— prevention of fraud unless such provisions are liable to impede the application of the definitions and rules laid down by this Directive,

— protection of industrial and commercial property, indications of source, registered designation of origin and prevention of unfair competition.

Article 7

1. Where, as a result of new information or of a reassessment of existing information made since the Directive was adopted, a Member State finds there is detailed evidence that the use in the products defined in Annexes I and II hereto of one of the substances referred to therein or the maximum quantity of such substance that may be used constitutes a danger to human health, even though it complies with the provisions of this Directive, that Member State may temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible the reasons given by the Member State concerned and shall consult the Member States within the Standing Committee for Foodstuffs; it shall then deliver its opinion forthwith and take the appropriate measures.

3. If the Commission considers that amendments to the Directive are necessary in order to remedy the difficulties referred to in paragraph 1 and to protect human health, it shall initiate the procedure provided for in Article 10 for the purpose of adopting such amendments. In that case, the Member State which has adopted safeguard measures may maintain them until the amendments enter into force.

Article 8

The Council, acting on a proposal from the Commission, shall adopt where necessary purity criteria for the technological adjuvants referred to in the Annexes.

Article 9

The following shall be determined in accordance with the procedure laid down in Article 10:

(a) the methods of analysis necessary for checking the purity criteria referred to in Article 8;

(b) the sampling procedures and methods of analysis necessary for checking the composition and manufacturing specifications at the time of manufacture of the products defined in the Annexes.

Article 10

1. Where the procedure laid down in this Article is invoked, the matter shall be referred to the Standing Committee for Foodstuffs set up by Decision 69/414/EEC, hereinafter referred to as 'the Committee', by its chairman, either on his own initiative or at the request of a representative of a Member State.

2. The Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall give its opinion on the said draft within such time as the chairman of the Committee may determine in the

light of the urgency of the matter in question. The Committee shall decide by a majority of at least 45 votes, the votes of the Member States being weighted in accordance with Article 148 (2) of the Treaty. The chairman shall not take part in the vote.

3. (a) The Commission shall adopt the measures contemplated where they are in accordance with the opinion of the Committee.

(b) Where the measures contemplated are not in accordance with the opinion of the Committee, or where no such opinion has been issued, the Commission shall forthwith submit to the Council a proposal on the measures to be taken. The Council shall act by a qualified majority.

(c) If, on expiry of a period of three months from the date on which the matter was referred to the Council, the latter has not acted, the proposed measures shall be adopted by the Commission.

Article 11

This Directive shall not apply to products referred to in Article 1 intended for export to third countries.

Article 12

Member States shall make such amendments to their laws as may be necessary to comply with this Directive and shall forthwith inform the Commission thereof; the laws thus amended shall be applied in such a way as to:

— permit trade in products complying with this Directive not later than two years after its notification (1),

— prohibit trade in products not complying with this Directive three years after its notification.

Article 13

This Directive is addressed to the Member States.

Done at Brussels, 25 July 1983.

For the Council

The President

C. SIMITIS

(1) This Directive was notified to the Member States on 2 August 1983.

ANNEX I

EDIBLE CASEINS

I. NAMES AND DEFINITIONS

(a) *'edible acid casein'* means edible casein obtained by precipitation using the technological adjuvants and bacterial cultures listed in Section II (d) which comply with the standards laid down in Section II.

(b) *'edible rennet casein'* means edible casein obtained by precipitation using the technological adjuvants listed in Section III (d) which comply with the standards laid down in Section III.

II. STANDARDS APPLICABLE TO 'EDIBLE ACID CASEIN'

(a) **Essential factors of composition**

1. Maximum moisture content	10,0	% 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	2,25	% 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	1 mg/kg

(c) **Impurities**

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

(d) **Harmless technological adjuvants and bacterial cultures suitable for human consumption**

(i) — lactic acid (E 270)
— hydrochloric acid
— sulphuric acid
— citric acid (E 330)
— acetic acid (E 260)
— orthophosphoric acid

(ii) — whey
— bacterial cultures producing lactic acid

(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.

III. STANDARDS APPLICABLE TO 'EDIBLE RENNET CASEIN'

(a) **Essential factors of composition**

1. Maximum moisture content	10	% 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_2O_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

(b) **Contaminants**

Maximum lead content	1	mg/kg

(c) **Impurities**

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

(d) **Harmless technological adjuvants suitable for human consumption**

— rennet

— other milk-coagulating enzymes

(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

I. DENOMINATIONS AND DEFINITIONS

'edible caseinates': means caseinates obtained from edible caseins using neutralizing agents of edible quality listed under Section II (d) and complying with the standards set out in Section II.

II. 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	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

(b) **Contaminants**

Maximum lead content	1	mg/kg

(c) **Impurities**

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

(d) **Technological adjuvants of edible quality**

(optional neutralizing and buffering agents)

hydroxides carbonates phosphates citrates	of	sodium potassium calcium ammonium 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 do not break under slight pressure.
3. *Solubility:* Almost entirely soluble in distilled water, except for the calcium caseinate.