COMMISSION OF THE EUROPEAN COMMUNITIES

COM (79) 9 final

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PROPOSAL FOR A COUNCIL DIRECTIVE ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO EDIBLE CASEINS AND CASEINATES

(Submitted to the Council by the Commission)

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EXPLANATORY MEMORANDUM

1. Preliminary explanation

Casein is the major protein constituent of cows milk. There are 27 grams of casein in each litre of milk and this is equivalent to 80 per cent of its protein content. Casein is separated from milk by precipitation using an enzymatic acidifying agent such as rennet (rennet casein), or by the direct addition of an acid, for example hydrochloric acid (acid casein). Caseins produced by these methods are insoluble in water. They can, for technological purposes be converted into caseinates soluble in water, by reaction with an alkali.

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2. Caseins and caseinates have a number of notable properties useful to the manufacture of foods and pharmaceuticals. In the first place their amino acid contents make them a protein of very high nutritional value. In the second place the water binding capacity of caseinates and their capacity to form an emulsion with fats have led to their use in a variety of applications and particularly in sausages and minced meats; they have been used to develop a number of new products, for example, powdered cream for coffee (coffee whitener); other important markets for caseinates are whipped dessert toppings, dietetic products and their use in milk substitute foods for calves. Food grade casein as such is also an expanding market; it is used to enrich certain plant based foods, breakfast cereals for example. As a result of the growing use of casein as a nutrient in the human diet and in spite of a reduction in its industrial use (even though it remains indispensible for paper glazings, and the manufacture of certain luxury buttons) the world production of casein has grown from 100 000 tons to 200 000 tons in the last 20 years. (Community production is running at 60 000 tons per annum worth 90 million U.S. dollars.)

3. There are a number of differences in the legislations of Member States concerning the definition and compositional standards for these products. Although in the Federal Republic of Germany distinctions are made between caseinates, food grade casein, edible acid casein, and edible rennet casein, in France there is simply a distinction between three qualities for casein; on the other hand in Italy the legal texts only take into account casein and potassium caseinate. There are further differences in these legislations concerning the

permitted compositional standards. These concern the quantitative limits for humidity, lactose, ash, lactic acid, arsenic, lead, and the insolubility index. Each limit for every one of these characteristics is alone sufficient to prevent products from passing intra Community barriers. The example of these three Member States is in point when one takes account of the fact that in 1970 France was the worlds third largest exporter of casein (following Australia and New Zealand), the Federal Republic of Germany, was the Community's second largest exporter and seventh in the world table. By contrast in the same year the Federal Republic of Germany was the worlds third largest importer following the United States and Japan, Italy was in fourth place and the United Kingdom fifth. Community rules eliminating the internal barriers to trade in these products would facilitate trade not only in the products themselves, but a fortiori in the very considerable range of products in which they are increasingly found.

4. On 13 January 1970 the Commission presented to the Council a proposal for a directive concerning the approximation of the laws of Member States relating to casein and caseinates. This proposal was made in accordance with the general programme of the Community dated 28 May 1969 relating to the elimination of technical barriers to trade. This proposal aimed to remove the barriers to trade arising from the legislative, regulatory, and administrative differences in the systems of the Member States concerning casein and caseinate and at the same time to produce a standard for the products as had been done several years previously in several large producer and consumer countries (notably New Zealand and the United States).

By resolution dated 14 May 1970 the European Parliament whilst approving the Commission initiative did make proposals for certain textual amendments.

On 21 October 1970 the Economic and Social Committee adopted an opinion asking that products dealt with by the proposal but not destined for human consumption should be treated flexibly and in a less restrictive way. At Council level the proposal was discussed at a number of meetings, the last of which was held on 13 May 1971.

The enlargement of the Community led to a reexamination of the proposal. Finally the Commission decided on 8 December 1976 to withdraw a

certain number of proposals which it had sent to the Council of which the casein proposal was one, because they needed amending in the light of technical progress. At the same time the Commission announced that it would send a new proposal for casein to the Council (OJ N° C 26/5 of 3.2.1977).

5. Further, following the Council decision in 1973 the Commission was anxious to extend the food legislation already adopted by the Community and to this end has concentrated greater efforts on areas of general interest for food processing. A range of directives of this type have already been adopted such as for example the directives concerning additives.

Caseins and caseinates fall into this area of general interest. They are in addition to being a food ingredient, also processing aids used in the manufacture of a large number of foods, and very close to being additives by virtue of their emulsifying properties.

The Community adopted a directive concerning emulsifiers in 1974[1], 74/329/EEC.

6. The new proposal is based as far as possible on the work of the experts from the International Dairy Federation, in particular on their recent work on the preparation of standards for edible rennet caseins. The proposal also takes into account the work of the joint FAO/WHO committee on the code of principle for milk and dairy products. This Committee is preparing standards for the composition of edible acid casein and caseinates, taking into account the work currently in hand at the IDF and the European Community.

These standards provide specifications for maximum and minimum levels. The minimum specifications relate to the minimum quality standard with which these products must comply if they are to be permitted to use the designations provided in the proposal (for example there must be a minimum protein content). The maximum specifications set limits for substances foreign to casein which are inevitably found in it (for example the maximum content in lactose). The use of the designations permitted by the directive require that casein should

[1] OJ L 189 of 12.7.1974, p. 1

comply with the specified maximum and minimum limits.

7. Furthermore, the progress that has been made since 1971, notably under the Commission's auspices, in the design of test methods has shown that certain standards laid down in the original proposal needed to be adapted.

8. As regards the introduction of microbiological standards, the Commission proposes the immediate adoption of certain specifications in order to protect the consumer. These specifications could subsequently be revised in the light of the Commission's recently started work on the definition of a general policy in the field of microbiological supervision.

9. In preparing its new proposal, the Commission ascertained the views of the Member States and the Advisory Committee on Foodstuffs, which is composed of representatives of industry, commerce, agriculture, consumers and trade unions.

10. This proposal is based upon Article 100. Bearing in mind that the implementation of the present proposal will require the amendment of the legislation of Member States the proposal must be referred both to the European Parliament and the Economic and Social Committee.

PROPOSAL FOR A COUNCIL DIRECTIVE ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO EDIBLE CASEINS AND CASEINATES

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,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee;

Whereas the provisions laid down by law, regulation or administrative action 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 caseins and caseinates are not intended for the ultimate consumer, their labelling being aimed at the professional user;

Whereas the preliminary programme of the European Economic Community for a consumer protection and information policy[1], 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 on Foodstuffs set up pursuant to Council Decision 69/414/EEC[2],

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to:

   (a) edible caseins and caseinates;

   (b) mixtures of edible caseins and caseinates.

2. For the purposes of this Directive,

   (a) edible caseins means the products intended for human consumption as defined in Annex I;

   (b) edible caseinates means products intended for human consumption as defined in Annex II.

Article 2

Member States shall take all necessary steps to ensure that the products defined in the Annexes hereto may be marketed only if they conform to the definitions and rules laid down in this Directive and the Annexes thereto.

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[1] OJ No C 92 of 25.4.1875, p. 1

[2] OJ No L 291 of 29.11.1969, p.9

Article 3

The names specified in the Annexes hereto shall be reserved for the products defined therein and shall be used commercially to designate those products.

Article 4

1. Without prejudice to Community provisions adopted on the labelling of foodstuffs/not intended for the ultimate consumer, the labelling of the products referred to in Article 1 shall indicate the following particulars in clearly visible, easily legible and indelible characters:

   (a) in the case of the products referred to in Article 1(1)(a), the words "edible acid casein or edible rennet casein" or "edible caseinate" with an indication of the nature of the cation or cations as appropriate;

   (b) in the case of the products referred to in Article 1(1)(b):

   - the words "mixture of caseins and/or caseinates for use in foodstuffs" with an indication of the nature of the cation or cations as appropriate;

   - information as to the constituents of the mixture, followed by an indication of the proportion, in decreasing order of concentration, in which they are present in the mixture or an indication of the minimum protein content;

   (c) in the case of packaged products, an indication of the net weight expressed in kilograms or grams. Pending the entry into force of relevant Community provisions, national provisions relating to the determination and/or indication of the net weight shall apply. Until the expiry of the transitional period during which the use of the Imperial units of measurement given in Annex II to Directive 71/354/EEC[1], as last amended by Directive 76/770/EEC[2], is authorized in the Community, the indication of

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[1] OJ No L 243 of 29.10.1971, p. 29

[2] OJ No L 262 of 27.9.1976, p. 204

the net weight in SI (Système international) units of measurement shall be accompanied, if Ireland or the United Kingdom so wish in the case of products marketed in their respective territories, by an indication of the net weight of the contents expressed in the equivalent Imperial units of measurement, calculated according to the following conversion rates:

1 ounce (avoirdupois) = 28.35 x 10^{-3} kg

1 ounce = 0.4536 kg

(d) the name or trade name and the address or registered office of the manufacturer or packer or of a seller established within the Community;

(e) in the case of products imported from non-member countries, the name of the country of origin shall appear in addition to the particulars referred to under (a) to (d) above;

(f) the date of expiry of shelf life.

Member States shall prohibit the marketing of edible caseins and caseinates in their territory if the particulars referred to in paragraph 1(a) to (d) above do not appear in a language easily understood by the purchaser, save where the latter is appropriately informed by other means; this provision shall not preclude the appearance of the said particulars in several languages.
the date of expiry of shelf life;

If the products referred to in the Annexes hereto are put in packages or containers of a nominal weight exceeding 20 kg the particulars specified in paragraph 1(a) to (d) and those referred to in the first subparagraph of this paragraph need appear only in the accompanying documents.

Article 5

Without prejudice to Community provisions to be adopted in the field of health and hygiene in connection with the products referred to in Annexes I and II, such products must be subjected to heat treatment at least equivalent to pasteurization where the process of manufacture of the products referred to in Article 1(1) does not include such treatment.

Article 6

1. Member States shall take all 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 frauds, 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 provenance and designations 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 establishes on the basis of a detailed statement of reasons 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 grounds 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 resolve the difficulties referred to in paragraph 1 above 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:

(a) where necessary, purity criteria for the adjurants and agents referred to in the Annexes hereto;

(b) hygienic, chemical and physical criteria for the products defined in the Annexes hereto;

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(a);

(b) the sampling procedures and methods of analysis necessary for checking the composition, manufacturing specifications, hygienic criteria and microbiological specifications at the time of manufacture of the products defined in the Annexes hereto;

(c) amendments to the microbiological specifications defined in the Annexes hereto.

Article 10

1. Where the procedure provided for in this Article is resorted to, the matter shall be referred to the Standing Committee on Foodstuffs set up by the Council Decision 69/414/EEC, hereinafter called "the Committee", by its Chairman either on his own initiative or at the request of a representative of a Member State.

2. The Commission representative 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 41 votes, and the votes of the Member States shall be weighted as provided in 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 accord with the opinion of the Committee.

(b) Where the measures contemplated do not accord 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 taken no action, the proposed measures shall be adopted by the Commission.

Article 11

The provisions of this Directive shall not apply to products referred to in Article 1 intended for export to non-member countries.

Article 12

1. Within 18 months after the date of notification of this Directive, the Member States shall amend their laws where necessary in order to comply with the provisions of this Directive and shall forthwith inform the Commission thereof.

Legislation giving effect to the provisions of this Directive shall apply not later than two years after the date of such notification to products manufactured in or imported into the Community.

2. Once this Directive has been notified, the Member States shall also ensure that they communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

Article 13

This Directive is addressed to the Member States.

ANNEX I

CASEINS

I. DEFINITION

"Casein" means the principal protein constituent of milk, washed and dried, insoluble in water and obtained from skimmed milk, generally by curdling with acid, rennet or other milk-coagulating enzymes.

For the purposes of the proceding paragraph:

- "skimmed milk" means the milk of one or more cows to which nothing has been added and the fat content of which does not exceed 0.1%.

In particular:

- "acid casein for use in foodstuffs" means the product defined in the first paragraph of this section, obtained exclusively by precipitation with the technological adjuvants listed in Section II(c) of this Annex and complying with the standards set out in Section II of this Annex;
- "rennet casein for use in foodstuffs" means the product defined in the first paragraph of this section, obtained exclusively by precipitation with rennet or other milk-coagulating enzymes authorized in the Member States and complying with the standards set out in Section III of this Annex.

II. STANDARDS APPLICABLE TO EDIBLE ACID CASEINS

(a) Essential factors of composition

1. Maximum moisture content	12.0% by weight
2. Minimum content of milk protein matter, calculated on the dried extract	90.0% by weight
3. Maximum content of milk fat, calculated on the dried extract	2.25% by weight
4. Extraneous matter (such as wood or metal particles, hairs or insect fragments)	nil in 25 g
5. Maximum sediment content (burnt particles)	22.5 mg in 25 g
6. Maximum acidity, expressed in ml of decinormal sodium hydroxide solution per g	0.27

7. Maximum ash content (P_2O_5 included)	2.5% by weight
8. Maximum anhydrous lactose content	1%

(b) Hygienic criteria

1. Metals (maximum)

- iron	20 mg/kg
- copper	5 mg/kg
- lead	2 mg/kg

(c) Microbiological specifications at the time of manufacture

1. Total germ content in 1 g: 100 000
2. Absence of pathogenic germs and their toxins
3. Enterobacteriaceae in 1 g: 20
4. Eschericia coli in 1 g: none
5. Salmonellae in 25 g: none
6. Thermophilic germs in 1 g: 5 000
7. Moulds and yeasts in 1 g: 100

(d) Technological adjuvants of edible quality authorized for precipitation

Lactic acid (E 270)
Hydrochloric acid
Sulphuric acid
Citric acid (E 330)
Acetic acid (E 260)
Whey
Orthophosphoric acid

(e) Organoleptic characteristics

1. Odour: Not 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 do not break under slight pressure.

III. STANDARDS APPLICABLE TO EDIBLE RENNET CASEINS

(a) Essential factors of composition

1. Maximum moisture content	12% by weight
2. Minimum content of milk protein matter, calculated on the dried extract	84% by weight
3. Maximum content of milk fat, calculated on the dried extract	2% by weight
4. Extraneous matter (such as wood or metal particles, hairs or insect fragments)	nil in 25 g
5. Maximum sediment content (burnt particles)	22.5 mg in 25 g
6. Minimum ash content (P_2O_5 included)	7.50% by weight
7. Maximum lactose content	1%

(b) Hygienic criteria

1. Metals (maximum)

- iron	20 mg/kg
- copper	5 mg/kg
- lead	2 mg/kg

(c) Microbiological specifications at the time of manufacture

1. Total germ content in 1 g: 100 000
2. Absence of pathogenic germs and their toxins
3. Enterobacteriaceae in 1 g: 20
4. Escherichia coli in 1 g: none
5. Salmonellae in 25 g: none
6. Thermophilic germs in 1 g: 5 000
7. Moulds and yeast in 1 g: 100

(d) Organoleptic characteristics

1. Odour: Not 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 do not break under slight pressure.

ANNEX II

CASEINATES

I. DEFINITION

"Edible caseinates" means products obtained from the reaction of edible caseins or curds of edible casein with neutralizing agents of edible quality listed under Section II (d) of this Annex. These products, with the exception of calcium caseinate, are almost totally soluble in distilled water; they comply with the standards set out in Section II of this Annex.

II. STANDARDS APPLICABLE TO EDIBLE CASEINATES

(a) Essential factors of composition

1. Maximum moisture content	8% by weight
2. Minimum content of milk protein matter, calculated on the dried extract	88% by weight
3. Maximum content of milk fat, calculated on the dried extract	2.0% by weight
4. Extraneous matter (such as wood or metal particles, hairs or insect fragments)	nil in 25 g
5. Maximum sediment content (burnt particles)	22.5 mg in 25 g
6. Maximum anhydrous lactose content	1.0% by weight
7. Maximum pH value	6.0 to 8.0

(b) Hygienic criteria

1. Metals (maximum)

- iron	20 mg/kg
- copper	5 mg/kg
- lead	2 mg/kg

(c) Microbiological specifications at the time of manufacture

1. Total germ content in 1 g: 100 000
2. Absence of pathogenic germs and their toxins
3. Enterobacteriaceae in 1 g: 20
4. Escherichia coli in 1 g: none

5. Salmonellae in 25 g: none
6. Thermophilic germs in 1 g: 5 000
7. Moulds and yeasts in 1 g: 100

(d) Edible neutralizing agents (optional neutralizing and buffering agents)

The hydroxides, carbonates and phosphates of sodium, potassium, calcium, ammonium and magnesium; calcium citrate.

(e) Organoleptic characteristics

1. Odour: Not 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 do not break under slight pressure.