COUNCIL DIRECTIVE

of 30 June 1982

concerning certain products used in animal nutrition

(82/471/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 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 livestock production occupies a very important place in the agriculture of the Community and satisfactory results depend to a large extent on the use of appropriate and good quality feedingstuffs;

Whereas the existence of rules concerning feedingstuffs is essential to an increase in agricultural productivity;

Whereas consumption of feed proteins is continually rising in the Community due to the ever increasing needs of livestock production;

Whereas this increasing demand has been accompanied in recent years by an appreciable decline in the supply on the world market of certain protein feedingstuffs;

Whereas this shortage has caused the feedingstuffs industry to carry out research into substitution products to assure the availability of supplies;

Whereas the provisions laid down in the Member States by law, regulation or administrative action concerning these products, in so far as they exist, differ as regards their basic principles; whereas it follows that they directly affect the establishment and functioning of the common market and should therefore be harmonized;

Whereas these substitution products are produced by new technical processes and it is therefore desirable to regulate their marketing as feedingstuffs or constituents of feedingstuffs by prescribing, for each group concerned, which individual products shall be authorized and under what conditions of use;

Whereas it is necessary, before including a new product in one of the groups concerned, to ascertain that it has the required nutritional value; whereas it must be established that these products, when used sensibly, have no detrimental effect on human or animal health or on the environment and do not harm the consumer by impairing the distinctive features of animal products;

Whereas, in order to ensure compliance with the fundamental principles laid down for the authorization, a dossier should be submitted officially by a Member State for products belonging to certain groups; whereas, in order to facilitate the examination of the substances concerned, these dossiers should be prepared in accordance with the common guidelines to be set by the Council not later than the date of application of the Directive;

Whereas it is desirable, pending a Community decision, to allow Member States temporarily to maintain the national authorizations they have granted for products which do not at present appear in the Annex to the Directive or for specific products meeting in certain cases other conditions; whereas, however, for products obtained from yeasts of the 'Candida' variety and cultivated on n-alkanes a Community decision should be taken within two years of the notification of this Directive;

Whereas non-protein nitrogenous compounds, by reason of their indirect provision of protein, must be subject to the provisions of this Directive; whereas it is consequently desirable to amend with regard to its Annexes Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (4), which temporarily regulates the use of products of this group;

(1) OJ No C 197, 18. 8. 1977, p. 3.
(2) OJ No C 63, 13. 3. 1978, p. 53.
(3) OJ No C 84, 8. 4. 1978, p. 4.

(4) OJ No L 270, 14. 12. 1970, p. 1.

Whereas the nutritional value and safety of the products in question depend to a large extent on their compositional characteristics, conditions of use and processes of manufacture; whereas it is therefore essential to provide in certain cases for labelling to protect the user against fraud and to facilitate the optimal use of the products available to him;

Whereas it is not appropriate to apply Community provisions to the products concerned, or to feedingstuffs containing these products, intended for export to third countries because in general these countries have their own regulations;

Whereas, in order to ensure that the requirements of this Directive are satisfied when these products, or feedingstuffs containing these products, are placed on the market, Member States must make provision for appropriate control arrangements;

Whereas products, or feedingstuffs containing such products, satisfying these requirements must be subject only to the marketing restrictions provided for in this Directive;

Whereas an appropriate Community procedure is essential to adapt the provisions of the Annex and the guidelines laid down for the submission of dossiers relating to certain products and, where necessary, to fix criteria of composition and purity as well as the physico-chemical and biological properties of these products in the light of the development of scientific and technical knowledge;

Whereas, with a view to providing all necessary guarantees, the Community procedure adopted should make provision in certain cases of amendment of the Annex for the compulsory consultation of the Scientific Committee for Animal Nutrition and the Scientific Committee for Food, set up by the Commission;

Whereas Member States should retain the power, if human or animal health is endangered, temporarily to suspend authorization of the use of a product or to amend any provisions relating thereto;

Whereas, in order that a Member State should not abuse that power, possible amendments to the Annex based on supporting documents should be decided by emergency Community procedure;

Whereas, in order to facilitate implementation of this Directive, a procedure should be applied which establishes close cooperation between Member States and the Commission within the Standing Committee for Feedingstuffs set up by Decision 70/372/EEC [1],

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns products which act as direct or indirect protein sources, are manufactured by certain technical processes and are put into circulation within the Community as feedingstuffs or in feedingstuffs.

2. This Directive shall be without prejudice to Community provisions concerning:

(a) additives in feedingstuffs;

(b) the fixing of maximum levels for undesirable substances and products in feedingstuffs;

(c) the fixing of maximum levels for pesticide residues on and in products intended for human or animal nutrition;

(d) the marketing of straight and compound feedingstuffs;

(e) pathogenic micro-organisms in feedingstuffs.

Article 2

The definitions contained in Article 2 of Council Directive 70/524/EEC shall apply to this Directive.

Article 3

1. Member States shall prescribe that feedingstuffs belonging to one of the product groups listed in the Annex or containing such products may be marketed only if:

(a) the product in question appears in the Annex;

(b) any conditions laid down therein are fulfilled.

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[1] OJ No L 170, 3. 8. 1970, p. 1.

2. Member States may, for experimental or scientific purposes, provide for derogations from the provisions of paragraph 1, provided that an adequate official inspection is carried out.

Article 4

1. Notwithstanding Article 3 (1), the Member States may, until such time as a decision has been taken in accordance with Article 6, maintain:

(a) authorizations granted within their territories before the date of application of this Directive concerning products not listed under the product groups indicated in the Annex with the exception of products obtained from yeasts of the 'Candida' variety and cultivated on n-alkanes;

(b) authorizations granted within their territories before notification of this Directive concerning on the one hand products obtained from yeasts of the 'Candida' variety and cultivated on n-alkanes and on the other hand products listed in the Annex, Section 1.2.1, meeting requirements different from those laid down therein.

2. Member States shall send to the other Member States and the Commission the list of products allowed on their territories in accordance with paragraph 1.

Article 5

1. Without prejudice to the labelling provisions applicable to straight and compound feedingstuffs, Member States shall prescribe that the products listed in the Annex may not be marketed as feedingstuffs or incorporated in feedingstuffs unless any particulars laid down in the Annex appear in the package or container or on a label attached thereto.

2. Member States shall prescribe that for material marketed in bulk the particulars referred to in paragraph 1 shall appear on an accompanying document.

Article 6

1. Amendments to be made to the Annex as a result of developments in scientific or technical knowledge shall be adopted in accordance with the procedure laid down in Article 13. In the case of the products referred to in Sections 1.1 and 1.2 of the Annex the Commission shall consult the Scientific Committee for Animal Nutrition and the Scientific Committee for Food.

However, in the case of products obtained from yeasts of the 'Candida' variety and cultivated on n-alkanes, referred to in Article 4 (1), a decision shall be adopted, in accordance with the procedure set out in Article 13, within two years of notification of this Directive, after consulting the Scientific Committee for Animal Nutrition and the Scientific Committee for Food.

2. In amending the Annex, the following principles shall be observed:

A. A product shall not be included in the Annex unless:

(a) it has nutritional value for animals because it provides nitrogen or protein;

(b) when used sensibly it has no detrimental effect on human or animal health or on the environment and does not harm the consumer by impairing the distinctive features of animal products;

(c) it can be monitored in feedingstuffs.

B. A product shall be deleted from the Annex if one of the conditions listed in A is not satisfied.

3. Criteria making it possible to define the products included in this Directive, particularly the criteria of composition and purity and the physico-chemical and biological properties, may be set in the light of scientific and technical knowledge and in accordance with the procedure laid down in Article 13.

Article 7

1. In order to ensure that the products referred to in Sections 1.1 and 1.2 of the Annex comply with the principles set out in Article 6 (2), the Member States shall ensure that a dossier, prepared in accordance with the provisions of paragraph 2 below, is sent officially to the Member States, to the Commission and, if it is requested that they be consulted, to the members of the Scientific Committees set up by the Commission.

2. On a proposal from the Commission, the Council shall adopt the guidelines to be observed in preparing the dossier referred to in paragraph 1 so that these guidelines can be applied on the date of application of this Directive at the latest.

The amendments to be made to the guidelines subsequently as a result of developments in scientific or technical knowledge shall be adopted in accordance with the procedure laid down in Article 13.

3. The Member States, the Commission and the other recipients of the dossier referred to in paragraph 1 shall ensure, if requested on good grounds by an applicant, that information whose disclosure could adversely affect industrial or commercial property rights is kept confidential.

Industrial and commercial secrecy shall not apply to:

— the names and composition of the product, and any information concerning the substrate and the micro-organism,

— the physico-chemical and biological properties of the product,

— the interpretation of the pharmacological, toxicological and ecotoxicological data,

— the analytical methods for monitoring the product in the feedingstuffs.

Article 8

1. If, on the basis of detailed grounds due to new data or a new evaluation of existing data that have become evident since the adoption of the provisions in question, a Member State finds that one of the products listed in the Annex or its use under any conditions that have been set represents a danger to human or animal health even though it complies with the provisions of this Directive, the Member States may temporarily suspend or restrict the application of those provisions in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the 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 in the Standing Committee for Feedingstuffs and shall then give its opinion without delay and take appropriate action.

3. If the Commission considers that amendments to the Directive are necessary to alleviate the difficulties referred to in paragraph 1 and to ensure the protection of human or animal health, it shall initiate the procedure laid down in Article 14 so as to adopt such amendments; in that case, the Member State which has adopted safeguard measures may retain them until the amendments come into force.

Article 9

With regard to marketing between Member States, the particulars referred to in Article 5 shall be given in at least one of the official languages of the country of destination.

Article 10

The Member States shall ensure that as far as the presence and labelling of the products listed in the Annex is concerned, feedingstuffs that comply with the provisions of this Directive are subject only to the marketing restrictions contained in this Directive.

Article 11

The Member States shall ensure that animal products are not subject to any marketing restriction as a result of the application of this Directive.

Article 12

The Member States shall take all measures necessary to ensure that the compliance of feedingstuffs with the requirements of this Directive is officially monitored, at least by sampling, during marketing.

Article 13

1. Where the procedure described in this Article is to be followed, matters shall be referred to the Standing Committee for Feedingstuffs (hereinafter called 'the Committee'), by its chairman, either on his own initiative or at the request of the 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 deliver its opinion on the draft within a time limit set by the chairman according to the urgency of the matter. It shall decide by a majority of 45 votes, the votes of the Member States being weighted as laid down in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged where they are in accordance with the Committee's opinion.

(b) Where the measures envisaged are not in accordance with the Committee's opinion, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal regarding the measures to be adopted. The Council shall act by a qualified majority.

(c) If the Council has not acted within three months of the date when the matter is referred to it, the proposed measures shall be adopted by the

Commission, except where the Council has decided against them by a simple majority.

Article 14

1. Where the procedure described in this Article is to be followed, matters shall be referred to the Committee by its chairman, either on his own initiative or at the request of the 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 deliver its opinion on the draft within two days. It shall decide by a majority of 45 votes, the votes of the Member States being weighted as laid down in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged where they are in accordance with the Committee's opinion.

(b) Where the measures envisaged are not in accordance with the Committee's opinion, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal regarding the measures to be adopted. The Council shall act by a qualified majority.

(c) If the Council has not acted within 15 days of the date when the matter is referred to it, the proposed measures shall be adopted by the Commission, except where the Council has decided against them by a simple majority.

Article 15

All references to non-protein nitrogenous compounds in Annex I, part K and Annex II, part Db to Directive 70/524/EEC shall be deleted.

Article 16

This Directive shall not apply to feedingstuffs which, as proved at least by the relevant information, are intended for export to third countries.

Article 17

The Member States shall bring into force, two years after notification of this Directive, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall immediately inform the Commission thereof.

Article 18

This Directive is addressed to the Member States.

Done at Luxembourg, 30 June 1982.

For the Council

The President

Ph. MAYSTADT

ANNEX

1	2	3	4	5	6	7
Name of product group	Name of product	Chemical designation of product or identity of micro-organism	Nutrient substrate (specifications, if any)	Composition characteristics of product	Animal species	Special provisions
1. Proteins obtained from the following groups of micro-organisms						
1.1. *Bacteria*						
1.2. *Yeasts*	All yeasts	Saccharomyces cerevisiae, Saccharomyces carlsbergiensis, Kluyveromyces lactis, Kluyveromyces fragilis	Molasses, distillery residues, cereals and products containing starch, fruit juice, whey, lactic acid, hydrolyzed vegetable fibres	—	All animal species	
1.2.1. Yeasts cultivated on substrates of animal or vegetable origin	— obtained from the micro-organisms and substrates listed in columns 3 and 4 respectively					
	— the cells of which have been killed					
1.2.2. Yeasts cultivated on substrates other than those given in 1.2.1						
1.3. *Algae*	—	—				
1.4. *Lower fungi*						
2. Non-protein nitrogenous compounds and similar products in the following groups						
2.1. *Urea and its derivatives*	2.1.1. Urea	$CO(HN_2)_2$	—	Minimum purity 98 %	Ruminants from the beginning of rumination	Declaration on the label or packaging of compound feedingstuffs: — name of product, with, where appropriate, the amount contained in the compound feedingstuff, provided official analysis methods exist,
	2.1.2. Biuret	$C_2H_5O_2N_3$	—			
	2.1.3. Ureaphosphate	$CO(NH_2)_2H_3PO_4$	—			
	2.1.4. Diureido-isobutane	$(CH_3)_2$-CH-CH $(NHCONH_2)_2$	—			

1	2	3	4	5	6	7
Name of product group	Name of product	Chemical designation of product or identity of micro-organism	Nutrient substrate (specifications, if any)	Composition characteristics of product	Animal species	Special provisions
						— proportion of nitrogen, expressed as protein equivalent, provided by the non-protein nitrogenous compound(s), — suitable instructions for use indicating the animals for which the feedingstuff is intended and the maximum level of total non-protein nitrogen which must not be exceeded in the daily ration
2.2. *Amino acids and similar products*	2.2.1. D,L-methionine	$CH_3S(CH_2)_2$-$CH(NH_2)$-COOH	–	Minimum purity 98 %	All animal species	–
	2.2.2. L-lysine	NH_2-$(CH_2)_4$-$CH(NH_2)$-COOH	–			–
	2.2.3. L-lysine hydrochloride	NH_2-$(CH_2)_4$-$CH(NH_2)$-COOH.HCL	–			–
	2.2.4. D,L-methionine hydroxy-analogue	$(CH_3$-S-$(CH_2)_2$-$(CH(OH)$-$COO)_2Ca$	–			–