Council Directive of 30 June 1982 concerning certain products used in animal nutrition (82/471/EEC) (repealed)

COUNCIL DIRECTIVE

of 30 June 1982

concerning certain products used in animal nutrition

(82/471/EEC) (repealed)

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;

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[(5)],

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 **[**[F1]**]**compound;

e pathogenic micro-organisms in feedingstuffs.

[[F2]f feedingstuffs for particular nutritional purposes;**]**

[[F3]g the circulation of feed materials.**]**

[[F4]3 This Directive does not apply to products which act as direct or indirect protein sources that fall within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[(6)].**]**

Textual Amendments

F1 Deleted by Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC.

F2 Inserted by Council Directive 93/74/EEC of 13 September 1993.

F3 Inserted by Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC.

F4 Inserted by Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance).

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.

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.

[[F5]3 Member States shall require that products referred to in Chapter I.1 (a) of Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector[(7)] may be put into circulation only by establishments or intermediaries which meet the conditions laid down in Article 2 or Article 3 of that Directive, as appropriate.**]**

[[F6]4 Paragraph 3 shall apply without prejudice to Article 4(2) of Directive 95/69/EC.**]**

Textual Amendments

F5 Inserted by Council Directive 95/69/EC of 22 December 1995.

F6 Inserted by Council Directive 1999/20/EC of 22 March 1999 amending Directives 70/524/EEC concerning additives in feedingstuffs, 82/471/EEC concerning certain products used in animal nutrition, 95/53/EC fixing the principles governing the organisation of official inspections in the field of animal nutrition and 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector.

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.

[[F7]3 In the territory of the former German Democratic Republic, the use in feedingstuffs of protein products obtained from yeast of the Candida genus cultured on n-alkanes shall not be prohibited until 31 December 1991. The Federal Republic of Germany shall ensure that the products in question are not dispatched to other parts of the Community.**]**

Textual Amendments

F7 Inserted by Council Directive of 4 December 1990 (90/654/EEC).

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.

[F8 Article 13

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002(8), hereinafter referred to as 'the Committee'.

2 Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC(9) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 The Committee shall adopt its rules of procedure.

Textual Amendments

F8 Substituted by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty.

Article 14

Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.]

Textual Amendments

F8 Substituted by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty.

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.

[F7However, the Federal Republic of Germany may until 31 December 1991 derogate from the labelling provisions in Article 5 for feedingstuffs produced in the territory of the former German Democratic Republic.]

Textual Amendments

F7 Inserted by Council Directive of 4 December 1990 (90/654/EEC).

Article 18

This Directive is addressed to the Member States.

ANNEX

1 **Name of product group**	2 **Name of product**	3 **[F9 Designation of nutritive principle or identity of micro-organism]**	4 **[F9 Culture substrate (specifications, if any)]**	5 **Composition, characteristics of product**	6 **Animal species**	7 **Special provisions**
1. Proteins obtained from the following groups of micro-organisms	**Proteins obtained from the following groups of micro-organisms**					
1.1. *Bacteria*						
[F10 1.1.1. Bacterial protein cultivated on methanol	1.1. Protein product of fermentation obtained by culture of *Methylophilus methylotrophus* on methanol	*Methylophilus methylotrophus* NCIB strain 10.515	Methanol	— Crude protein: min. 68 % — Reflectance index at least 50	Pigs Calves Poultry Fish	Declarations to be made on the label or packaging of the product: — name of the product, — crude protein, — crude ash, — crude fat, — moisture content, — instructions for use,

a [F9 The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.]

								— Declaration of the words 'Avoid inhalation'. — [F11as from 1 April 2001: approval number Declarations to be made on the label or packaging of compound feedingstuffs: — amount of the product contained in the feedingstuff.]
[F12 1.1.2.	Bacteria cultivated on natural gas	1.1.2.1.	protein product of fermentation from natural gas obtained by culture of: *Methylococcus capsulatus (Bath), Alcaligenes acidovorans, Bacillus brevis et Bacillus firmus,*	*Methylococcus capsulatus (Bath)* NCIMB strain 11132, *Alcaligenes acidovorans* NCIMB strain 12387, *Bacillus brevis* NCIMB strain 13288 *Bacillus firmus strain* NCIMB strain	Natural gas (approx. 91 % methane, 5,2% ethane, 2,2% propane, 0,3% isobutane, 0,5 % n-butane, 1,% other components), ammonia, mineral salts	Crude protein: min. 65 %	— Pigs for fattening from 25 to 60 kg — Calves from 80 kg on — Salmon	Declarations to be made on the label or the packaging of the product: — the name: 'Protein product of fermentation from natural gas obtained by culture of *Methylococcus capsulatus*

a [F9The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.]

		and the cells of which have been killed	13280				*(Bath), Alcaligenes acidovorans, Bacillus brevis* and *Bacillus firmus,'* — crude protein — crude ash — crude fat — moisture content — instructions for use — maximum incorporation rate in the feed: — 8 % pigs for fattening — 8 % calves — 19 % salmon (freshwater) — 33 % salmon (seawater) — declaration of the words: 'avoid inhalation' — as from 1 April 2001: approval number

a **[**[F9]The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

							Declarations to be made on the label or packaging of the compound feedingstuffs: — The name: 'Protein product obtained by bacterial fermentation of natural gas' — amount of the product contained in the feedingstuffs**]**
1.2. 1.2.1.	Yeasts Yeasts cultivated on substrates of animal or vegetable origin	All yeasts obtained from the micro-organisms and substrates listed in columns 3 and 4 respectively	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	
		— the cells of which have been killed					

a **[**F9The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

1.2.2.	Yeasts cultivated on substrates other than those given in 1.2.1.						
1.3.	*Algae*	—	—				
1.4.	*Lower fungi*						
[F13 1.4.1.	Products from production of antibiotics by fermentation	1.4.1.	Mycelium, wet by-product from the production of penicillin, ensiled by means of *lactobacillus brevis,* plantarun, sake, collenoid and *streptococcus lactis* to inactive the penicillin and heat treated	Nitrogenous compound Penicillium chrysogenum ATCC 48271	Different sources of carbohydrates and their hydrolysates	Nitrogen expressed as crude protein: min. 7 %	Ruminants Pigs	Declaration be be made on the label or packaging of the product: — the name: ‘Mycelium silage from the production of penicillin’ — Nitrogen expressed as crude protein — crude ash — moisture — animal species or category

a [F9The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.]

							— as from 1 April 2001: approval number
							Declaration to be made on the label or packaging of the compound feedingstuff:
							— the name: ‘Mycelium silage from the production of penicillin’.]
[F9 2.Non-protein nitrogenous compoundsNon-protein nitrogenous compounds							
2.1.	*Urea and its derivatives*	2.1.1.	Urea, technically pure	$CO(NH_2)_2$	—	Urea: minimum 97 %	Ruminants from the beginning of rumination	Declarations to be made on the label or packaging of the product:
		2.1.2.	Biuret, technically pure	$(CONH_2)_2$-NH	—	Biuret: minimum 97 %		— the name ‘Urea’, ‘Biuret’, ‘Urea-phosphate’ or ‘Diureidoisobutane’, as

a [F9 The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.]

						the case may be,
	2.1.3.	Urea-phosphate, technically pure	$CO(NH_2)_2 \cdot H_3PO_4$	—	Nitrogen: minimum 16,5 % Phosphorus: minimum 18 %	— nitrogen level; and in addition for product 2.1.3, phosphorus level,
	2.1.4.	Diureidoisobutane, technically pure	$(CH_3)_2\text{-}(CH)_2\text{-}(NHCONH_2)_2$	—	Nitrogen: minimum 30% Isobutyraldehyde: minimum 35 %	— animal species or category.
						Declarations to be made on the label or packaging of compound feedingstuffs:
						— the name ‘Urea’, ‘Biuret’, ‘Urea-phosphate’ or ‘Diureidoisobutane’ as the case may be,
						— amount of the product contained in

a **[**[F9]The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

						the feedingstuff,
						— percentage of the total crude protein provided by non-protein nitrogen,
						— indication, in the instructions for use, of the level of total non-protein nitrogen which should not be extended in the daily ration of each animal species or category.
2.2.	*Ammonium salts*	2.2.1	Ammonium lactate, produced by fermentation with $CH_3CHOHCOONH_4$	Min. 85 %	Nitrogen expressed as crude protein: minimum 44 %	Ruminants from the beginning of rumination	Declarations to be made on the label or packaging

a [F9The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.]

		Lactobacillus bulgaricus				of the product:
						— the name ‘Ammonium lactate from fermentation’,
						— nitrogen expressed as crude protein,
						— crude ash,
						— moisture,
						— animal species or category.
						Declarations to be made on the label or packaging of compound feedingstuffs:
						— the name ‘Ammonium-lactate from fermentation’,
						— amount of product contained in the feedingstuff,

a **[**[F9]The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

						— percentage of the total crude protein provided by non-protein nitrogen,
						— indication, in the instructions for use, of the level of total non-protein nitrogen which should not be exceeded in the daily ration of each animal species or category.]
[F10	2.2.2. Ammonium acetate in aqueous solution	CH_3COONH_4 —		Ammonium acetate: min. 55 %	Ruminants, from the start of rumination	Declarations to be made on the label or packaging of the product:

a [F9The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.]

						— the words: Ammonium acetate,
						— nitrogen and moisture contents,
						— animal species or category.
						Declarations to be made on the label or packaging of compound feedingstuffs:
						— the words: Ammonium acetate
						— the amount of the product contained in the feedingstuff,
						— percentage of the total crude protein provided by non protein nitrogen,

a **[**[F9]The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

						— indication in the instructions for use of the level of total non-protein nitrogen which should not be exceeded in the daily ration of each animal species or category.]
[F14	2.2.3 Ammonium sulfate in aqueous solution	$(NH_4)_2SO_4$	—	Ammonium sulfate: 35 %	Ruminants, from the start of rumination	Declarations to be made on the label or packaging of the product:
						— the words: ‘Ammonium sulfate’,
						— nitrogen and moisture contents,
						— animal species,

a [F9The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.]

						— in the case of young ruminants, the incorporation rate in the daily ration may not exceed 0,5 %
						Declarations to be made on the label or packaging of the compound feedingstuffs:
						— the words: ‘Ammonium sulfate’,
						— the amount of the product contained in the feedingstuff,
						— percentage of the total crude protein provided by

a **[**[F9]The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

						non-protein nitrogen,
						— indication in the instruction for use of the level of total non-protein nitrogen which should not be exceeded in the daily ration of each animal species,
						— in the case of young ruminants, the incorporation rate in the daily ration may not exceed 0,5 %**]**

a **[**[F9]The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

[F9 2.3.	*By-products from the production of amino acids by fermentation*	2.3.1.	Concentrated liquid by-products from the production of L-glutamic acid by fermentation with Corynebacterium melassecola	Ammonium salts and other nitrogenous compounds	Sucrose, molasses, starch products and their hydrolysates	Nitrogen expressed as crude protein: minimum 48 % Moisture: maximum 28 %	Ruminants from the beginning of rumination	Declarations to be made on the label or packaging of the product: — the name ‘by-products from the production of L-glutamic acid’ in the case of product 2.3.1; ‘by-products from the production of L-lysine’ in the case of product 2.3.2, — nitrogen, expressed as crude protein, — crude ash, — moisture, — animal species or category.
		2.3.2.	Concentrated liquid by-products from the production of L-lysine monohydrochloride by fermentation with Brevibacterium lactofermentum	Ammonium salts and other nitrogenous compounds	Sucrose, molasses, starch products and their hydrolysates	Nitrogen expressed as crude protein: minimum 45 %	Ruminants from the beginning of rumination]	

a [F9 The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.]

						— as from 1 April 2001: approval number Declarations to be made on the label or packaging of compound feedingstuffs: — percentage of the total crude protein provided by non-protein nitrogen, — indication, in the instructions for use, of the level of total non-protein nitrogen which should not be exceeded in the daily ration of each

a [F9The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.]

							animal species or category.
[F16 3. Amino acids and their salts							
3.1.	Methionine	3.1.1.	DL-Methionine, technically pure	$CH_3S(CH_2)_2$-$CH(NH_2)$-COOH	—	DL-Methionine: minimum 98 %	All animal species	Declarations to be made on the label or packaking of the product: — the name ‘DL-methionine’, in the case of products 3.1.1, ‘Dihydrated calcium salt of N-hydroxy-menthyl-DL-mentionine’ in the case of product 3.1.2, ‘Zinc-methionine’ in the case of products 3.1.3,
		3.1.2.	Dihydrated calcium salt of N-hydroxy-methyl-DL-methionine, technically pure	$[CH_3S(CH_2)_2$-$CH(NH$-CH_2-$OH)$-$COO]_2Ca$-$2H_2O$	—	DL-Methionine: minimum 67 % Formaldehyde: maximum 14 % Calcium: minimum 9 %	Ruminants from the beginning of rumination	
		3.1.3.	Methionine-zinc, technically pure	$[CH_3S(CH_2)_2$-$CH(NH_2)$-$COO]_2Zn$	—	DL-Methionine: minimum 80 % Zn: maximum 18,5 %		— DL-methionine and

a **[F9** The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

						— moisture contents, — animal species or category in the case of products 3.1.2. and 3.1.3, — — as from 1 April 2001: approval number
[F17	3.1.4.	Concentrated liquid sodium DL-methionine technically pure	[CH_3 S $(CH_2)_2$-$CH(NH_2)$-COO]Na	—	DL-Methionine: minimum 40,0 % Sodium: minimum 6,2 %	All animal species	Declarations to be made on the label or packaging of the product:
						— the name ‘concentrated liquid sodium-DL-methionine’
						— DL-Methionine content
						— moisture content
						— as from 1 April 2001:

a **[**[F9]The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

							approval number**]**
[[F18]	3.1.5.	DL-methionine, technically pure protected with copolymer vinylpyridine/ styrene	$CH_3S(CH_2)_2$-$CH(NH_2)$-COOH	—	DL-Methionine: minimum 65 % copolymer vinylpyridine/ styrene: maximum 3 %	Dairy cows	Declarations to be made on the label or packaging of the product:
							— ‘Protected methionine with copolymer vinyl-pyridine/ styrene’
							— DL-methionine and moisture contents
							— animal species
							— as from 1 April 2001: approval number**]**
3.2. Lysine	3.2.1.	L-Lysine, technically pure	NH_2-$(CH_2)_4$-$CH(NH_2)$-COOH	—	L-Lysine: minimum 98 %	ll animal species	Declarations to be made on the label or packaging of the product: — the name ‘L-lysine’ in the
	3.2.2.	Concentrated liquid L-lysine (base)	NH_2-$(CH_2)_4$-$CH(NH_2)$-COOH	Saccharose, molasses, starch products and their hydrolysates	**[**[F12]L-Lysine: min. 50 %**]**		

a **[**[F9]The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

3.2.3.	L-Lysine-monohydrochloride, technically pure	NH_2-$(CH_2)_4$-$CH(NH_2)$-COOH-HCl	—	L-Lysine: min. 78 %		case of product 3.2.1, 'Concentrated liquid L-lysine base' in the case of product 3.2.2, 'L-lysine-monohydrochloride' in the case of product 3.2.3, 'Concentrated liquid L-lysine monohydrochloride' in the case of product 3.2.4, 'L-lysine sulphate and its by-products from fermentation' in the case of product 3.2.5,
3.2.4.	Concentrated liquid L-lysine-monohydrochloride	NH_2-$(CH_2)_4$-$CH(NH_2)$-COOH-HCl	Saccharose, molasses, starch products and their hydrolysates	L-Lysine: min. 22.4 %		
3.2.5.	L-Lysine-sulphate produced by fermentation with *Corynebacterium glutamicum*	$[NH_2$-$(CH_2)_4$-$CH(NH_2)$-$COOH]_2 \cdot H_2SO_4$	Sugar syrup, molasses, cereals, starch products and their hydrolysates	L-Lysine: min. 40 %		

a [F9The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.]

						—	L-lysine and moisture contents
						—	as from 1 April 2001: approval number
[F13	3.2.6.	L-lysine phosphate and its by-products produced by fermentation with *Brevibacterium lactofermentum* NRRL B-11470	[NH_2-$(CH_2)_4$-$CH(NH_2)$-$COOH$].H_3PO_4	Sucrose ammonia and fish solubles	L-lysine: min. 35 % Phosphorus: min: 4,3 %	Poultry Pigs	Declaration to be made on the label or packaging of the product:
						—	the name ‘L-lysine phosphate and its by-products from fermentation’.
						—	L-lysine and moisture content.
						—	as from 1 April 2001: approval number]
[F18	3.2.7.	Mixtures of:	NH_2-$(CH_2)_4$-$CH(NH_2)$-	—	L-lysine: + DL-methionine:	Dairy cows	Declarations to be made on the

a [F9The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.]

	(a) L-lysine monohydrochloride, technically pure and, (b) DL-methionine, technically pure protected with copolymer vinyl-pyridine/ styrene	$CH_3-CH(NH_2)-CH_2-CH_2-CH_2-CH(NH_2)-COOH \cdot HCl$		minimum 50 % (including DL-methionine: minimum 15 %) Copolymer vinyl-pyridine/ styrene: maximum 3 %		label or packaging of the product: — the name ‘mixture of L-lysine monohydrochloride and DL-methionine protected with copolymer vinyl-pyridine/ styrene’ — L-lysine, DL-methionine and moisture contents — animal species — as from 1 April 2001: approval number**]**
3.3.	Threonine	L-Threonine, technically pure	$CH_3-CH(OH)-CH(NH_2)-COOH$	—	L-Threonine: minimum 98 %	All animal species	Declarations to be made on the label or packaging of the product: — the name

a **[**F9The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

							‘L-threonine’,
						—	L-threonine and moisture contents
						—	as from 1 April 2001: approval number
3.4	Tryptophan	3.4.1.	L-Tryptophan technically pure	$(C_8H_5NH)-CH_2-CH(NH_2)-COOH$	—	L-Tryptophan: minimum 98 %	All animal species	Declarations to be made on the label or packaging of the product:
						—	the name ‘L-tryptophan’,
						—	L-tryptophan and moisture contents
						—	as from 1 April 2001: approval number
		3.4.2.	DL-Tryptophan technically pure	$(C_8H_5NH)-CH_2-CH(NH_2)-COOH$	—	DL-Tryptophan: minimum 98 %	All animal species	Declarations to be made on the label or packaging of the product:

a **[**[F9]The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

						— the name 'DL-tryptophan',
						— DL-tryptophan and moisture contents
						— as from 1 April 2001: approval number**]**
[F18 4.Analogues of amino acids						
4.1.	Analogues of methionine	4.1.1. Hydroxy analogue of methionine	$CH_3S(CH_2)_2$-CH(OH)-COOH	—	Total of acids: minimum 85 % Monomer acid: minimum 65 %	All animal species **[F19]**	Declarations to be made on the label or packaging of the product: — if appropriate, the name (column 2), — monomer acid and total acids contents in the case of product 4.1.1. and monomer acid
		4.1.2. Calcium salt of hydroxy analogue of methionine	$[CH_3$-S-$(CH_2)_2$-CH(OH)-$COO]_2Ca$	—	Monomer acid: minimum: 83 % Calcium: minimum 12 %		

a **[F9**The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

						content in the case of product 4.1.2, — moisture content, — animal species. — — as from 1 April 2001: approval number**]** Declarations to be made on the label or packaging of compound feedingstuffs: — if appropriate, the name (column 2), — monomer acid and total acids contents in the case of product 4.1.1. and monomer acid content in the case

a **[**[F9]The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

						of product 4.1.2, — amount of the product contained in the feedingstuff.
[F20	4.1.3	Isopropyl ester of the hydroxylated analogue of methionine	CH_3-S-$(CH_2)_2$-CH(OH) - COO-CH-$(CH_3)_2$	—	— Monomer esters: 90 % minimum — Humidity: maximum 1 %	Dairy cows	Statement to be included on the label or the packaging of the product: — Isopropyl ester of 2-hydroxy-4-methylthiobutanoic acid Statements to be included on the labelling or the packaging of the compounded feed: — Analogue of methionine: Isopropyl ester of 2-hydroxy-4-methylthiobutanoic acid — Percentage of incorporation of analogue

a [F9The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.]

						of methionine in the feed.**]]**

a **[**[F9]The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.**]**

Textual Amendments

F9 Inserted by Commission Directive of 26 July 1984 (84/443/EEC).

F10 Inserted by Commission Directive of 28 October 1986 (86/530/EEC).

F11 Substituted by Council Directive 1999/20/EC of 22 March 1999 amending Directives 70/524/EEC concerning additives in feedingstuffs, 82/471/EEC concerning certain products used in animal nutrition, 95/53/EC fixing the principles governing the organisation of official inspections in the field of animal nutrition and 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector.

F12 Inserted by Commission Directive 95/33/EC of 10 July 1995.

F13 Inserted by Commission Directive of 24 July 1990 (90/439/EEC).

F14 Inserted by Commission Directive 93/56/EEC of 29 June 1993.

F15 Deleted by Commission Directive of 6 November 1985 (85/509/EEC).

F16 Inserted by Commission Directive of 26 July 1988 (88/485/EEC).

F17 Substituted by Commission Directive of 6 September 1989 (89/520/EEC).

F18 Inserted by Commission Directive 93/26/EEC of 4 June 1993.

F19 Deleted by Commission Directive 93/56/EEC of 29 June 1993.

F20 Inserted by Commission Directive 2003/104/EC of 12 November 2003 authorising isopropyl ester of the hydroxylated analogue of methionine.

(**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.

(**5**) OJ No L 170, 3. 8. 1970, p. 1.

(**6**) **[**[F4]OJ L 268, 18.10.2003, p. 1.**]**

(**7**) **[**[F5]OJ No L 332, 30.12.1995, p. 15.**]**

(**8**) **[**[F8]OJ L 31, 1.2.2002, p. 1.

(**9**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).**]**

Textual Amendments

F4 Inserted by Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance).

F5 Inserted by Council Directive 95/69/EC of 22 December 1995.

F8 Substituted by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty.