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COUNCIL DIRECTIVE
of 30 June 1982
concerning certain products used in animal nutrition
 (82/471/EEC)
 (OJ L 213, 21.7.1982, p. 8)

Amended by:

	Official Journal		
	No	page	date
► M1 Commission Directive 84/443/EEC of 26 July 1984	L 245	21	14.9.1984
► M2 Commission Directive 85/509/EEC of 6 November 1985	L 314	25	23.11.1985
► M3 Council Regulation (EEC) No 3768/85 of 20 December 1985	L 362	8	31.12.1985
► M4 Commission Directive 86/530/EEC of 28 October 1986	L 312	39	7.11.1986
► M5 Commission Directive 88/485/EEC of 26 July 1988	L 239	36	30.8.1988
► M6 Commission Directive 89/520/EEC of 6 September 1989	L 270	13	19.9.1989
► M7 Commission Directive 90/439/EEC of 24 July 1990	L 227	33	21.8.1990
► M8 Council Directive 90/654/EEC of 4 December 1990	L 353	48	17.12.1990
► M9 Commission Directive 93/26/EEC of 4 June 1993	L 179	2	22.7.1993
► M10 Commission Directive 93/56/EEC of 29 June 1993	L 206	13	18.8.1993
► M11 Council Directive 93/74/EEC of 13 September 1993	L 237	23	22.9.1993
► M12 Commission Directive 95/33/EC of 10 July 1995	L 167	17	18.7.1995
► M13 Council Directive 95/69/EC of 22 December 1995	L 332	15	30.12.1995
► M14 ► M15 Council Directive 96/25/EC of 29 April 1996 ◀	L 125	35	23.5.1996
► M15 amended by Directive 2000/16/EC of the European Parliament and the Council of 10 April 2000	L 105	36	3.5.2000
► M16 Council Directive 1999/20/EC of 22 March 1999	L 80	20	25.3.1999
► M17 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003	L 268	1	18.10.2003
► M18 Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003	L 284	1	31.10.2003
► M19 Commission Directive 2003/104/EC of 12 November 2003	L 295	83	13.11.2003

Amended by:

► A1 Act of Accession of Austria, Sweden and Finland	C 241	21	29.8.1994
(adapted by Council Decision 95/1/EC, Euratom, ECSC)	L 1	1	1.1.1995

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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;

⁽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.

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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⁽¹⁾, 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⁽²⁾,

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;

⁽¹⁾ OJ No L 270, 14. 12. 1970, p. 1.

⁽²⁾ OJ No L 170, 3. 8. 1970, p. 1.

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- (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 ► **M14** ————— ◀ compound;
- (e) pathogenic micro-organisms in feedingstuffs.

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- (f) feedingstuffs for particular nutritional purposes;

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- (g) the circulation of feed materials.

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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⁽¹⁾.

▼B*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.

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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⁽²⁾ 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.

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

▼B*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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ OJ No L 332, 30.12.1995, p. 15.

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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.

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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.

▼B*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

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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 feeding-stuffs.

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.

▼M18*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⁽¹⁾, hereinafter referred to as 'the Committee'.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC⁽²⁾ 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.

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.

▼B*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.

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However, 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.

▼B*Article 18*

This Directive is addressed to the Member States.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ 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).

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ANNEX

1	2	3	4	5	6	7
Name of product group	Name of product	► <u>M1</u> Designation of nutritive principle or identity of micro-organism ◀	► <u>M1</u> Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions
1. Proteins obtained from the following groups of micro-organisms 1.1. <i>Bacteria</i> 1.1.1. Bacteria cultivated on methanol	1.1.1.1. Protein product of fermentation obtained by culture of <i>Methylophilus methylotrophus</i> on methanol	<i>Methylophilus methylotrophus</i> 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, — Declaration of the words 'Avoid inhalation'. ► <u>M16</u> — as 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 feeding-stuff.

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1	2	3	4	5	6	7
Name of product group	Name of product	►M1 Designation of nutritive principle or identity of micro-organism ◀	►M1 Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions
1.1.2. Bacteria cultivated on natural gas	1.1.2.1. protein product of fermentation from natural gas obtained by culture of: <i>Methylococcus capsulatus (Bath)</i> , <i>Alcaligenes acidovorans</i> , <i>Bacillus brevis</i> et <i>Bacillus firmus</i> , and the cells of which have been killed	<p><i>Methylococcus capsulatus (Bath)</i> NCIMB strain 11132</p> <p><i>Alcaligenes acidovorans</i> NCIMB strain 12387</p> <p><i>Bacillus brevis</i> strain NCIMB strain 13288</p> <p><i>Bacillus firmus</i> strain NCIMB strain 13280</p>	Natural gas: (approx. 91 % methane, 5 % ethane, 2 % propane, 0,5 % isobutane, 0,5 % n-butane, 1 % other components), ammonia, mineral salts	Crude protein: min. 65 %	<ul style="list-style-type: none"> — Pigs for fattening from 25 to 60 kg — Calves from 80 kg on — Salmon 	<p>Declarations to be made on the label or the packaging of the product:</p> <ul style="list-style-type: none"> — the name: 'Protein product of fermentation from natural gas obtained by culture of <i>Methylococcus capsulatus (Bath)</i>, <i>Alcaligenes acidovorans</i>, <i>Bacillus brevis</i> and <i>Bacillus firmus</i>.' — crude protein — crude ash — crude fat — moisture content — instructions for use — maximum incorporation rate in the feed: <ul style="list-style-type: none"> — 8 % pigs for fattening — 8 % calves — 19 % salmon (fresh-water) — 33 % salmon (seawater) — declaration of the words: 'avoid inhalation'

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1	2	3	4	5	6	7
Name of product group	Name of product	► M1 Designation of nutritive principle or identity of micro-organism ◀	► M1 Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions

▼ **M12**

► **M16** — as from 1 April 2001: approval number ◀

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 feeding-stuffs

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1.2. *Yeasts*

1.2.1. 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
- the cells of which have been killed

Saccharomyces cerevisiae, Saccharomyces carlsbergensis
Kluyveromyces lactis, Kluyveromyces fragilis

Molasses, distillery residues, cereals and products containing starch, fruit juice, whey, lactic acid, hydrolyzed vegetable fibres

—

All animal species

1.2.2. Yeasts cultivated on substrates other than those given in 1.2.1.

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1	2	3	4	5	6	7
Name of product group	Name of product	► M1 Designation of nutritive principle or identity of micro-organism ◀	► M1 Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions
1.3. <i>Algae</i> 1.4. <i>Lower fungi</i>	—	—	—	—	—	—
▼ M7 1.4.1. Products from production of antibiotics by fermentation	1.4.1.1. Mycelium, wet by-product from the production of penicillin, ensiled by means of <i>Lactobacillus brevis</i> , planarun, sake, collenoid and <i>Streptococcus lactis</i> to inactivate 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 to 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 ► M16 — 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'.

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1	2	3	4	5	6	7
Name of product group	Name of product	► M1 Designation of nutritive principle or identity of micro-organism ◀	► M1 Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions

▼ **M1**

2. **Non-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: — the name 'Urea', 'Biuret', 'Urea-phosphate' or 'Diureidoisobutane', as the case may be, — nitrogen level; and in addition for product 2.1.3, phosphorus level, — animal species or category.
2.1.2. Biuret, technically pure	(CONH ₂) ₂ -NH	—	Biuret: minimum 97 %		
2.1.3. Urea-phosphate, technically pure	CO(NH ₂) ₂ · H ₃ PO ₄	—	Nitrogen: minimum 16,5 % Phosphorus: minimum 18 %		
2.1.4. Diureidoisobutane, technically pure	(CH ₃) ₂ -(CH) ₂ -(NHCONH ₂) ₂	—	Nitrogen: minimum 30% Isobutyraldehyde: minimum 35 %		
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 the feeding-stuff, — percentage of the total crude protein provided by non-protein nitrogen,					

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1	2	3	4	5	6	7
Name of product group	Name of product	► <u>M1</u> Designation of nutritive principle or identity of micro-organism ◀	► <u>M1</u> Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions

▼M1

2.2. <i>Ammonium salts</i>	2.2.1. Ammonium lactate, produced by fermentation with <i>Lactobacillus bulgaricus</i>	CH ₃ CHOHCOONH ₄	Whey	Nitrogen expressed as crude protein: minimum 44 %	Ruminants from the beginning of rumination	<p>— 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.</p> <p>Declarations to be made on the label or packaging of the product:</p> <ul style="list-style-type: none"> — the name ‘Ammonium lactate from fermentation’, — nitrogen expressed as crude protein, — crude ash, — moisture, — animal species or category. <p>Declarations to be made on the label or packaging of compound feedingstuffs:</p> <ul style="list-style-type: none"> — the name ‘Ammonium-lactate from fermentation’, — amount of product contained in the feeding-stuff, — percentage of the total crude protein provided by non-protein nitrogen,
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1	2	3	4	5	6	7
Name of product group	Name of product	► <u>M1</u> Designation of nutritive principle or identity of micro-organism ◀	► <u>M1</u> Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions

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	2.2.2. Ammonium acetate in aqueous solution	CH ₃ COONH ₄	—	Ammonium acetate: min. 55 %	Ruminants, from the start of rumination	<p>— 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.</p> <p>Declarations to be made on the label or packaging of the product:</p> <ul style="list-style-type: none"> — the words: Ammonium acetate, — nitrogen and moisture contents, — animal species or category. <p>Declarations to be made on the label or packaging of compound feedingstuffs:</p> <ul style="list-style-type: none"> — the words: Ammonium acetate — the amount of the product contained in the feeding-stuff, — 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.
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1	2	3	4	5	6	7
Name of product group	Name of product	► <u>M1</u> Designation of nutritive principle or identity of micro-organism ◀	► <u>M1</u> Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions

▼M10

	2.2.3 Ammonium sulfate in aqueous solution	(NH ₄) ₂ SO ₄	—	Ammonium sulfate: 35 %	Ruminants, from the start of rumination	<p>Declarations to be made on the label or packaging of the product:</p> <ul style="list-style-type: none"> — the words: ‘Ammonium sulfate’, — nitrogen and moisture contents, — animal species, — in the case of young ruminants, the incorporation rate in the daily ration may not exceed 0,5 % <p>Declarations to be made on the label or packaging of the compound feedingstuffs:</p> <ul style="list-style-type: none"> — the words: ‘Ammonium sulfate’, — the amount of the product contained in the feeding-stuff, — percentage of the total crude protein provided by 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 %
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1	2	3	4	5	6	7
Name of product group	Name of product	► <u>M1</u> Designation of nutritive principle or identity of micro-organism ◀	► <u>M1</u> Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions
2.3. <i>By-products from the production of amino acids by fermentation</i>	2.3.1. Concentrated liquid by-products from the production of L-glutamic acid by fermentation with <i>Corynebacterium melassecola</i>	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. ► <u>M16</u> — as from 1 April 2001: approval number ◀ Declarations to be made on the label or packaging of compound feedingstuffs: ► <u>M2</u> — ◀ — 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.
	2.3.2. Concentrated liquid by-products from the production of L-lysine monohydrochloride by fermentation with <i>Brevibacterium lactofermentum</i>	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	

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▼ **B**

1	2	3	4	5	6	7
Name of product group	Name of product	► M1 Designation of nutritive principle or identity of micro-organism ◀	► M1 Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions
▼ M5 3. Amino acids and their salts 3.1. Methionine	3.1.1. DL-Methionine, technically pure	$\text{CH}_3\text{S}(\text{CH}_2)_2\text{-CH}(\text{NH}_2)\text{-COOH}$	—	DL-Methionine: minimum 98 %	All animal species Ruminants from the beginning of rumination	Declarations to be made on the label or packaging of the product: — the name 'DL-methionine', in the case of products 3.1.1, 'Dihydrated calcium salt of N-hydroxy-methyl-DL-methionine' in the case of product 3.1.2, 'Zinc-methionine' in the case of products 3.1.3, — DL-methionine and moisture contents, — animal species or category in the case of products 3.1.2. and 3.1.3, ► M16 — as from 1 April 2001: approval number ◀
	3.1.2. Dihydrated calcium salt of N-hydroxy-methyl-DL-methionine, technically pure	$[\text{CH}_3\text{S}(\text{CH}_2)_2\text{-CH}(\text{NH}-\text{CH}_2\text{-OH})\text{-COO}]_2\text{Ca}\cdot 2\text{H}_2\text{O}$	—	DL-Methionine: minimum 67 % Formaldehyde: maximum 14 % Calcium: minimum 9 %		
	3.1.3. Methionine-zinc, technically pure	$[\text{CH}_3\text{S}(\text{CH}_2)_2\text{-CH}(\text{NH}_2)\text{-COO}]_2\text{Zn}$	—	DL-Methionine: minimum 80 % Zn: maximum 18,5 %		
	3.1.4. Concentrated liquid sodium DL-methionine technically pure	$[\text{CH}_3\text{S}(\text{CH}_2)_2\text{-CH}(\text{NH}_2)\text{-COO}]\text{Na}$	—	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 ► M16 — as from 1 April 2001: approval number ◀

▼ **M6**

▼B

1	2	3	4	5	6	7
Name of product group	Name of product	►M1 Designation of nutritive principle or identity of micro-organism ◀	►M1 Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions
▼M9 ▼M5 3.2. Lysine	3.1.5. DL-methionine, technically pure protected with copolymer vinylpyridine/styrene	$\text{CH}_3\text{S}(\text{CH}_2)_2\text{-CH}(\text{NH}_2)\text{-COOH}$	—	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 vinylpyridine/styrene’ — DL-methionine and moisture contents — animal species ►M16 — as from 1 April 2001: approval number ◀
	3.2.1. L-Lysine, technically pure	$\text{NH}_2\text{-(CH}_2)_4\text{-CH}(\text{NH}_2)\text{-COOH}$	—	L-Lysine: minimum 98 %	All animal species	Declarations to be made on the label or packaging of the product: — the name ‘L-lysine’ in the 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,
	3.2.2. Concentrated liquid L-lysine (base)	$\text{NH}_2\text{-(CH}_2)_4\text{-CH}(\text{NH}_2)\text{-COOH}$	Saccharose, molasses, starch products and their hydrolysates	►M12 L-Lysine: min. 50 % ◀		
	3.2.3. L-Lysine-monohydrochloride, technically pure	$\text{NH}_2\text{-(CH}_2)_4\text{-CH}(\text{NH}_2)\text{-COOH-HCl}$	—	L-Lysine: min. 78 %		
	3.2.4. Concentrated liquid L-lysine-monohydrochloride	$\text{NH}_2\text{-(CH}_2)_4\text{-CH}(\text{NH}_2)\text{-COOH-HCl}$	Saccharose, molasses, starch products and their hydrolysates	L-Lysine: min. 22.4 %		
	3.2.5. L-Lysine-sulphate produced by fermentation with <i>Corynebacterium glutamicum</i>	$[\text{NH}_2\text{-(CH}_2)_4\text{-CH}(\text{NH}_2)\text{-COOH}]_2 \cdot \text{H}_2\text{SO}_4$	Sugar syrup, molasses, cereals, starch products and their hydrolysates	L-Lysine: min. 40 %		

▼B

1	2	3	4	5	6	7
Name of product group	Name of product	►M1 Designation of nutritive principle or identity of micro-organism ◀	►M1 Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions
						— L-lysine and moisture contents ►M16 — as from 1 April 2001: approval number ◀
▼M7	3.2.6. L-lysine phosphate and its by-products produced by fermentation with <i>Brevibacterium lactofermentum</i> NRRL B-11470	[NH ₂ -(CH ₂) ₄ -CH(NH ₂)-COOH].H ₃ PO 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. ►M16 — as from 1 April 2001: approval number ◀
▼M9	3.2.7. Mixtures of: (a) L-lysine-monohydrochloride, technically pure and, (b) DL-methionine, technically pure protected with copolymer vinyl-pyridine/styrene	NH ₂ -(CH ₂) ₄ -CH(NH ₂)-COOH-HCl CH ₃ S(CH ₂) ₂ -CH(NH ₂)-COOH	—	L-lysine: + DL-methionine: minimum 50 % (including DL-methionine: minimum 15 %) Copolymer vinyl-pyridine/styrene: maximum 3 %	Dairy cows	Declarations to be made on the 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 ►M16 — as from 1 April 2001: approval number ◀

▼B

1	2	3	4	5	6	7
Name of product group	Name of product	► M1 Designation of nutritive principle or identity of micro-organism ◀	► M1 Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions
3.3. Threonine	3.3.1. L-Threonine, technically pure	$\text{CH}_3\text{-CH(OH)-CH(NH}_2\text{)-COOH}$	—	L-Threonine: minimum 98 %	All animal species	Declarations to be made on the label or packaging of the product: — the name 'L-threonine', — L-threonine and moisture contents ► M16 — as from 1 April 2001: approval number ◀
3.4 Tryptophan	3.4.1. L-Tryptophan, technically pure	$(\text{C}_8\text{H}_5\text{NH})\text{-CH}_2\text{-CH(NH}_2\text{)-COOH}$	—	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 ► M16 — as from 1 April 2001: approval number ◀
	3.4.2. DL-Tryptophan, technically pure	$(\text{C}_8\text{H}_5\text{NH})\text{-CH}_2\text{-CH(NH}_2\text{)-COOH}$	—	DL-Tryptophan: minimum 98 %	All animal species	Declarations to be made on the label or packaging of the product: — the name 'DL-tryptophan', — DL-tryptophan and moisture contents ► M16 — as from 1 April 2001: approval number ◀

▼M5

▼ **B**

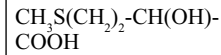
1	2	3	4	5	6	7
Name of product group	Name of product	► M1 Designation of nutritive principle or identity of micro-organism ◀	► M1 Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions

▼ **M9**

4. Analogues of amino acids

4.1. Analogues of methionine

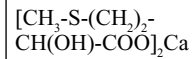
4.1.1. Hydroxy analogue of methionine



—

Total of acids:
minimum 85 %
Monomer acid:
minimum 65 %

4.1.2. Calcium salt of hydroxy analogue of methionine



—

Monomer acid:
minimum: 83 %
Calcium: minimum
12 %

All animal species
► **M10** ◀

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 content in the case of product 4.1.2,
- moisture content,
- animal species.

► **M16** — 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 of product 4.1.2,
- amount of the product contained in the feedingstuff.

▼ B

1	2	3	4	5	6	7
Name of product group	Name of product	► <u>M1</u> Designation of nutritive principle or identity of micro-organism ◀	► <u>M1</u> Culture substrate (specifications, if any) ◀	Composition characteristics of product	Animal species	Special provisions
	4.1.3 Isopropyl ester of the hydroxylated analogue of methionine	$\text{CH}_3\text{-S-(CH}_2\text{)}_2\text{-CH(OH)-COO-CH-(CH}_3\text{)}_2$	—	<ul style="list-style-type: none"> — Monomer esters: 90 % minimum — Humidity: maximum 1 % 	Dairy cows	<p>Statement to be included on the label or the packaging of the product:</p> <ul style="list-style-type: none"> — Isopropyl ester of 2-hydroxy-4-methylthiobutanoic acid <p>Statements to be included on the labelling or the packaging of the compounded feed:</p> <ul style="list-style-type: none"> — Analogue of methionine: Isopropyl ester of 2-hydroxy-4-methylthiobutanoic acid — Percentage of incorporation of analogue of methionine in the feed.

▼ M1

(*) The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.