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(Acts whose publication is not obligatory)

# COUNCIL

#### COUNCIL DIRECTIVE

of 29 June 1982

on measures to facilitate the effective exercise of freedom of establishment and freedom to provide services in respect of activities of self-employed persons in certain services incidental to transport and travel agencies (ISIC Group 718) and in storage and warehousing (ISIC Group 720)

(82/470/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 49, 57 and 66 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, pursuant to the Treaty, all discriminatory treatment based on nationality with regard to establishment and provision of services is prohibited as from the end of the transitional period; whereas the principle of such treatment based on nationality applies in particular to the right to join professional organizations where the professional activities of the person concerned necessarily involve the exercise of this right;

Whereas, moreover, Article 57 of the Treaty provides that, in order to make it easier for persons to take up

and pursue activities as self-employed persons, directives are to be issued for the mutual recognition of diplomas, certificates and other evidence of formal qualifications and for the coordination of the provisions laid down by law, regulation or administrative action in Member States;

Whereas, in the absence of mutual recognition of diplomas and of immediate coordination, it nevertheless appears desirable to facilitate the attainment of freedom of establishment and freedom to provide services in respect of the activities falling within ISIC Groups 718 and 720 by the adoption of measures intended primarily to avoid causing exceptional difficulties for nationals of Member States in which the taking up of such activities is not subject to any conditions;

Whereas, in order to prevent such difficulties arising, the main object of the measures should be to allow, as sufficient qualification for taking up the activities in question, excluding transport activities proper, in host Member States which have rules governing the taking up of such activities, the fact that the activities have been pursued in the country of provenance for a reasonable period of time, such period being, in cases where no previous training is required, sufficiently recent to ensure that the person concerned possesses professional knowledge equivalent to that required of the host country's own nationals;

<sup>(1)</sup> OJ No 73, 23. 4. 1966, p. 1099/66.

<sup>(2)</sup> OJ No 201, 5. 11. 1966, p. 3475/66.

<sup>(3)</sup> OJ No 17, 28. 1. 1967, p. 284/67.

Whereas the activity in question must have been pursued and any vocational training received in the same branch of trade as that in which the beneficiary wishes to establish himself in the host Member State, where the latter country imposes this requirement on its own nationals;

Whereas, in accordance with the general principles of the Treaty as to equality of treatment and with the judgments of the Court of Justice on this matter, the freedom to provide services in each Member State is exercised on the same terms as such State imposes in its laws and regulations on its own nationals engaged in the same activity; whereas it is incumbent on Member States, when they adopt the measures necessary to comply with this Directive, to ensure equivalence of conditions for their own nationals and nationals of other Member States as regards their freedom to engage in the activities concerned, with particular reference to operating conditions and financial guarantees required;

Whereas, in so far as in Member States the taking up or pursuit of the activities referred in this Directive is also dependent in the case of employed persons on the possession of general, commercial or professional knowledge and ability, this Directive should also apply to this category of persons in order to remove an obstacle to the free movement of workers and thereby to supplement the measures adopted in Council Regulation (EEC) No 1612/68 of 15 October 1968 on freedom of movement for workers within the Community (1);

Whereas, for the same reason, the provisions relating to proof of good repute and proof of no previous bankruptcy should also apply to employed persons,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

1. Member States shall adopt the measures set out in this Directive in respect of establishment or provision of services in their territories by natural persons and companies or firms covered by Title I of the General Programmes (2) (hereinafter called 'beneficiaries') in the sector of activities coming within Article 2.

2. This Directive shall also apply to nationals of Member States who, as provided in Regulation (EEC) No 1612/68, wish to pursue as employed persons activities coming within Article 2 of this Directive.

#### Article 2

This Directive shall apply to the activities appearing in Annex I of the General Programme for the abolition of restrictions on freedom of establishment, ISIC Groups 718 and 720.

These activities shall comprise in particular:

- A. (a) acting as an intermediary between contractors for various methods of transport and persons who dispatch or receive goods and who carry out various related activities:
  - (aa) by concluding contracts with transport contractors, on behalf of principals;
  - (bb) by choosing the method of transport, the firm and the route considered most profitable for the principal;
  - (cc) by arranging the technical aspects of the transport operation (e.g. packing required for transportation); by carrying out various operations incidental to transport (e.g. ensuring ice supplies for refrigerated wagons);
  - (dd) by completing the formalities connected with the transport such as the drafting of way bills; by assembling and dispersing shipments;
  - (ee) by coordinating the various stages of transportation, by ensuring transit, reshipment, transhipment and other terminal operations;
  - (ff) by arranging both freight and carriers and means of transport for persons dispatching goods or receiving them;
  - (b) assessing transport costs, and checking the detailed accounts;
  - (c) hiring railway cars or wagons for transporting persons or goods;

<sup>(1)</sup> OJ No L 257, 19. 10. 1968, p. 2.

<sup>(2)</sup> OJ No 2, 15. 1. 1962, pp. 32/62 and 36/62.

- (d) taking certain temporary or permanent measures in the name of and on behalf of a shipowner or sea transport carrier (with the port authorities, ship's chandlers, etc.);
- (e) acting as an intermediary in the sale, purchase or hiring of ships;
- B. (a) organizing, offering for sale and selling, outright or on commission, single or collective items (transport, board, lodging, excursions, etc.) for a journey or stay, whatever the reason for travelling;
  - (b) arranging, negotiating and concluding contracts for the transport of emigrants;
- C. (a) receiving all objects and goods deposited, on behalf of the depositor, whether under customs control or not, in warehouse, general stores, furniture depots, coldstores, silos, etc.
  - (b) supplying the depositor with a receipt for the object or goods deposited;
  - (c) providing pens, feed and sales rings for livestock being temporarily accommodated while awaiting sale or while in transit to or from the market;
- D. (a) carrying out inspection or technical valuation of motor vehicles;
  - (b) measuring, weighing and gauging goods.

#### Article 3

In respect of the activities listed in Article 2, the usual titles current in Member States are given below for guidance:

### Belgium

A. Commissionnaire de transport
Vervoercommissionair
Courtier de transport
Vervoermakelaar
Commissionnaire-expéditeur au transport
Commissionair-expediteur bij het vervoer
Commissionnaire affréteur
Commissionair-bevrachter
Commissionnaire-affréteur routier
Commissionair-wegbevrachter

Affréteur routier
Wegbevrachter
Affréteur fluvial
Binnenvaartbevrachter of rivierbevrachter
Affréteur maritime
Scheepsbevrachter
Agent maritime
Scheepsagent
Courtier de navires
Scheepsmakelaar

- B. Agent de voyages
   Reisagent
   Agent d'émigration
   Emigratieagent
- C. Entrepositaire Depothouder
- D. Expert en automobiles
   Deskundige inzake auto's
   Peseur mesureur jaugeur juré
   Beëdigde wegers, meters en ijkers

#### Germany

- A. Spediteur
  Abfertigungsspediteur
  Güterkraftverkehrsvermittler
  Schiffsmakler
  Vermieter von Eisenbahnwagen und Eisenbahnwaggons
- B. Reisebürounternehmer Auswanderungsagent
- C. Lagerhalter
- D. Kraftfahrzeugsachverständiger Wäger

#### Denmark

- A. Speditør Skibsagent
- B. Rejsebureau
- C. Opbevaring
- D. Vejer og måler Bilinspektør og bilassistent

#### France

- A. Commissionnaire de transport
   Courtier de fret routier
   Dépositaire de colis
   Courtier de fret de navigation intérieure
   Agent maritime
   Agent consignataire de navires
- B. Agent de voyage
- C. Entrepositaire Exploitant de magasin général
- D. Expert en automobiles Peseur — mesureur juré

#### Greece

Α. Πράκτορας μεταφορῶν
 Ναυτικός πράκτορας
 Ἐφοδιαστής πλοίων
 Ναυλομεσίτης ἐπαγγελματικῶν τουριστικῶν πλοίων καί πλοιαρίων
 Ναυλομεσίτες πλοίων

- Β. Πράκτορας γιά ἐπιβατικά ἀκτοπλοϊκά πλοῖα Τουριστικά γραφεῖα:
  - 1. Γενικοῦ τουρισμοῦ
  - 2. Έσωτερικοῦ τουρισμοῦ
  - 3. Tour operator

Πράκτορες μεταναστεύσεως καί άντιπρόσωποί τους

- Γ. Γενικές ἀποθῆκες
- Δ. Πραγματογνώμονες έπί τροχαίων άτυχημάτων

#### Ireland

- A. Forwarding agent
  Shipping and forwarding agent
  Shipbroker
  Freight agent
  Shipping agent
  Air freight agent
  Road haulage broker
- B. Travel agent
  Tour operator
  Air broker
  Air travel organizer
- C. Bonder Warehouseman Market or lairage operator
- D. Motor vehicle examiner

#### Italy

- A. Spedizioniere (commissionario)
  Mediatore
  Agente marittimo raccomandatario
  Mediatore marittimo
- B. Agente di viaggio e turismo Mandatario di vettore di emigrante
- C. Esercenti depositi in magazzini doganali di proprietà privata
   Esercenti magazzini generali
   Esercenti depositi franchi
- D. Stimatore e pesatore pubblico

#### Luxembourg

- A. Commissionnaire de transport Commissionnaire expéditeur au transport
- B. Agent de voyage Agent d'émigration

- C. Entrepositaire
- D. Expert en automobiles Peseur

#### Netherlands

A. Expediteur
Bevrachter
Scheepsmakelaar
Scheepsagent
Verhuren van spoorrijtuigen en spoorwagens

- B. Reisbureaubedrijf Reisagentschap Emigratieagent
- C. Douane-entrepot (publiek, particulier, fictief) Gewone opslagplaatsen
- D. Technische inspectie van motorrijtuigen Meter, wagen en ijken

#### United Kingdom

- A. Freight forwarder
  Shipbroker
  Air cargo agent
  Shipping and forwarding agent
- B. Tour operator
  Travel agent
  Air broker
  Air travel organizer
- C. Storekeeper
  Livestock dealer
  Market or lairage operator
  Warehousekeeper
  Wharfinger
- D. Motor vehicle examiner Master porter Cargo superintendent

- 1. Where a host Member State requires of its own nationals wishing to take up one of the activities coming within Article 2 proof of good repute and proof that they have not previously been declared bankrupt, or proof of either one of these, that State shall accept as sufficient evidence, in respect of nationals of other Member States, the production of an extract from the 'judicial record' or, failing this, of an equivalent document issued by a competent judicial or administrative authority in the country of origin or of provenance showing that these requirements have been met.
- 2. Where a host Member State imposes on its own nationals wishing to take up one of the activities

referred to in Article 2 (B) certain requirements as to good repute, and evidence that such requirements are satisfied cannot be obtained from the document referred to in paragraph 1, that State shall accept as sufficient evidence, in respect of nationals of other Member States, a certificate issued by a competent judicial or administrative authority in the country of origin or in the country of provenance, indicating that the requirements in question have been met. Such certificate shall relate to the specific facts regarded as relevant by the host country.

3. Where the country of origin or the country whence the foreign national comes does not issue the document referred to in paragraph 1 or the certificate referred to in paragraph 2, furnishing proof of good repute or proof of no previous bankruptcy, such proof may be replaced by a declaration on oath — or, in States where there is no provision for declaration on oath, by a solemn declaration — made by the person concerned before a competent judicial or administrative authority, or where appropriate a notary, in the country of origin or the country whence that person comes; such authority or notary will issue a certificate attesting the authenticity of the declaration on oath or solemn declaration. The declaration in respect of no previous bankruptcy may also be made before a competent professional or trade body in the said country.

Notwithstanding the foregoing, the host Member State may also take into account specific information which it has acquired through its own means.

- 4. Where in the host Member State proof of financial standing is required, that State shall regard certificates issued by banks in other States as equivalent to certificates issued in its own territory.
- 5. Documents issued in accordance with paragraphs 1, 2, 3 and 4 shall not be produced more than three months after their date of issue.
- 6. Member States shall, within the time limit laid down in Article 8, designate the authorities and bodies competent to issue the documents referred to above and shall forthwith inform the other Member States and the Commission thereof.

#### Article 5

Member States in which the taking up or pursuit of any activity referred to in Article 2 is subject to possession of certain qualifications shall ensure that any beneficiary who applies therefor be provided, before he establishes himself or before he begins to pursue any activity on a temporary basis, with information as to the rules governing the activity which he proposes to pursue.

- 1. Where, in a Member State, the taking up or pursuit of any activity coming within Article 2 (A) (a), (b) or (d) is dependent on the possession of general, commercial, or professional knowledge and ability, that Member State shall accept as sufficient evidence of such knowledge and ability the fact that the activity in question has been pursued in another Member State for any of the following periods:
- (a) five consecutive years in an independent capacity or in a managerial capacity; or
- (b) either:
  - two consecutive years in an independent capacity or in a managerial capacity, where the beneficiary proves that for the activity in question he has received previous training lasting at least three years, attested by a certificate recognized by the State, or regarded by the competent professional or trade body as fully satisfying its requirements, or
  - three consecutive years either in an independent capacity or in a managerial capacity, where the beneficiary proves that for the activity in question he has received previous training lasting at least two years, attested by a certificate recognized by the State, or regarded by the competent professional or trade body as fully satisfying its requirements; or
- (c) two consecutive years in an independent capacity or in a managerial capacity, where the beneficiary proves that he has pursued the activity in question for at least three years in a non-independent capacity; or
- (d) three consecutive years in a non-independent capacity where the beneficiary proves that for the activity in question he has received at least two years of previous training, attested by a certificate recognized by the State or regarded by the competent professional or trade body as fully satisfying its requirements.
- 2. Where, in a Member State, the taking up or pursuit of any activity coming within Article 2, point A (c) or (e), point B (b), point C or D is dependent on the possession of general, commercial, or professional knowledge and ability, that Member State shall accept as sufficient evidence of such knowledge and ability the fact that the activity in question has been pursued in another Member State for any of the following periods:
- (a) three consecutive years in an independent capacity or in a managerial capacity; or
- (b) two consecutive years either in an independent capacity or in a managerial capacity, where the

beneficiary proves that for the activity in question he has received previous training, attested by a certificate recognized by the State, or regarded by the competent professional or trade body as fully satisfying its requirements; or

- (c) two consecutive years in an independent capacity or in a managerial capacity, where the beneficiary proves that he has pursued the activity in question for at least three years in a non-independent capacity; or
- (d) three consecutive years in a non-independent capacity where the beneficiary proves that for the activity in question he has received previous training, attested by a certificate recognized by the State or regarded by the competent professional or trade body as fully satisfying its requirements.
- 3. Where, in a Member State, the taking up or pursuit of the activities coming within Article 2 (B) (a) is dependent on the possession of general, commercial, or professional knowledge and ability, that Member State shall accept as sufficient evidence of such knowledge and ability the fact that the activity in question has been pursued in another Member State for any of the following periods:
- (a) six consecutive years in an independent capacity or in a managerial capacity; or
- (b) either:
  - three consecutive years either in an independent capacity or in a managerial capacity, where the beneficiary proves that for the activity in question he has received previous training lasting at least three years, attested by a certificate recognized by the State, or regarded by the competent professional or trade body as fully satisfying its requirements, or
  - four consecutive years either in an independent capacity or in a managerial capacity, where the beneficiary proves that for the activity in question he has received previous training lasting at least two years, attested by a certificate recognized by the State, or regarded by the competent professional or trade body as fully satisfying its requirements; or
- (c) three consecutive years in an independent capacity or in a managerial capacity, where the beneficiary proves that he has pursued the activity in question for at least five years in a non-independent capacity; or
- (d) either:
  - five consecutive years in a non-independent capacity where the beneficiary proves that for

- the activity in question he has recieved previous training lasting at least three years, attested by a certificate recognized by the State or regarded by the competent professional or trade body as fully satisfying its requirements, or
- six consecutive years in a non-independent capacity where the beneficiary proves that for the activity in question he has received previous training lasting at least two years, attested by a certificate recognized by the State or regarded by the competent professional or trade body as fully satisfying its requirements.
- 4. The host Member State may require of nationals of other Member States, in so far as it so requires of its own nationals, that the activity in question should have been pursued and vocational training received in the same branch of trade as that in which the beneficiary wishes to establish himself in the host Member State.
- 5. In the cases referred to in paragraphs 1 (a) and (c), 2 (a) and (c) and 3 (a) und (c), pursuit of the activity shall not have ceased more than 10 years before the date on which the application provided for in Article 7 (3) is made. However, where a shorter period is laid down in a Member State for its own nationals, that period may also be applied in respect of beneficiaries.

- 1. A person shall be regarded as having pursued an activity in a managerial capacity within the meaning of Articles 6 (1) and (2) if he has pursued such an activity in an undertaking in the occupational field in question:
- (a) as manager of an undertaking or manager of a branch of an undertaking; or
- (b) as deputy to the proprietor or to the manager of an undertaking, where such post involves responsibility equivalent to that of the proprietor or manager represented; or
- (c) in a managerial post with duties of a commercial nature and with responsibility for at least one department of the undertaking.
- 2. A person shall be regarded as having pursued an activity in a managerial capacity within the meaning of Article 6 (3) if he has pursued such an activity in an undertaking in the occupational field in question:

- (a) as manager of an undertaking; or
- (b) as deputy to the proprietor or to the manager of an undertaking or manager of a branch of an undertaking, where such post involves responsibility equivalent to that of the proprietor or manager represented; or
- (c) in a managerial post with duties of a commercial nature and with responsibility for at least one department of the undertaking.
- 3. Proof that the conditions laid down in Article 6 are satisfied shall be established by a certificate issued by the competent authority or body in the Member State of origin or Member State whence the person concerned comes, which such person shall submit in support of his application for authorization to pursue the activity or activities in question in the host country.
- 4. Member States shall, within the time limit laid down in Article 8, designate the authorities and bodies competent to issue the certificates referred to in paragraph 3 and shall forthwith inform the other Member States and the Commission thereof.

#### Article 8

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Member States shall adopt the measures necessary to comply with this Directive within 18 months of its notification and shall forthwith inform the Commission thereof.

#### Article 9

Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 10

This Directive is addressed to the Member States.

Done at Brussels, 29 June 1982.

For the Council The President P. de KEERSMAEKER

#### COUNCIL DIRECTIVE

#### of 30 June 1982

#### concerning certain products used in animal mutrition

(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;

<sup>(1)</sup> OJ No C 197, 18. 8. 1977, p. 3.

<sup>(2)</sup> OJ No C 63, 13. 3. 1978, p. 53.

<sup>(3)</sup> OJ No C 84, 8. 4. 1978, p. 4.

<sup>(4)</sup> 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.

- 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.

<sup>(1)</sup> 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.

- 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.
- (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

NNEX

| 7  | Special provisions  |  |  |  |  |            |   | 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,                                |
|----|---|--|--|--|--|------------|---|---|
| 9  | Animal species  |  | All animal species   |  |  |            |   | Ruminants from the beginning of rumination  |
| 5  | Composition<br>characteristics<br>of product                  |  | 1  |  |  |            |   | Minimum purity 98 %   |
| 4  | Nutrient substrate<br>(specifications, if any)                |  | Molasses, distillery residues, cereals and products containing starch, fruit juice, whey, lactic acid, hydrolyzed vegetable fibres |  |  |            |   | 1 1 1   |
| £. | Chemical designation of product or identity of micro-organism |  | Saccharomyces cerevisiae, Saccharomyces carlsbergiensis, Kluyveromyces lactis, Kluyveromyces fragilis                              |  |  | ł          |   | CO(HN <sub>2</sub> ) <sub>2</sub> C <sub>2</sub> H <sub>5</sub> O <sub>2</sub> N <sub>3</sub> CO(NH <sub>2</sub> ) <sub>2</sub> H <sub>3</sub> PO <sub>4</sub> (CH <sub>3</sub> ) <sub>2</sub> -CH-CH (NHCONH <sub>2</sub> ) <sub>2</sub> |
| 2  | Name of product   |  | All yeasts  — obtained from the micro-organisms and substrates listed in columns  3 and 4 respectively                             | — the cells of which<br>have been killed |  | <b>!</b>   |   | 2.1.1. Urea 2.1.2. Biuret 2.1.3. Ureaphosphate 2.1.4. Diureido- isobutane   |
| -  | Name of product group   | Proteins obtained from<br>the following groups of<br>micro-organisms     1.1. Bacteria | 1.2. Yeasts 1.2.1. Yeasts cultivated on substrates of animal or vegetable origin   |  | 1.2.2. Yeasts cultivated on substrates other than those given in 1.2.1 | 1.3. Algae | 1.4. Lower tungs  2. Non-protein nitrogenous compounds and similar products in the following groups | 2.1. Urea and its derivatives   |

| 7 | 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 | ı   | l                           | l   | į   |
|---|--|---|---|-----------------------------|---|---|
| 9 | Animal species   |   |   | All                         | species   |   |
| S | Composition<br>characteristics<br>of product                           |   |   | Minimum                     | 0. 00 Amm   |   |
| 4 | Nutrient substrate<br>(specifications, if any)                         |   | l.  | . 1                         | I   | I   |
| 3 | Chemical designation<br>of product or<br>identity of<br>micro-organism |   | CH <sub>3</sub> S(CH <sub>2</sub> ) <sub>2</sub> -<br>CH(NH <sub>2</sub> )-COOH | NH2-(CH2)4-<br>CH(NH2)-COOH | NH <sub>2</sub> -(CH <sub>2</sub> ) <sub>4</sub> -<br>CH(NH <sub>2</sub> )-COOH.HCL | (CH <sub>3</sub> -S-(CH <sub>2</sub> ) <sub>2</sub> -<br>(CH(OH)-COO) <sub>2</sub> C <sub>2</sub> |
| 2 | Name of product  |   | 2.2.1. D,L-methionine   | 2.2.2. L-lysine             | 2.2.3. L-lysine hydro-<br>chloride  | 2.2.4. D,L-methionine<br>hydroxy-analogue   |
| 1 | Name of product group  |   | L.L. Anmo acas and smuar<br>products  |                             |   |   |

#### COUNCIL RECOMMENDATION

#### of 30 June 1982

concerning the registration of work involving recombinant deoxyribonucleic acid (DNA)

(82/472/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 235 thereof,

Having regard to the draft recommendation submitted by the Commission,

Having regard to the opinion of the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas the development of fundamental and applied biological research is such as to contribute to the economic expansion of the Member States; whereas this implies, in several sectors, that recombinant DNA work will be performed on certain organisms;

Whereas the risks associated with work involving recombinant DNA are of a conjectural nature; whereas a permanent inventory within each Member State is necessary to allow the possible imposition of protection measures and, in the very unlikely event of conjectural

hazards proving real, to trace the origin of any deleterious effects that may arise;

Whereas a continual analysis of the situation in each Member State must be undertaken in order to promote in the case where unforeseen developments so require, both the establishment of lists of work which ought to be banned or subjected to compulsory safety measures in all Member States and the harmonization of national provisions;

Considering the complexity of the problem posed by the conjectural risks of certain types of work involving recombinant DNA, the rapid developments in the understanding of this problem, the extension of the research sector concerned and the importance that must be attached to the consideration of local circumstances when assessing the hazards involved in performing scientific work;

Whereas it is necessary, in order to safeguard scientific and industrial secrecy and to protect intellectual property, to minimize the dissemination of the substance of experimental protocols prepared for the execution of the work as well as the dissemination of the substance of research projects based on the production and utilization of recombinant DNA,

#### HEREBY RECOMMENDS TO THE MEMBER STATES:

that they adopt all laws, regulations and administrative provisions in order that:

Notification by laboratories

- 1. Any laboratory wishing to undertake, in the territory of a Member State, work involving recombinant DNA notifies the competent national or regional authority;
- 2. Such notification is given, for each of the research projects envisaged, before the date on which it is begun or, where the competent authorities so decide and in the case of work falling within a category of very low risk potential, if possible within six months and not later than 12 months after the date on which the project is begun,

<sup>(1)</sup> OJ No C 66, 15. 3. 1982, p. 112.

<sup>(2)</sup> OJ No C 353, 31. 12. 1980, p. 19.

# Supplementary information

- Such notification is accompanied, for each of the projects which is subject to prior notification, by the following documents:
  - the portion of the experimental protocol which is required for the evaluation of safety at the site where the proposed activities are to be carried out,
  - a list of the protective and supervisory measures to be applied throughout the duration of the experimental work,
  - a description of the general education in recombinant DNA research and of the training received by the members of the team which will participate in the proposed activities or will be responsible for supervision, monitoring or safety;

# Classification of files

4. Each notification and the accompanying documents are classified and stored by the national authorities or regional authorities for safety and health protection to which they have been submitted;

# Consultation of files

 Each notification and its accompanying documents may be consulted by national experts authorized to that effect by the national authorities;

# Definition of work involving recombinant DNA

6. Work involving recombinant DNA is defined as the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside the cell, into any virus, bacterial plasmid or other vector system so as to allow their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.

Done at Luxembourg, 30 June 1982.

For the Council
The President
Ph. MAYSTADT

# **COMMISSION**

#### **COMMISSION DIRECTIVE**

of 10 June 1982

adapting to technical progress Council Directive 73/173/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (solvents)

(82/473/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 73/173/EEC of 4 June 1973 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (solvents) (1), as last amended by Council Directive 80/781/EEC (2), and in particular Article 10 thereof,

Whereas examination of the list of dangerous substances in the Annex to Directive 73/173/EEC has shown that this list needs to be amended in the light of both the new requirements and the latest scientific and technical knowledge and, more precisely, that it is necessary to change the classes and/or sub-classes of certain substances and to include substances which are not yet on the list, giving details of the classes and sub-classes to which they belong or of the concentration limits for substances which are classified as being corrosive and/or irritant;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Committee for Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in Dangerous Substances and Preparations,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

The Annex to Directive 73/173/EEC is hereby replaced by the Annex to this Directive.

#### Article 2

By 1 July 1983 the Member States shall adopt and publish the provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply such provisions not later than 1 January 1984.

#### Article 3

This Directive is addressed to the Member States.

Done at Brussels, 10 June 1982.

For the Commission

Karl-Heinz NARJES

Member of the Commission

<sup>(1)</sup> OJ No L 189, 11. 7. 1973, p. 7.

<sup>(2)</sup> OJ No L 229, 30. 8. 1980, p. 57.

# ANNEX

CLASS I
VERY TOXIC AND TOXIC SUBSTANCES

### CLASS I/a

| Reference No<br>in Directive<br>67/548/EEC | Substance                 |  |
|--|---------------------------|--|
| 006-003-00-3                               | Carbon disulphide         |  |
| 601-020-00-8                               | Benzene                   |  |
| 602-008-00-5                               | Carbon tetrachloride      |  |
| 602-015-00-3                               | 1,1,2,2-Tetrachloroethane |  |
| 602-017-00-4                               | Pentachloroethane         |  |
| 609-003-00-7                               | Nitrobenzene              |  |
| 612-008-00-7                               | Aniline                   |  |
| 602-016-00-9                               | 1,1,2,2-Tetrabromoethane  |  |
| 603-015-00-6                               | 2-Propen-1-ol             |  |
| 602-010-00-6                               | 1,2-Dibromoethane         |  |
| 603-028-00-7                               | 2-Chloroethanol           |  |

# CLASS I/b

| Reference No<br>in Directive<br>67/548/EEC | Substance .             |
|--|-------------------------|
| 608-029-00-2                               | Bis(2-chloroethyl)ether |
| 604-001-00-2                               | Phenol                  |
| 604-004-00-9                               | Cresol                  |
| 605-010-00-4                               | 2-Furaldehyde           |
| 613-027-00-3                               | Piperidine              |

# CLASS I/c

| Reference No<br>in Directive<br>67/548/EEC | Substance      |
|--|----------------|
| 602-019-00-5                               | 1-Bromopropane |
| 603-001-00-X                               | Methanol       |
| 608-001-00-3                               | Acetonitrile   |
| 606-030-00-6                               | Hexan-2-one    |

# **CLASS II**

### HARMFUL SUBSTANCES

### CLASS II/a

| Reference No<br>in Directive<br>67/548/EEC | Substance   |  |
|--|---|--|
| 602-014-00-8                               | 1,1,2-Trichloroethane   |  |
| 603-018-00-2                               | Furfuryl alcohol  |  |
| 606-009-00-1                               | 4-Methyl-3-penten-2-one   |  |
| 613-002-00-7                               | Pyridine  |  |
| 602-006-00-4                               | Trichloromethane  |  |
| 602-034-00-7                               | 1,2-Dichlorobenzene   |  |
| 609-001-00-6                               | 1-Nitropropane  |  |
| 609-002-00-1                               | 2-Nitropropane  |  |
| 602-012-00-7                               | 1,2-Dichlorethane   |  |
| 602-033-00-1                               | Chlorobenzene   |  |
| 610-007-00-6                               | 1-Chlor-1-nitropropane  |  |
| 601-007-01-4                               | Hexane — mixture of isomers containing more than 5 % n-hexane (1) |  |
| 603-024-00-5                               | 1,4-Dioxane   |  |

<sup>(1)</sup> In this specific instance the concentration to be taken into account for the calculation formula defined in Article 2 should be the n-hexane concentration in the preparation.

# CLASS II/b

| Reference No<br>in Directive<br>67/548/EEC | Substance             |  |
|--|-----------------------|--|
| 602-003-00-8                               | Dibromomethane        |  |
| 602-011-00-1                               | 1,1-Dichloroethane    |  |
| 602-020-00-0                               | Dichloropropane       |  |
| 602-025-00-8                               | 1,1-Dichloroethylene  |  |
| 602-026-00-3                               | 1,2-Dichloroethylene  |  |
| 602-027-00-9                               | Trichloroethylene     |  |
| 602-028-00-4                               | Tetrachloroethylene   |  |
| 616-001-00-X                               | N,N-Dimethylformamide |  |
| 609-036-00-7                               | Nitromethane          |  |
| 609-035-00-1                               | Nitroethane           |  |
| 616-011-00-4                               | N,N-Dimethylacetamide |  |
| 603-014-00-0                               | 2-Butoxyethanol       |  |

# CLASS II/c

| Reference No<br>in Directive<br>67/548/EEC | Substance             |  |
|--|-----------------------|--|
| 607-013-00-6                               | Dimethyl carbonate    |  |
| 650-002-00-6                               | Turpentine            |  |
| 606-011-00-2                               | 2-Methylcyclohexane   |  |
| 603-051-00-2                               | 2-Ethylbutan-1-ol     |  |
| 603-057-00-5                               | Benzyl alcohol        |  |
| 606-029-00-0                               | Pentane-2,4-dione     |  |
| 601-028-00-1                               | O-Methylstyrene       |  |
| 601-023-00-4                               | Ethylbenzene          |  |
| 602-013-00-2                               | 1,1,1-Trichloroethane |  |
| 602-018-00-X                               | Chloropropane         |  |
| 602-022-00-1                               | Chloropentane         |  |
| 601-022-00-9                               | Xylene                |  |
| 601-021-00-3                               | Toluene               |  |
| 606-010-00-7                               | Cyclohexanone         |  |
| 603-011-00-4                               | 2-Methoxyethanol      |  |

# CLASS II/d

| Reference No<br>in Directive<br>67/548/EEC | Substance                          |  |
|--|------------------------------------|--|
| 603-009-00-3                               | Cyclohexanol                       |  |
| 603-010-00-9                               | 2-Methylcyclohexanol               |  |
| 603-004-00-6                               | Butanol except tert-Buthyl alcohol |  |
| 603-005-00-1                               | 2-Methylpropan-2-ol                |  |
| 603-027-00-1                               | 1,2-Ethanediol                     |  |
| 603-006-00-7                               | Amyl alcohol except tert-Pentanol  |  |
| 603-007-00-2                               | 2-Methylbutan-2-ol                 |  |
| 607-037-00-7                               | 2-Ethoxyethyl acetate              |  |
| 607-038-00-2                               | 2-Butoxyethyl acetate              |  |
| 603-050-00-7                               | 1-(2-Butoxypropoxy)propan-2-ol     |  |
| 603-059-00-6                               | Hexan-1-ol                         |  |
| 606-024-00-3                               | 2-Heptan-2-one                     |  |
| 607-036-00-1                               | 2-Methoxyethylacetate              |  |
| 016-031-00-8                               | Tetrahydrothiophene-1,1-dioxide    |  |
| 602-004-00-3                               | Dichloromethane                    |  |
| 603-013-00-5                               | 2-Isopropoxyethanol                |  |

#### **CORROSIVE SUBSTANCES**

Preparations containing more than one of the substances classified as corrosive in this Annex in individual concentrations not exceeding the specfied corrosive limits shall be considered corrosive if the sum of the quotients obtained by dividing the weight percentage of each substance in the preparation by the corrosive limit specified for that substance exceeds 1.

| Reference No<br>in Directive<br>67/548/EEC | Substance           | at which p | Individual concentration<br>at which preparation<br>takes symbol indicated |  |  |
|--|---------------------|------------|--|--|--|
|  |                     | С%         | Xi%  |  |  |
| 607-008-00-9                               | Acetic anhydride    | > 20       | 8-20   |  |  |
| 607-010-00-X                               | Propionic anhydride | > 25       | 10-25  |  |  |
| 612-006-00-6                               | 1,2-Diaminoethane   | > 10       | 2-10   |  |  |

#### **IRRITANT SUBSTANCES**

Preparations containing more than one of the substances classified as corrosive or irritant in this Annex in individual concentrations not exceeding the specified irritant limits shall be considered irritant if the sum of the quotients obtained by dividing the weight percentage of each substance in the preparation by the irritant limit specified for that substance exceeds 1.

| Reference No<br>in Directive<br>67/548/EEC | Substance                          | Individual concentration<br>at which preparation<br>takes symbol indicated |      |  |
|--|------------------------------------|--|------|--|
| 6//348/EEC                                 |                                    | С%   | Xi%  |  |
| 603-012-00-X                               | 2-Ethoxyethanol                    |  | ≥ 25 |  |
| 603-025-00-0                               | Tetrahydrofuran                    |  | ≥ 25 |  |
| 601-027-00-6                               | Isopropenylbenzene                 |  | ≥ 25 |  |
| 601-025-00-5                               | Mesitylene                         |  | ≥ 25 |  |
| 601-026-00-0                               | Styrene                            |  | ≥ 25 |  |
| 606-005-00-X                               | 2,6-Dimethylheptan-4-one           |  | ≥ 10 |  |
| 605-015-00-1                               | 1,1-Diethoxyethane                 |  | ≥ 10 |  |
| 603-016-00-1                               | 4-Hydroxy-4-methylpentan-2-one     |  | ≥ 10 |  |
| 603-053-00-3                               | 2-Methylpentane-2,4-diol           |  | ≥ 10 |  |
| 603-054-00-9                               | Dibutylether                       |  | ≥ 10 |  |
| 606-020-00-1                               | 5-Methylheptan-3-one               |  | ≥ 10 |  |
| 603-052-00-8                               | 3-Butoxypropan-2-ol                |  | ≥ 25 |  |
| 606-021-00-7                               | N-Methyl-2-pyrrolidone             |  | ≥ 10 |  |
| 603-061-00-7                               | Tetrahydro-2-furylmethanol         |  | ≥ 10 |  |
| 603-062-00-2                               | Tetrahydrofuran-2,5-diyldimethanol | 1.   | ≥ 10 |  |
| 601-029-00-7                               | o-Mentha-1,8(9)-diene              |  | ≥ 25 |  |
| 601-024-00-X                               | Propylbenzene and Isopropylbenzene |  | ≥ 25 |  |
| 603-008-00-8                               | Methylpentan-2-ol                  |  | ≥ 25 |  |
| 606-012-00-8                               | 3,5,5-Trimethylcyclohex-2-enone    |  | ≥ 25 |  |

#### FORTIETH COMMISSION DIRECTIVE

of 23 June 1982

amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs

(82/474/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (1), as last amended by the Thirty-Ninth Commission Directive 82/91/EEC (2), and in particular Article 6 thereof,

Whereas Directive 70/524/EEC provides for regular amendment of the content of its Annexes to take account of advances in scientific and technical knowledge;

Whereas additional research has revealed new uses for the antibiotic 'Virginiamycin' and the coccidiostats 'Monensin sodium' and 'Robenidine'; whereas these new uses should therefore be authorized in the Community on certain conditions;

Whereas the current provisions of the Directive should be amended to allow all colouring matters added to foodstuffs or used to denature foodstuffs in accordance with Community legislation to be permitted in feedingstuffs where such colouring matters are present in the ingredients used in their manufacture; whereas the provisions governing the use of copper in feedingstuffs should also be amended;

Whereas the use of 'Narasin' and 'Salinomycine sodium' as coccidiostats has been tested successfully in some Member States; whereas such use should be permitted at national level at least, provisionally and on certain conditions, until such time as it is permitted at Community level;

Whereas the investigation of various additives currently listed in Annex II and therefore authorizable at national level has not yet been completed; whereas, therefore, the period of authorization of these substances should be extended for a fixed period;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Feedingstuffs,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

The Annexes to Directive 70/524/EEC are hereby amended as follows:

#### 1. In Annex I:

(a) in Part A 'Antibiotics', under item No E 711 'Virginiamycin', the entries relating to calves are replaced by the following:

<sup>(1)</sup> OJ No L 270, 14. 12. 1970, p. 1.

<sup>(2)</sup> OJ No L 42, 13. 2. 1982, p. 16.

| EEC<br>No | A 11:-:   | Additives Chemical formula, description | Species      | Maximum                        | Minimum content                  | Maximum<br>content | Other                 |
|-----------|-----------|---|--------------|--------------------------------|----------------------------------|--------------------|-----------------------|
|           | Additives |   | of<br>animal | age                            | ppm of complete<br>feedingstuffs |                    | provisions            |
|           |           |   | Calves       | 16<br>weeks                    | 5                                | 50                 |                       |
|           |           |   |              | 17th<br>week<br>to 6<br>months | 5                                | 20                 |                       |
|           |           |   |              | 6 months                       | 5                                | 80                 | In milk replacer only |

# (b) in Part D 'Coccidiostats':

# (aa) item No E 757 'Monensin sodium' is supplemented as follows:

| EEC | Additives | Additions Chemical formula, |                                  | Maximum     | Minimum<br>content               | Maximum content | Other  |  |
|-----|-----------|-----------------------------|----------------------------------|-------------|----------------------------------|-----------------|--|--|
| No  | Additives | description                 | of animal                        | age         | ppm of complete<br>feedingstuffs |                 | provisions   |  |
|     |           |                             | Chickens<br>reared for<br>laying | 16<br>weeks | 100                              | 120             | Instructions for use to include 'Dangerous for equines; to be kept out of their reach' |  |

# (bb) item No E 758 'Robenidine' is supplemented as follows:

| EEC<br>No | Additives | Chemical formula,<br>description | Species<br>of animal  | Maximum<br>age | Minimum<br>content               | Maximum<br>content | Other   |
|-----------|-----------|----------------------------------|-----------------------|----------------|----------------------------------|--------------------|---|
|           |           |                                  |                       |                | ppm of complete<br>feedingstuffs |                    | provisions                                      |
|           |           |                                  | Rabbits for fattening |                | 50                               | 66                 | Use prohibited at least 5 days before slaughter |

# (c) Part F 'Colouring matters including pigments' is replaced by the following:

| EEC    | Addition  | Chemical formula,                              | Species   | Maximum | Minimum<br>content               | Maximum<br>content             | Other      |  |
|--------|---|--|-----------|---------|----------------------------------|--------------------------------|------------|--|
| No     | Additives   | description                                    | of animal | age     | ppm of complete<br>feedingstuffs |                                | provisions |  |
|        | F. Colouring matters including pigments           |  |           |         |                                  |                                |            |  |
|        | 1. Carotenoids and xanthophylls:                  |  |           |         |                                  |                                |            |  |
| E 160c | Capsanthin  | C <sub>40</sub> H <sub>58</sub> O <sub>3</sub> | h         |         |                                  | )                              |            |  |
| E 160e | Beta-apo-8'-<br>carotenal                         | C <sub>30</sub> H <sub>40</sub> O              | -         |         |                                  | 80: alone or                   |            |  |
| E 160f | Ethyl ester of<br>beta-apo-8'-<br>carotenoic acid | C <sub>32</sub> H <sub>44</sub> O <sub>2</sub> | Poultry   |         | -                                | with the other carotenoids and |            |  |
| E 161b | Lutein  | C40H56O2                                       |           |         |                                  | xanthophylls                   |            |  |
| E 161c | Cryptoxanthin                                     | C40H56O  |           |         |                                  |                                |            |  |

| EEC    |   | Chemical formula,   | Species  | Maximum | Minimum content                  | Maximum content                             | Other   |  |
|--------|---|---|--|---------|----------------------------------|---|---|--|
| No     | Additives   | description   | of animal  | age     | ppm of complete<br>feedingstuffs |   | provisions  |  |
| E 161e | Violaxanthin  | C <sub>40</sub> H <sub>56</sub> O <sub>4</sub>  | J  |         |                                  |   |   |  |
| E 161g | Canthaxanthin   | C <sub>40</sub> H <sub>52</sub> O <sub>2</sub>  | (a) Poultry  |         |                                  | ]   | ·   |  |
|        |   |   | (b) Dogs<br>and<br>cats  |         |                                  | _   |   |  |
| E 161h | Zeaxanthin  | C40H56O2  | Poultry  |         |                                  | 80: alone or                                |   |  |
| E 161i | Citranaxanthin  | C <sub>33</sub> H <sub>44</sub> O   | Laying<br>hens   |         |                                  | with the other carotenoids and xanthophylls |   |  |
| E 131  | 2.1. Patent Blue V  2.2. Acid brilliant green BS (lissamine green)  | Calcium salt of disulphonic acid of m-hydroxytetraethyl-diaminotriphenyl-carbinol ahydride  Sodium salt of 4,4-bis (dimenthylamino) diphenylmethylene-2-naphthol-3,6-disulphonic acid | (a) All species of animals with the exception of dogs and cats |         |                                  |   | Permitted in anima feedingstuffs only in products from processed:  (i) waste products or foodstuffs  (ii) denatured cereals or manioc flour  (iii) other base substances denatured by means of these agents or coloured during technica preparation to ensure the necessary identification during manufactures        |  |
|        | 3. All colouring agents authorized for colouring foodstuffs by Community rules, other than those already covered by 2.1 and 2.2 |   | (a) All species of animals with the exception of dogs and cats |         |                                  |   | Permitted in anima feedingstuffs only in products processed from:  (i) waste products or foodstuffs  (ii) other base substances, with the exception of cereal and manioc flour denatured by mean of these agents or coloured during technical preparation to ensure the necessary identification during manufactured. |  |
|        |   |   | (b) Dogs and cats  |         |                                  |   | _   |  |

(d) in Part I 'Trace elements', under item No E 4 'Copper — Cu', the wording in the column headed 'Maximum content of the element in ppm of the complete feedingstuff' is replaced by the following:

| EEC<br>No | Component | Additives | Chemical<br>formula | Maximum content of the element in ppm of the complete feedingstuff |
|-----------|-----------|-----------|---------------------|--|
| ٠         |           |           |                     | Swine: 125 (total) Sheep: 20 (total)                               |
|           |           |           |                     | Other species of animals: 50 (total)                               |

#### 2. In Annex II:

- (a) in Part A 'Antibiotics', the date '30 June 1982' in the column headed 'Period of authorization' is replaced by '30 November 1982' for item No 21 'Virginiamycin';
- (b) in Part B 'Coccidiostats and other medicinal substances', the following items are added:

| EEC          | Additives                  | Chemical formula,  | Species of                   | Maximum | Minimum content                  | Maximum content | Other   | Period of              |
|--------------|----------------------------|--|------------------------------|---------|----------------------------------|-----------------|---|------------------------|
| No Additives | Additives                  | description  | animal                       | age     | ppm of complete<br>feedingstuffs |                 | provisions  | authorization          |
| 26           | Narasin                    | C <sub>43</sub> H <sub>72</sub> O <sub>11</sub><br>(Polyether<br>monocarboxylic acid<br>produced by<br>Streptomyces<br>aureofaciens) | Chickens<br>for<br>fattening |         | 60                               | 80              | Use prohibited at least 5 days before slaughter   | 30<br>November<br>1984 |
|              | ,                          |  |                              |         |                                  |                 | Instructions for use to<br>include 'Danger for<br>equine species; keep<br>out of their reach' |                        |
| 27           | Salino-<br>mycin<br>sodium | C <sub>42</sub> H <sub>69</sub> O <sub>11</sub> Na<br>· (Polyether<br>monocarboxylic acid<br>produced by<br>Streptomyces albus)      | Chickens<br>for<br>fattening |         | 50                               | 70              | Use prohibited at<br>least 5 days before<br>slaughter   | 30<br>November<br>1984 |
|              |                            |  |                              |         |                                  |                 | Instructions for use to<br>include 'Danger for<br>equine species; keep<br>out of their reach' |                        |

(c) in Part D (a) 'Trace elements', the provisions concerning item No 3 'Copper — Cu' are replaced by the following:

| EEC<br>No | Additives | Chemical formula,<br>description | Species of animal | Maximum<br>age | Maximum content complete gstuffs | Other<br>provisions | Period of authorization |
|-----------|-----------|----------------------------------|-------------------|----------------|----------------------------------|---------------------|-------------------------|
|           | Copper    | Cu                               | Swine             | 4 months       | 200                              |                     | 30<br>November<br>1984  |

<sup>(</sup>d) in Part F 'Growth promoters', the date '30 June 1982' in the column headed 'Period of authorization' shall be replaced by '30 November 1982' for item No 2 'Carbadox'.

#### Article 2

The Member States shall, on 1 December 1982, bring into force the laws, regulations or administrative provisions necessary to comply with point 1 of Article 1, and shall immediately inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 23 June 1982.

For the Commission
Poul DALSAGER
Member of the Commission

#### **COMMISSION DIRECTIVE**

#### of 23 June 1982

laying down the categories of ingredients which may be used for the purposes of labelling compound feedingstuffs for pet animals

(82/475/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES.

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedindstuffs (1), as last amended by Commission Directive 80/695/EEC (2), and in particular Article 10 (b) thereof,

Whereas the abovementioned Directive lays down that Member States may require or allow the ingredients used in the manufacture of compound feedingstuffs to be declared; whereas, pending the adoption of Community provisions, Member States may allow the declaration of ingredients to be replaced by the declaration of categories comprising several ingredients;

Whereas some Member States' national provisions permit the grouping of ingredients in different categories; whereas identical provisions concerning labelling should therefore be laid down so as to facilitate trade between Member States;

Whereas these rules should only apply to compound feedingstuffs for pet animals;

Whereas rules relating to the labelling of compound feedingstuffs must primarily ensure adequate information for users of the products;

Whereas a category may be indicated only where the ingredient or ingredients used are covered by the definition of the category in question;

Whereas, by analogy with the provisions laid down for the declaration of ingredients, the list of categories should be given, depending on the provisions laid down by the Member States, either by indicating the amount of each category present or in descending order of their proportion by weight in the compound feedingstuff; Whereas, however, it is not possible to establish categories covering all the ingredients of compound feedingstuffs; whereas, therefore, the manufacturer must indicate in addition any ingredients not belonging to any of the categories listed in the Annex;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Feedingstuffs,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

Where, pursuant to Article 5 (7) of Directive 79/373/EEC, the national provisions of Member States lay down that the indication of ingredients may be replaced by the indication of categories comprising several ingredients, only the categories listed in the Annex hereto may be indicated on the packaging, container or label of compound feedingstuffs for pet animals.

#### Article 2

The Member States shall bring into force not later than 1 January 1985 the laws, regulations and administrative provisions necessary to comply with the provisions of this Directive. They shall forthwith inform the Commission thereof.

#### Article 3

This Directive is addressed to the Member States.

Done at Brussels, 23 June 1982.

For the Commission
Poul DALSAGER
Member of the Commission

<sup>(1)</sup> OJ No L 86, 6. 4. 1979, p. 30.

<sup>(2)</sup> OJ No L 188, 22. 7. 1980, p. 23.

 $\label{eq:annex} ANNEX$  Categories of ingredients which may be indicated in place of individual ingredients

|     | Description of the category     | Definition  |  |  |  |  |  |
|-----|---------------------------------|---|--|--|--|--|--|
| 1.  | Meat and animal derivatives     | All the fleshy parts of slaughtered warm-blooded land animals fresh or preserved by appropriate treatment, and all products and derivatives of the processing of the carcase of parts of the carcase of warm-blooded land animals |  |  |  |  |  |
| 2.  | Milk and milk derivatives       | All milk products, fresh or preserved by appropriate treatment, and derivatives from the processing thereof   |  |  |  |  |  |
| 3.  | Eggs and egg derivatives        | All egg products fresh or preserved by appropriate treatment and derivatives from the processing thereof  |  |  |  |  |  |
| 4.  | Oils and fats                   | All animal and vegetable oils and fats  |  |  |  |  |  |
| 5.  | Yeasts                          | All yeasts, the cells of which have been killed and dried   |  |  |  |  |  |
| 6.  | Fish and fish derivatives       | Fish or parts of fish, fresh or preserved by appropriate treatment, and derivatives from the processing thereof   |  |  |  |  |  |
| 7.  | Cereals                         | All types of cereal, regardless of their presentation, or products made from the starchy endosperm  |  |  |  |  |  |
| 8.  | Vegetables                      | All types of vegetables and legumes, fresh or preserved by appropriate treatment  |  |  |  |  |  |
| 9.  | Derivatives of vegetable origin | Derivatives resulting from the treatment of vegetable products, in particular cereals, vegetables, legumes and oil seeds  |  |  |  |  |  |
| 10. | Vegetable protein extracts      | All products of vegetable origin in which the proteins have been concentrated by an adequate process to contain at least 50% crude protein, as related to the dry matter, and which may be restructured (textured)                |  |  |  |  |  |
| 11. | Minerals                        | All inorganic substances suitable for animal feed   |  |  |  |  |  |
| 12. | Various sugars                  | All types of sugar  |  |  |  |  |  |
| 13. | Fruit                           | All types of fruit, fresh or preserved by appropriate treatment   |  |  |  |  |  |
| 14. | Nuts                            | All kernels from shells   |  |  |  |  |  |
| 15. | Seeds                           | All types of seeds as such or roughly crushed   |  |  |  |  |  |
| 16. | Algae                           | Algae, fresh or preserved by appropriate treatment  |  |  |  |  |  |
| 17. | Molluscs and crustaceans        | All types of molluscs, crustaceans, shellfish, fresh or preserved by appropriate treatment, and their processing derivatives  |  |  |  |  |  |
| 18. | Insects                         | All types of insects and their stages of development  |  |  |  |  |  |
| 19. | Bakery products                 | All bread, cakes, biscuits and pasta products   |  |  |  |  |  |